United States Environmental Protection Agency

Office of Pollution Prevention and Toxics (7406)

EPA 744-P-98-001
June 1998

Design for the Environment
U.S. EPA

Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes: Response to Peer Review Comments

INTRODUCTION

In January 1993, responding to recommendations in the report Safeguarding the Future: Credible Science, Credible Decisions, Administrator William Reilly issued an Agency-wide policy for peer review. Administrator Carol Browner confirmed and reissued the policy on June 7, 1994. As a result, EPA established standard operating procedures for the organization and conduct of peer reviews. The primary objective of any peer review is to uncover technical problems or unresolved issues for use in revising the final work product so it will reflect sound technical information and analyses. Peer review is considered a process for enhancing the scientific integrity of the end product. Peer reviews are usually conducted by a panel of independent peer reviewers who are experts in relevant scientific areas. Independent reviewers are not associated with the generation of the specific work product, either directly by substantial contribution to its development or indirectly by consultation during the development of the specific product.

The fabricare CTSA was identified as a major scientific and technical work product, and as such required an independent peer review. The technical peer review of the fabricare CTSA was conducted according to the SOP in place at the time, the Office of Prevention, Pesticides and Pollution Prevention (OPPTS) "Standard Operating Procedures for Peer Review of Major Scientific and Technical Documents, October 1, 1996 - September 30, 1997". The OPPTS SOP set forth methods for: identifying work products for peer review, including the selection process and mechanisms for peer review; planning and conducting a peer review, including selecting reviewers and scheduling reviews; completing the review, including methods for evaluating comments and recommendations; the final work product; and maintaining a peer review record. The GTCP chose a balanced ad hoc panel of independent experts from outside the Agency as the mechanism to assure an objective, fair, and responsible evaluation of the work product. Information presented in the peer review was used to update and enhance the final CTSA document. All requirements in the OPPTS SOP were met or exceeded.

The peer review copy of the CTSA document was reviewed by a large and well balanced independent panel of experts from the dry cleaning industry and the environmental and scientific communities (Table 1). The review was initiated on Thursday, July 24, 1997. Reviewers were given four weeks to complete their review and were requested to submit their comments to Battelle Memorial Institute by Monday, August 25, 1997. Thirty-six of the initial 40 reviewers on the panel submitted a total of 1,855 comments to Battelle.

This document contains a list of verbatim comments as submitted by each peer reviewer and formal responses written by the EPA/OPPT Technical Workgroup responsible for the development of the document. Comments are separated into the following categories:

- General Comments on the CTSA Document,
- Executive Summary,
- Chapters 1-8, and
- Appendices A-C.

A complete record of the formal technical PR Process is available to the public in EPA's Public Reading Room, Administrative Record #199. The contents of the AR are included as Exhibit 1.

Table 1. Final CTSA Peer Review Panel

Ken C. Adamson
General Manager
Langley Parisian

Frank Arnold, Ph.D.
Consulting Economist

Charlene Bayer, Ph.D.
Georgia Tech Research Institute

Arnold Brown., M.D. - retired
Professor Emeritus of Pathology
and Universal Medicine
Univ. of Wisconsin, Madison

Pamela Christenson
Wisconsin Dept. of Dev.

Dick Clapp, Sc.D., M.P.H.
Boston University School of Public
Health
Dept of Environmental Health

James Cone, M.D., M.P.H.

Elden Dickinson
Michigan Department of
Environmental Quality

Paul Dugard, Ph.D.
Senior Vice President
ICI Americas, Inc.

Diane Echeverria, Ph.D.
Battelle Seattle Operations

Adam Finkel, Ph.D.
Director
OSHA Health Standards Directorate
U.S. Department of Labor

George Gray, Ph.D.
Harvard Center for Risk Analysis
Harvard School of Public Health

Dale Hattis, Ph.D.
Research Associate Professor
Center for Technology,
Environment, & Development
(CENTED)
Clark University

Ms. Chris Hayes
Greater Chicago P2 Program,
MWRD

Denny Hjeresen, Ph.D.
Los Alamos National Labs

Rudolf Jaeger, Ph.D.
Environmental Medicine,
Incorporated

Ellen Kirrane
Hunter College Center for
Occupational & Environmental
Health

Josef Kurz, Ph.D.
Schloss Hohenstein

Jack Lauber, P.E.-D.A.A.E.E.
Consulting Engineer

James Melius, M.D., Ph.D.
Director
NY State Laborer's Health & Safety
Trust Fund

Frank Mirer, Ph.D.
Director
Health & Safety Dept., UAW

Kenneth Mundt, Ph.D.
University of Massachusetts
Department of Biostatistics &
Epidemiology
School of Public Health & Health
Sciences

D. Warner North, Ph.D.
Decision Focus Inc.

Peter Orris, M.D.
Division of Occupational Medicine
Cook County Hospital

David Ozonoff, M.D., M.P.H.
Boston University School of Public
Health
Department of Environmental
Health

Andrew Persily, Ph.D.
NIST

Routt Reigart, M.D.
Medical University of South
Carolina

Charles Riggs, Ph.D.
Texas Women's University,
Department of Fashion & Textiles

Judy Schreiber, Ph.D.
NY State Department of Health

Tom Starr, Ph. D.
Environ Corp.

Mike Tatch
Tatch Technical Services

Kimberly Thompson, Sc.D.
Consultant
Harvard Center for Risk Analysis

Joel Tickner
MSC/University of Massachusetts
Lowell

Greg Traynor
T. Marshall Associates

Arthur Upton, M.D.
Clinical Professor
Environmental & Occupational
Health Sciences Institute

David Votaw
Education and Information Division
(C15)
National Institute for Occupational
Safety and Health

Clifford Weisel, Ph.D.
Associate Professor
Deputy Director
Exposure Measurement and
Assessment Division
Environmental and Occupational
Health Sciences Institute

Noel Weiss, M.D., Dr. P.H.
Professor
University of Washington
School of Health & Community
Medicine
Department Of Epidemiology

Manfred Wentz, Ph.D.
Chairperson, AATCC Research
Committee RA43: Dry Cleaning

Kathleen Wolf, Ph.D.
Institute for Research and Technical
Assistance

Note: No known conflicts of interest existed with any peer reviewers.

INDEX to Administrative Record #199

of the
Technical Peer Review of the US EPA Report:
Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes
EPA 744-B-98-001, June 1998

A. ***Office of Prevention, Pesticides and Toxic Substances STANDARD OPERATING PROCEDURES FOR PEER REVIEW OF MAJOR SCIENTIFIC AND TECHNICAL DOCUMENTS, October 1, 1996 - September 30, 1997,*** under which this technical peer review was conducted.

B. **The official technical peer review version of the *Cleaner Technologies Substitutes Assessment for Fabricare: Including Wet and Dry Cleaning Technologies, (CTSA) July 1997.*** (NOTE: After the peer review was completed, the final document title was changed to: ***Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes***).

C. **Materials and information sent to peer reviewers during course of peer review**

1. July 21, 1997 letter from Bruce E. Buxton, Ph.D., Battelle Program Manager, mailed to 29 peer reviewers who were to be paid for their review, requesting information and transmitting a non-disclosure agreement and contracts information. With enclosures:
   a. *Peer Reviewer Non-Disclosure Agreement*
   b. *Battelle's Special and General Provisions Technical Services for Government Time and Material, Labor Hour Contracts*

2. July 21, 1997 letter from Bruce E. Buxton, Ph.D., Battelle Program Manager, mailed to 11 peer reviewers who were not to be paid for their review, requesting information and transmitting a non-disclosure agreement. With enclosure:
   a. *Peer Reviewer Non-Disclosure Agreement*

3. July 25, 1997 letter from Bruce Buxton, Ph.D., Battelle Program Manager, mailed to 40 peer reviewers and transmitting the official peer review version of the fabricare CTSA. Specific guidance to the reviewers and a list of references cited in the CTSA were bound into each official peer review copy of the CTSA:
   a. Reminder page to return signed non-disclosure agreement to Battelle
   b. Bound in the front of each peer review copy: **July 1977 *Charge to CTSA Peer Reviewers***
   c. Bound at the end of each peer review copy: **July 1997 *Peer Review Reference List*** of all references that were cited in the peer review version of the fabricare CTSA.

4. August 6, 1997 letter from Bruce Buxton, Ph.D., Battelle Program Manager, faxed to 40 peer reviewers, clarifying carcinogenic potential of perchloroethylene. With enclosure:
   a. August 6, 1997 ***Clarification for CTSA Peer Reviewers of EPA's Position on the Carcinogenic Potential of Perchloroethylene (Perc)***

5. August 14, 1997, letter from Brandon Wood, Battelle CTSA Task Leader, to Kimberly Thompson, Dr.S., transmitting requested references from peer review version of CTSA. With the following list of enclosures (see AR Section C3c for actual references):
   a. List of references sent to K. Thompson

D. **Comments, information, and materials received from the peer reviewers**

1. Signed Non-Disclosure Agreements from 40 peer review panelists
2. Proposals from panelists that were to be paid for their review
3. Invoices submitted to Battelle from panelists that were to be paid for their review
4. Original comments and additional materials as submitted by the 36 peer reviewers that responded
5. List of additional materials submitted by each peer reviewer

E. **Information about the peer reviewers**

1. List of 40 technical peer reviewers on the panel and their affiliations
2. Biosketches submitted by peer reviewers
3. Table of the 113 nominated candidate reviewers and detailed information on their technical expertise, who nominated them, and why they were or were not on the panel.

F. ***Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes: Peer Review Process*, EPA 744-S-98-002, June 1998.** (NOTE: This EPA report summarizes the entire process that was followed for the technical peer review of the fabricare CTSA, how the panel was selected, all logistical information, and the results. This report was prepared for stakeholders and other interested parties, and to document the peer review process from start to finish as part of this Administrative Record.)

G. ***Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes: Response to Peer Review Comments*, EPA 744-P-98-001, June 1998**

H. **Final CTSA and related documents**

1. ***Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes***, EPA 744-B-98-001, June 1998 (final CTSA)
2. ***Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes: SUMMARY***, EPA 744-S-98-001, June 1998 (summary version abstracted directly from the full CTSA)
3. **Federal Register Notice of Availability of CTSA and Summary CTSA**
4. ***Fact Sheet: Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes***, EPA 744-F-98-011, June 1998

5. ***Frequently Asked Questions About Drycleaning,*** EPA 744-K-98-002, June 1998

I. **Indexed list and a copy of each of the 404 references cited in the final published report:** ***Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes***, EPA 744-B-98-001, June 1998

Cleaner Technologies
Substitutes Assessment for Professional Fabricare Processes

Response to Peer Review Comments

Note: Comments are organized into general comments and then those pertaining to each chapter of the CTSA. For example, Comment #4-1 is the first comment pertaining to Chapter 4.

General Comments

Comment #G-1: I have reviewed the CTSA draft and find it generally quite good. I have a number of comments ranging from minor edits required, to more general ones concerning the economic sections, as well the method for presenting the large amounts of information contained in the document. I will begin with the purely editorial comments, and then turn to the broader issues.

Editorial: I cannot claim to have read all of the document in great detail. Nevertheless, a few editorial items did come to my attention.

Response: No response required.

Comment #G-2: Do a global search on "comprised" and "comprises". In several places, e.g., ES-2 next to last line, the word is used incorrectly. Usually I think you mean "composed" or "consists".

Response: EPA has incorporated this change.

Comment #G-3: Do a global search on "which". Often it is used when it should be "that". This will take a little time to do because the correct usage depends on the context. As a general rule, use "which" when a comma comes before it, otherwise "that".

Response: EPA has modified the CTSA to consider this comment.

Comment #G-4: Chapter 2 title seems odd given the content of the chapter.

Response: EPA has made significant revisions to the CTSA's organization and renamed chapters accordingly.

Comment #G-5: Chapter 6 title might be better as plural - Process Cost Estimates.

Response: EPA has incorporated this change.

Comment #G-6: As I said, I did not undertake to do a full edit sort of read. But for the most part, the writing is very good. Just a few things here and there that I saw.

Response: No response required.

Comment #G-7: The industry and technology overviews and surveys are nice.

Response: No response required.

Comment #G-8: "I gave the chapters on risk a very cursory read. No comments there."

Response: No response required.

Comment #G-9: I would recommend porting the document over to Lotus Notes format so that the advantages of viewing the document from many different directions, indexing, "tell me about" features, automatic gathering of material on a topic in different places in a view, and so forth can be brought to bear. The report as it stands is not for your audience; it is for regulatory analysts. I would port it to LN and make it available on the Web. I have been working on similar projects with Alan Carlin in OPPE/EED (260-5499). I suggest that you contact him about Web-based publishing and LN documents.

Response: EPA will consider alternative modes of presenting the CTSA in the future. The CTSA is expected to be available on the Web.

Comment #G-10: I should emphasize that I found the report very good. It is a very well-done compendium of information on fabricare. I think that the problem, if there is one, has to do with flexibility for input assumptions, and ultimate method of presentation.

Response: EPA has attempted to identify inputs and assumptions to allow users to modify information accordingly.

Comment #G-11: Each chapter clearly explains its purpose and sets the stage for the evaluation to follow.

Response: No response required.

Comment #G-12: The text is clear and well presented.

Response: No response required.

Comment #G-13: The tables and figures are helpful and clear.

Response: No response required.

Comment #G-14: I detected no inconsistencies in the presentation of data.

Response: No response required.

Comment #G-15: I know of no different or more current sources of pertinent information.

Response: No response required.

Comment #G-16: Relevant and appropriate references are provided.

Response: No response required.

Comment #G-17: I know of no newer or better data on the quantities listed.

Response: No response required.

Comment #G-18: Although I found the report to be remarkably free from typographical or grammatical flaws, I would recommend that the word "business" on page ES-2, line 5, and on page 1-2, line 9, be replaced by the word "businesses".

Response: This change has been incorporated.

Comment #G-19: This letter serves as our peer review comments on the document Cleaner Technologies Substitutes Assessment for Fabricare: Including Wet and Drycleaning Technologies. Overall, we judge the document to be well written. It clearly distinguishes among the various alternatives possible and concludes that the choices should be made on an individual basis. This document delineates the trade-offs and advantages/disadvantages of each cleaning technologies, processes and products. We judge the document to be informative and proves the reader/use with a better understanding of his/her options so that a more educated decision can be made.

Response: No response required.

Comment #G-20: There are no comments concerning Chapters 5-7, as these were out of my area of expertise. I felt that I could not contribute to subjects concerning Performance Data Analysis, Process Cost Estimate, and P2 Opportunities, Best Management Practices, and Control Options, and thus I chose not to comment. My associate, who also read the document did read these sections and found no syntactical issues of note.

Response: No response required.

Comment #G-21: Attached to these comments are several enclosures. The first is the IDLH documentation for PCE and for Stoddard Solvent. I believe these are important and should be incorporated into the document in light of the revised IDLH for PCE in that it is very close to the OSHA PEL. Secondly, a recent review by Thompson and Evans (1997) which used improved National Exposure Information for PCE to evaluate risk. Parts of this review may be added to Appendix B and C. Lastly, a copy of the paper by Dr. Gerarde concerning the aspiration potential of petroleum solvents is attached.

[Copies of web pages at: http//www.cdc.gov/niosh/127184.html -- http//www.cdc.gov/niosh/8052413.html.
Thompson, K.M., and J. S. Evans, 1997. The value of improved National Exposure information for perchloroethylene (Perc): A case study for drycleaners. Risk Analysis. 17:253-271.
Gerade, H.W. 1963. Toxicological Studies on Hydrocarbons IX. The Aspiration Hazard and Toxicity of Hydrocarbons and Hydrocarbon Mixtures. archives of Environ. Health. 6:329-341.]

Response: The IDLHs have been incorporated into the document. It is not apparent to which parts of the reference (Thompson and Evans, 1997) the commenter referred for inclusion. However, some worker exposure data from Reference 35 (IFI) of Thompson and Evans has been included in the PCE worker exposure section of the CTSA.

The analysis by Thompson and Evans, 1997 aims to synthesize exposure, cancer potency and valuation information to identify the most useful avenue for further information development. It appeared after the draft CTSA was completed. Many of its sources are already cited in the draft CTSA. Since, however, the Agency is relying on existing decisions, not providing a new analysis, the CTSA did not insert it, per se, for its risk characterization development. As a commenter noted, Thompson and Evans is a "first-cut"; it makes a number of assumptions about the appropriate input and only cancer hazard is considered (neither noncancer nor ecological hazard is included). Regarding the third part, the Gerarde reference was also identified at comment #2-98. Any discussion of aspiration potential is speculative; there is no direct evidence for aspiration toxicity of Stoddard solvent mentioned in this article.

Comment #G-22, References: I suggest adding the 6/3/94 paper, "State-of-the-Art Technologies for Multi-media Pollution Control in the Drycleaning Industry", by J. D. Lauber and G. Pallante, which is enclosed for your reference. This gives further information on the four generations of drycleaning equipment and on reduced costs of PCE usage and hazardous waste disposal for 4th generation equipment, in comparison to 2nd and 3rd generation systems. It also contains a concise summary of the N.Y. State part 232 drycleaning regulations and the new fugitive emission limits for PCE that were previously mentioned.

[Lauber, J.D., and G. Pallante, 1994. State-of-the-art technologies for multi-media pollution control in the drycleaning industry. Presented at the Seventh Annual Pollution Prevention Conference. June 3, 1994, Albany, NY.]

Response: Information on the four generations of equipment has been incorporated in the document based on other references. State regulations were not covered in the CTSA. Instead, the CTSA recommends that readers consider these on their own.

Comment #G-23: I am enclosing the review copy of the Cleaner Technologies Substitutes Assessment for Fabricare: Including Wet and Drycleaning Technologies (July 1997), and copies of a number of references that I believe will be helpful in revising the draft. My comments on the draft are attached to this letter. I believe that a number of improvements could and should be

made to the draft prior to its release. In particular, I believe that the focus should be shifted from individual risks to population risks.

Response: EPA has not included population risk estimates in the CTSA because of concerns regarding the uncertainties of modeling those risks for the case and because they are not necessary for meeting the goals of this CTSA.

Comment #G-24: Overall, I believe that a different structure would be easier for the reader to follow and would facilitate direct inferences about the amount of information available regarding the different technologies. I also believe that the exposure and risk assessments could be dramatically improved and that it would be more helpful for individual drycleaners if the risk analyses for the different technologies all looked at comparable facilities (e.g., the facility that cleaned 40,000 kg/yr of clothes considered for the cost estimates) as the cost analysis did. My comments are divided into general comments that apply to the draft as a whole, responses to questions to the reviewers, and specific comments that discuss particular portions of sections 1,3,4,7, and 8. I did not have sufficient time to review the remaining chapters. I would be happy to discuss any of my comments with you if you have questions about them.

Response: Regarding worker exposure assessment. Facility size was not a factor in the exposure and risk assessments because not enough information are available to determine comparability of facility sizes in most studies. However, new data in the NIOSH, 1997 reference from the updated exposure chapter do give insights as to how numbers of machines impact exposures.

The structure of the CTSA has been revised to improve presentation of information.

Comment #G-25, Overall: The text is reasonably clear and well presented, some organizational changes would improve its readability as discussed below. The tables and figures are generally helpful. There are some sources of more recent information about exposure and risk that are not included as discussed below, but the document does include most of the relevant references. The document relies on a large number of personal communications that I assume have been verified with the people who are cited.

Response: To the extent possible, personal references have been replaced by other more readily available reference types.

Comment #G-26, Organization: The organization of the draft makes the reader consider all technologies sequentially and sets up PCE drycleaning as the comparator for all other technologies. This may be an effective style of presentation for some people, but I would have much preferred to see the draft organized as follows:

Chapter 1: Purpose of the CTSA, Overview of the historical development of solvents and technologies for the industry including a discussion of the concepts of cleaning and possible technologies (see Ref. 1 and Thompson, 1997), Introduction to the components of each assessment for each solvent/technology choice (this section would include subsections for description of the technology, control options, chemical information intro, health hazard intro, environmental hazard intro, review of relevant laws, release estimate and general exposure

assessment intro, risk characterization intro, performance intro, cost intro, etc.), Present goals for the CTSA and briefly describe the types of comparisons to be made in the last chapter.

Chapters 2-5: Separate chapters for each solvent choice (e.g., Ch 2 on PCE, Ch 3 on PS (both uncontrolled and controlled), Ch 4 on wetcleaning (including ultrasound and microwave drying), Ch 5 on Liquid CO_2. Organized in this fashion, it will be obvious to the reader that a lot of information is available about PCE and very little information is available regarding the use of liquid CO_2. In addition, it is inconsistent to separate controlled PS from uncontrolled PS but not to do the same for PCE sources. I believe ideally that each chapter should include the cost-benefit analysis of using different technologies or control strategies at the end. For example, the PCE and PS sections should discuss the incremental costs and benefits of adding a control device to an existing machine. With this type of information drycleaners can compare their current facility configurations to the alternatives. Then, the cross-cutting comparisons can be made in the last chapter.

Chapter 6: Comparisons of different technologies: Expected performance, costs, risks and benefits of alternatives. Again, this should be based on the incremental costs and benefits for different facilities. For example, I believe that it should suggest higher incremental costs and lower incremental benefits associated with switching from a brand new state-of-the-art dry-to-dry machine to wetcleaning than from an old uncontrolled transfer machine to wetcleaning.

Chapter 7: References: As it is currently structured, the reader first encounters the general intro and then the specific information about each technology sequentially. This does not strike me as the optimal approach for a drycleaner interested in evaluating different technologies (although it was an effective way for reviewers to reach it and probably to prepare it). Let's say, for example, that a drycleaner is only interested in comparing PCE technologies to wetcleaning ones (perhaps because PS technologies are unallowable given the cleaner's zoning). I think that the cleaner should be able to read only the relevant chapters and not have to both reading the PS chapter or skim through PS sections if PS is not an option. In addition, instead of simply referring back to introductory text in the first chapter, one has to find section 3.2 for general information about exposure, section 4.1 for information about risk characterization, etc. Further, the current structure requires one to look back in chapter 3 for the relevant descriptions of the exposure scenarios for the risk estimates discussed in section 4. Finally, when one thinks about future revisions to the CTSA, it might be that you would want to issue a revised Ch 5 (as more information about liquid CO_2 becomes available), but not have to redo the entire document.

Response: EPA has considered these, and many other comments, and modified the organization of the CTSA.

Comment #G-27: Focus on individual risk and risk characterization -- the draft presents quantitative risk estimates for PCE only, and these are all screening level point estimates for individual risk. If the CTSA is going to talk about social costs and benefits as one would hope in Ch 8 and as promised on page 1-7, then it should deal with the issues associated with population risk since it is the sum of the individual risks that lead to net social costs and benefits. Having attempted to grapple with these issues ... I know that this is a difficult task (see Thompson and Evans, 1997). However, if the draft does not deal with population risk, then it will fail to assess all of the benefits of exposure reduction for those groups of the population that experience low exposures, but do so in large numbers. In particular, Thompson and Evans (1997) estimated the reductions in population exposure (and risk) that would occur if EPA implemented different control technologies considered for the NESHAP. We found that four groups of the population could

benefit from reduced exposures associated with the control technologies: (1) workers, (2) families of workers, (3) consumers of drycleaning services, and (4) people exposed to ambient emissions (both locally and globally).

[Thompson, K.M. and J.S. Evans. 1997. The value of improved national exposure information for perchloroethylene (Perc): A case study for drycleaners. Risk Analysis. 17:253-271.]

Of the four groups Thompson and Evans (1997) considered, the CTSA only considers workers, people exposed locally to ambient emissions, and consumer exposure vis clothes brought into the home. Thompson and Evans (1993) suggested that workers could act as a source of PCE exposure to their families via their exhaled breaths. Although this exposure pathway is relatively small compared to the other three considered by Thompson and Evans (1997), it is certainly worth mentioning in a document that is intended to inform drycleaners about risks. Consumer-related exposures also occur when large numbers of individuals enter facilities to drop-off and pick-up clothes, and in aggregate these exposures are important. Finally, due to PCE's long lifetime in the atmosphere, all emissions of PCE from U.S. drycleaners contribute to the global background of PCE. We suggested that it is theoretically possible for the same molecule of PCE to travel around the globe so that the PCE emissions from a drycleaner in New York could be a source of exposure to a person in California, Japan, or Europe. Finally, although the CTSA assesses local population exposures, Thompson and Evans (1997) did this differently using better national meteorological and population data available in the EPA's Human Exposure Model. We have used this same approach to discuss the concept of exposure efficiency (Evans and Thompson, 1997) which would also apply to PS sources. I believe that this approach could be easily adopted for use in the CTSA and it should be considered.

[Thompson, K.M. and J.S. Evans. 1993. Workers' breath as a source of perchloroethylene (Perc) in the home. J. of Exposure Analysis and Environmental Epidemiology. 3:417-430.]

Thompson and Evans (1997) also concluded from a population exposure perspective, for those relatively few facilities that were co-located with residences, it was probably best to assess the costs and benefits on a case-by-case basis. That is, although we recognized this as a problem, we did not base our analysis on the presence of co-located residents. In addition, from a population perspective, the risks associated with nursing infants of mother's exposed at the TV is very small (even smaller than the risks to family members exposed via the worker's exhaled breath), so this was not a focus of our efforts.

While Thompson and Evans (1997) represents a first-cut at the decision analysis for the NESHAP, it goes beyond the current version of the CTSA in its characterization of uncertainty and variability of risks associated with using PCE for drycleaning. However, since we were only considering controllable risks associated with the NESHAP technologies (which did not consider wet-cleaning as an alternative, largely because the analysis was primarily done in 1993 and 1994 when wetcleaning was not established as economically viable), we did not go as far in the analysis as would be required for the CTSA. To perform this broader decision analysis, for example, one would also need to characterize the benefits from elimination of off-gassing of residual PCE concentrations on clothes since wet-cleaning eliminates this exposure pathway.

The focus on individual risk in this case is particularly problematic because workers experience the highest individual risks and EPA has no authority over regulation of these risks. In addition, if workers (in some cases the owners themselves) are willing to accept these risks, then facility owners may not feel compelled to consider other lower individual risks and they will not be aware of the population risk issue.

Response: It is true the CTSA opens by describing that DfE projects include "encouraging business to ... incorporate environmental concerns into decision-making processes" and closes by conveying the concepts of a social cost and benefits. The evaluation, however, is acknowledged to be difficult and therefore, focuses primarily on private costs. These costs are ones that each business owner or manager incurs directly. They entail information that he or she can obtain either from this CTSA volume (e.g., individual risk estimates, technology details) or from observation of his or her own site (e.g., numbers of employees engaged in different activities, current site location).

To appropriately estimate population risk, accurate, detailed, and site-specific information is required for all of the release sites. This information is used in the environmental modeling. Uncertainties in locations, releases, and the conditions of releases (including stack heights and duration of release) create uncertainties in the modeled concentrations. These uncertainties can lead to significant inaccuracies in the results.

It is possible to model population risk as Thompson and Evans (1997) have done. However, as stated above, numerous assumptions are required to perform this modeling. There are so many uncertainties involved when estimates or default values are used for missing data that people could be unnecessarily alarmed (or reassured) if estimates of population risk were provided.

The National Research Council book Science and Judgment in Risk Assessment quotes the Risk Assessment Council's 1991 Guidance: "Information about individual exposure and risk is important to communicating the results of a risk assessment...Population risk refers to an assessment of the extent of harm for the population as a whole. In theory, it can be calculated by summing the individuals for all individuals within the subject population. This task, of course, requires a great deal more information than is normally, if ever, available." (pp. 368-371).

It seems the best appeal of a CTSA will be to the reader who wants to personalize the results. That is, the reader must be able to find the information that applies to his or her situation. The concept of the magnitude of the accompanying risk that may be imposed on the wider community is more a qualitative issue at this early stage of education, than a quantitative one, particularly since he or she will not see the situation as "average." This argues against a quantitative presentation of population risk.

Comment #G-28: Characterization of exposure for workers. The available data for workers exposed to PCE suggest that worker exposures depend on machine type and job type (see Thompson and Evans, 1993 for a review of these data). Overall, these data suggest that workers in facilities with transfer machines experience exposures roughly two times higher than those in facilities with dry-to-dry machines, and that machine operators have exposures roughly two times higher than non-operators, independent of the type of control (note that I was not sent the Ref. By Ewers, 1997 since it was unavailable so your information may be different than mine based on this reference). In some cases the CTSA mixes data from facilities with transfer machines with facilities from dry-to-dry machines, even though these facilities have been shown to have different levels of exposure. Since the CTSA is intended to help facilities evaluate their options, it is important for owners of different machine types to be able to distinguish the different types of facilities (see Thompson and Evans, 1997). In addition, the CTSA should cite additional data reported in the peer-reviewed literature by Petreas et al. (1992) or Moschandreas and O'Dea (1995). The paper by Moschandreas and O'Dea (1995) is particularly important because it

addresses occupational exposures in sources with state-of-the-art PCE machines (i.e., controlled dry-to-dry machines).

[Thompson, K.M. and J.S. Evans. 1993. Workers' breath as a source of perchloroethylene (Perc) in the home. J. of Exposure Analysis and Environmental Epidemiology. 3:417-430.
Thompson, K.M. and J.S. Evans. 1997. The value of improved national exposure information for perchloroethylene (Perc): A case study for drycleaners. Risk Analysis. 17:253-271.
Petreas, M.K., Rappaport, S.M., Materna, B.L., and D.M. Rempel. 1992. Mixed-exhaled air measurements to assess exposure to tetrachloroethylene in drycleaners. J. of Exposure Analysis and Environ. Epi. Supp. 1:25-39.]

Response: The peer review document showed a small amount of data distinguishing exposures at different facilities having different machine types. The updated CTSA shows more data on these differences from both the Thompson and Evans, 1993 reference and a newer 1997 NIOSH reference. Several other data sets have been included in the updated CTSA. As a result, the Petreas and Mochandreas references do not bring any new information to the updated CTSA.

Comment #G-29, Table of Contents: A section of Environmental Hazard Summary for Alternative Technologies is missing (should be 2.3.5), Section 2.4.7 related to the NFPA does not really fit under federal regulatory summary. Instead I believe that this section which is specific to PS belongs in the PS chapter. In addition, I believe that section 2.4 would be better if titled "Regulatory requirements" and if it included a section on state and local requirements that may apply (at least indicating that they may differ from federal standards). As suggested above, I think sections 3.1.2 and 3.1.3 should be combined. It does not make sense to me to have uncontrolled and controlled PCE sources lumped but not to do the same with PS sources. (Same issues applies throughout the draft). In addition, I believe that ultrasound techniques and microwave drying should be considered as a part of wetcleaning, not separately.

Response: EPA has reviewed this, and many other similar comments, and modified the organization of the CTSA. Because many of the NFPA standards, which are voluntary, have been adopted into law by many states, EPA believes the discussions on them is appropriate for the chapter on regulations. The regulatory requirements have been moved to a chapter entitled "Select Federal Regulations"; however, state requirements have not been included. Microwave drying was removed from the CTSA.

Comment #G-30, List of exhibits: Note that many of the entries contain superscripts to notes that don't appear at the end (e.g., see the 3rd one on the list for Exhibit 1-3).

Response: Tables have been revised to remove extraneous notes.

Comment #G-31: 1. Does each of these chapters clearly explain its purpose? Generally, although as will be seen, I have great difficulties with the execution of both the data gathering and analysis.

Response: No response necessary.

Comment #G-32: 2. Is the text clear and well presented? The text is voluminous. It is generally clear enough, but the reader becomes impatient wading through repetitive statements of the obvious* while looking in vain for some helpful bottom-line conclusions about the relative hazard

and economic costs/viability of the different technical alternatives. The executive summary is particularly irritating and unhelpful in this respect. For 7 pages of effort, the reader learns practically nothing about what was found. The busy "executive" recipient of such a "summary" is unlikely to be impressed enough read further.

*Such as, for example, the stunning insight that workers and people living in the same building with PCE-based drycleaning operations will have greater exposures than other people (e.g., top of page 6).

Response: The Executive Summary has been revised to strengthen its presentation of information.

Comment #G-33: 3. Do tables/figures enhance understanding of the information presented? The tables were helpful to me in, unfortunately, a rather negative way. In at least two cases they revealed serious deficiencies in the underlying analysis:

• Tables 4-3 through 4-5 show calculations of cancer risk based on "average" exposures that are actually geometric means, rather than arithmetic means. This is wrong. When the underlying data represent one-day snapshots of individual exposure in a mixed group, and the object is to characterize likely lifetime average (that is, arithmetic mean) daily dose, as is called for in conventional cancer risk calculations, then the arithmetic mean is the appropriate summary measure. The arithmetic mean averages out the contributions of individual daily fluctuations in the exposures of individual people, and differences across individuals due to systematic differences in ventilation, machine containment, etc. in different workplaces/residences. Assuming low dose linearity in the dose response relationship, as the conventional cancer risk calculation dose, the arithmetic mean is the only appropriate measure of central tendency of concentration that should be used in calculations of the long term cancer risks of people who move from workplace to workplace over their working lifetimes in the industry; or people whose practical exposures fluctuate from day to day (as they nearly all will). It is also the only measure that can be correctly used in calculations of population aggregate cancer risk that are needed for cost benefit comparisons (as are rather feebly attempted later in the document).

• Table 8-2 (and Table 6-2, on which it is based) presents a comparison of process-dependent costs of different PCE dry-cleaning machine configurations. Cost data (to 4-5 significant figures) are presented in a way that gives the impression of a very extensive and refined assessment, cost-category by cost-category. The tip-off that the data gathering and analysis was less extensive than what appears to meet the eye is the fact that annual costs of labor are quoted as identical (to 4 significant figures, $8,804) for all 13 configuration options. There is not even any distinction between the set of "transfer" machines (which require workers to unload clothes wet with PCE, and reload them into separate dryers) and the set of newer "dry-to-dry" machines, which do not require this labor-consuming step. The discussion of this point in the text (bottom of p. 8-4) accompanying Table 8-2 is limited to the undocumented assertion that "Labor costs are estimated to be similar for all machine types."

This seemed implausible to me on its face that as part of this review I called a health worker in the relevant union* to check. It was his opinion that the labor required for loading and unloading the transfer machines was likely to be at least double that required for the dry to dry machines. The loading/unloading labor is likely to be more than double because in addition to requiring two loadings and unloadings compared to one, the clothes are heavier when wet with PCE than they are in the dry state before and after cleaning and drying. Additionally, there probably is some additional hassle factor as whatever other work the drycleaner is doing needs to be interrupted to make the transfer in order to keep the machines functioning near capacity.

*I called Eric Frumin. Mr. Frumin was on vacation so I spoke with Albert Arroyo of his office, who has personal experience in the drycleaning industry.

The discussion of the details of the underlying comparative cost analysis appears in Section 6.3. On its face this appears to reflect an extensive set of comparative cost assessments, but on closer examination, it develops that the same explanatory paragraph has been repeated 13 times for the 13 options.* [On still further examination, I find that a slight variant of the same paragraph** has been repeated three additional times for the first three petroleum solvent configurations, yielding identical annual labor cost estimates.]

***Labor Costs:** The machine capacity is 35 pounds, and each load is run at 90 percent capacity (USEPA, 1993a); therefore each load is 32 pounds. Assuming the plant runs 321 days per year, four loads per day will be required for a 39,465 pound per year throughput (USEPA, 1993a). Using the algorithm established in USEPA (1993a), each load takes 30 minutes plus an additional 30 minutes per day for cleaning up after the final load. Labor costs $10.85 per hour ,and the total equals $8,804, including record keeping costs of $341 for leak detection and repair (BLS, 1996a; USEPA, 1993b). If spotting labor time (24 percent of the total labor) is removed from this figure, the total annual labor cost is $6,691, including record keeping costs." The reference cited as "USEPA, 1993a" is U.S. Environmental Protection Agency, Multiprocess Wet Cleaning--Cost and Performance Comparison of Conventional Drycleaning and An Alternative Process, office of Pollution Prevention and Toxics, EPA Document 744-$-93-004, September, 1993.

**The only difference is that the first line now reads "The machine capacity is 40 pounds and each load is run at 80 percent capacity (Jenkins, 1994); therefore each load is 32 pounds..."

I obtained the main cited reference (USEPA 1993a) referred to in the repeated paragraph. This document reports an empirical test comparison of <u>one</u> alternative system. There are no direct observations or clear analysis of the extent of possible differences in labor requirements among the different PCE machine configurations.* What is potentially seriously disturbing to the reader here is that not only have the authors apparently failed to seek information on this economically important point through, for example, interviews with knowledgeable people in the industry or affected labor groups, but they have not been as open as they should have been about their lack of differential information. Indeed, a reader who had some tendency not to trust the good faith of the analysis might conclude that the authors had attempted to hide their lack of specific comparative information with a misleading precise tabular presentation of their generic estimate, and a misleading and wastefully redundant presentation of the minimal documentation they do have for their generic estimate. Casual readers might also be somewhat mislead by the presentation of maintenance cost estimates in these tables. The detailed discussions of the cost numbers here as well show a generic assumption that annual maintenance costs will be a particular percentage of initial capital costs. Thus although the tabular summary presentations might be read to imply that the authors have gathered detailed actual reliability/maintenance experience information, in reality the authors are making a simple calculation from a generic percentage assumption that has who knows what basis in actual empirical fact. In the light of the fact that this information is meant to provide a basis for drycleaners to make choices of technology options, it is particularly important for the authors to disclose that they in fact do not have specific comparative data on these significant components of operating costs. Better yet, the analysis/data gathering should be redone to provide the kind of comparative information that would actually be complete and accurate enough to be useful to both drycleaning firms and agency/community decision makers in making technological choices.

*The data could, however, be used for at least some comparative cost evaluation. If we assume, as reported by the union representative, that loading/unloading labor requirements for transfer machines are at least double those of comparable dry-to-dry machines, then data in one of the tables in USEPA 1993a can be used to make at least a generic estimate of labor differences between these two broad PCE machine configuration types. Data reported in Table II.2 of Appendix II can be used to calculate the average fraction of total process labor per load that is represented by loading/unloading:

Run Load ID No.	Weight of Clothes (lbs)	Load/unload Time (min)	Total Time (min)
100	39	3.90	25.88
110	53	3.92	44.85
120	38	3.52	19.00
130	10	0.63	9.48
140	49	2.33	31.55
150	48	2.48	20.10
160	52	3.17	44.85
170	50	2.13	20.65
180	10	2.02	9.10
190	48	2.43	25.52
Avg, 10 runs	39.7	2.65	25.10

The 2.65 minutes of loading/unloading time therefore represents about 10.6% of the total measured process labor time. If this component of the totaled ry cleaning labor requirement were doubled or tripled, then the $8,804 baseline annual process labor requirement would rise by about $900-$1400 for the transfer configurations, relative to the dry-to-dry systems. This is not massive, but it is important enough to make a difference in the analysis. For comparison, the annual savings of about 364 gallons of perchloroethylene between a completely uncontrolled transfer machine and the best dry to dry PCE machine configuration (in terms of pollution prevention, PCE-M) translates into an annual cost savings of about $1,960 at the reported PCE price of $5.38/gallon.

Each of these problems is serious enough that alone it would have the effect of significantly undermining the credibility of the analysis for a knowledgeable reader. They suggest that it may be advisable for EPA not only to redo the research underlying these tables but to recheck other aspects of the data gathering and processing for more subtle errors that are not as easy to spot as these. I would strongly recommend that EPA abandon its plans to publish the document next month, but take the time that is apparently needed to produce a product that delivers reasonably complete and comparable information on the hazards and economics of the different choices of cleaning technology. I think the resulting analysis will be of significantly more value to the audience than the present tome, which is really too extensive in gross appearance to pass as a "screening" level analysis, regardless of what the language of the introduction may say.

Response: Changes have been made to most exhibits in the risk chapter, except to the extent where exposure sources have provided only geometric means.

The quantitative analysis of labor costs has been dropped from the CTSA due to insufficient data. As the commenter noted, the labor required for loading and unloading different machine configurations can vary significantly. However, a complete analysis of labor costs appropriate for comparing among technologies requires consideration of a broader range of factors. A thorough analysis of the labor costs associated with clothes cleaning would include time for garment sorting, preparing the machine, loading and unloading the clothes. pressing and packaging the garments. The relative labor costs will also depend on the operation's size and clothing stream content. Because EPA could find no publicly available data that allow an analyst to distinguish adequately among technologies, EPA chose to limit its analysis to a qualitative discussion of labor rates.

Comment #G-34: 4. Are there any inconsistencies between the data presented in the tables and text? Not that I noticed.

Response: No response necessary.

Comment #G-35: 5. Are you aware of any specific sources where information is more current or different from that quoted in any chapter? There are unfortunately rather a lot of examples of this.

From the dates of their health/toxicology references,* the health information reviewed by the authors seems generally to be no more recent than 1994. I have included the results from a couple of recent literature searches (done on Medline) as an appendix to this letter. I have put in bold face references and portions of the aspects that I believe are particularly salient for a good review of the recent health/toxicity literature for PCE.

*For example, the citation for the Ruder et al. (1994) epidemiological study is listed as "accepted for publication" and refers to a presentation of the material made in November 1993.

A good search of the recent biomedical literature should be a basic precaution in finalizing a document such as this (preferably before sending it out for review). The reader of an EPA publication with a late 1997 or early 1998 date has a right to expect that the literature covered at least reflects the state of the relevant science through mid-1997. In this case, such a search would have spared the authors the embarrassment of repeatedly making a major point of an early report of a failure to detect activity in humans for one pathway of metabolic activation for PCE--the glutathione reaction pathway (see p. A-1, 5th par; p. A-3, 1st and 2nd new paragraph; p. A-10, 2nd paragraph under "Mutagenicity"; p. A-13, 1st 2 lines). As it happens, human measurements of glutathione-based metabolic activation of PCE have been made, and in occupationally-exposed drycleaning workers at that. These results were apparently published in January of 1996:

AU - Birner G
AU - Rutkowska A
AU - Dekant W
TI - N-acetyl-S-(1,2,2-trichlorovinyl)-L-cysteine and 2,2,2-trichloroethanol: two novel metabolites of tetrachloroethylene in humans after occupational exposure.
AB - The excretion of tetrachloroethylene metabolites in urine was studied in occupationally exposed workers to **identify and quantify metabolites formed by glutathione conjugation and by cytochrome P450 oxidation of tetrachloroethylene in humans.** The glutathione conjugation pathway has been implicated in the chronic toxicity and possible tumorigenicity of tetrachloroethylene to the kidney in rats. The biosynthesis of S-(1,2,2-trichlorovinyl)glutathione and N-acetyl-S-(1,2,2-trichlorovinyl)-L-cysteine in humans had not been demonstrated. **In this study, we investigated the biotransformation of tetrachloroethylene in humans occupationally exposed during drycleaning.** Tetrachloroethylene concentrations in the air of the drycleaning shop were 50+/-4 ppm; two individuals were exposed for 8 hr daily and two individuals were exposed for 4 hr daily. **In urine samples collected from the individuals at the beginning and at the end of the work week, N-acetyl-S-(1,2,2-trichlorovinyl)-L-cysteine and 2,2,2-trichloroethanol as tetrachloroethylene metabolites in humans were identified by GC/MS. The concentrations of N-acetyl-S-(1,2,2-trichlorovinyl)-L-cysteine in the urine of the individuals were not significantly different at the start and at the end of the work week; however, concentrations of both N-acetyl-S-(1,2,2-trichlorovinyl)-L-cysteine and 2,2,2-trichloro compounds (trichloroacetic acid and 2,2,2-trichlorovinyl)-L-cysteine and 2,2,2-trichloro compounds (trichloroacetic acid and 2,2,2-trichloroethanol) as a marker for cytochrome P450-mediated metabolism were proportional to the length of daily tetrachloroethylene exposure.** A remarkable difference in the excretion pattern of 2,2,2-trichloro compounds, the major tetrachloroethylene metabolites, was observed. Trichloroacetic acid and 2,2,2-trichloroethanol were present in the urine of two of the exposed individuals. Only 2,2,2-trichloroethanol was identified as a major urinary tetrachloroethylene metabolite in two other individuals who did not excrete detectable amounts of trichloroacetic acid. **The obtained results indicate that humans also have the ability to biosynthesize nephrotoxic glutathione S-conjugates from tetrachloroethylene; however, when compared with rats, the human capacity for the biosynthesis of N-acetyl-S-(1,2,2-trichlorovinyl)-L-cysteine seems to be lower.**
SO - Drug Metab Dispos 1996 Jan;24(1):41-8

Analogous measurements have also been made for the related chemical, trichloroethylene.*

Additionally I think it is particularly unfortunate that the authors have not chosen to draw some health risk assessment results from an excellent PCE risk analysis completed recently by the New York Department of Health.** I note that the authors must have been in touch with this group, because a considerable amount of exposure data has been included from that source on exposures of residents of buildings containing PCE drycleaners. I can't imagine why there has been no mention of the New York Department of Health's innovative analysis comparing risk estimates derived from both the human epidemiological information and the latest PBPK-modeling approach from the animal data. The authors have also done their work under the needless handicap of neglecting my own PBPK-based risk assessment modeling work for PCE:

Hattis, D., Tuler, S., Finkelstein, L., and Luo, Z., A Pharmacokinetic/Mechanism-Based Analysis of the Carcinogenic Risk of Perchloroethylene, National Technical Information Service, No. NTIS/PB88-163209, Report to the National Institute for Occupational Safety and Health and the National Institute for Environmental Health Sciences; M.I.T. Center for Technology, Policy and Industrial Development, Report No. CTPID 86-7, September, 1986.

Hattis, D., White, P, Marmorstein, L., and Koch, P., "Uncertainties in Pharmacokinetic Modeling for Perchloroethylene. I. Comparison of Model Structure, Parameters, and Predictions for Low-Dose Metabolism Rates for Models Derived by Different Authors," Risk Analysis, Vol. 10, pp. 449-457, 1990.

Hattis, D., "Use of Biological Markers and Pharmacokinetics in Human Health Risk Assessment," Environmental Health Perspectives, Vol. 89, pp. 230-238, 1991.

Hattis, D., and Goble, R., "Expected Values for Projected Cancer Risks from Putative Genetically-Acting Agents," Risk Analysis, Vol. 11, pp. 359-363, 1991.

Hattis, D., White P., and Koch, P. "Uncertainties in Pharmacokinetic Modeling for Perchloroethylene. II. Comparison of Model Predictions with Data for a Variety of Different Parameters" Risk Analysis, Vol. 13, pp. 599-610, 1993.

*AU - Bernauer U
AU - Birner G
AU - Dekant W
AU - Henschler D
TI - Biotransformation of **trichloroethylene: dose-dependent excretion of 2,2,2-trichlorometabolites and mercapturic acids in rats and humans after inhalation.**
AB - Chronic bioassays with trichloroethylene (TRI) demonstrated carcinogenicity in mice (hepatocellular carcinomas) and rats (renal tubular cell adenomas and carcinomas). The chronic toxicity and carcinogenicity is due to bioactivation reactions. TRI is metabolized by cytochrome P450 and by conjugation with glutathione. Glutathione conjugation results in S-(dichlorovinyl) glutathione (DCVG) and is presumed to be the initial biotransformation step resulting in the formation of nephrotoxic metabolites. Enzymes of the mercapturic acid pathway cleave DCVG to the corresponding cysteine S-conjugate, which is, after translocation to the kidney, cleaved by renal cysteine s-conjugate beta-lyase to the electrophile chlorothioketene. After N-acetylation, cysteine S-conjugates are also excreted as mercapturic acids in urine. **The object of this study was the dose-dependent quantification of the two isomers of N-acetyl-S-(dichlorovinyl)-L cysteine, trichloroethanol and trichloroacetic acid, as markers for the glutathione- and cytochrome P450-mediated metabolism, respectively, in the urine of humans and rats after exposure to TRI.** Three male volunteers and four rats were exposed to 40, 80 and 160 ppm TRI for 6 h. **A dose-dependent increase in the excretion of trichloroacetic acid, trichloroethanol and N-acetyl-S-(dichlorovinyl)-L-cysteine after exposure to TRI was found both in humans and rats. Amounts of 3100 mumol trichloroacetic acid + trichloroethanol and 0.45 mumol mercapturic acids were excreted in urine of humans over 48 h after exposure to 160 ppm TRI. The ratio of trichloroacetic acid + trichloroethanol/mercapturic acid excretion was comparable in rats and humans.** A slow rate of elimination with urine of N-acetyl-S-(dichlorovinyl)-L-cysteine was observed both in humans and in rats. However, the ratio of the two isomers of N-acetyl-S-(dichlorovinyl)-L-cysteine was different in man and rat. **The results confirm the finding of the urinary excretion of mercapturic acids in humans after TRI exposure and suggest the formation of reactive intermediates in the metabolism of TRI after bioactivation by glutathione also in humans.**
SO - Arch Toxicol 1996;70(6):338-46

**New York State Department of Health, Tetrachloroethene--Ambient Air Criteria Document Preprint Draft, Bureau of Toxic Substance Assessment, Center for Environmental Health, 2 University Place, Albany NY, February 1997. (This is a final review draft, but I believe that a final copy must be available.

Response: Several early decisions, in fact, handicapped EPA's summary: 1) to use only published decisions, and the support for them, unless the science completely turned about; 2) not to include as if de novo, all literature found, particularly if it was cited elsewhere; 3) time spent for passage from authors to reviewers. Consequently, except for the IARC monograph of 1995, the health information continues, on the whole, to date from 1994 or before. The CTSA now includes the Birner et al. (1996) paper in the revised text; as noted there, it gives evidence supportive of an additional metabolic pathway.

Comment #G-36: 6. Are relevant references provided for the information contained in each of these chapters? Generally.

Response: No response necessary.

Comment #G-37: It is a lengthy document which requires many hours of continued and concentrated work. The quantity of information is overwhelming but the quality of the information is often questionable. Without major revisions, this document is likely to give EPA a black eye and would not foster industry cooperation so essential for voluntarily implementing more environmentally acceptable technologies. As I begin to write today, I have already spent more hours reviewing the document than the suggested 24 hours in the contract.

In my judgement, a reviewer will have to read and study the complete report to get a holistic impression about EPA's objectives and strategies concerning the fabricare industry. I am sure that most reviewers are in the same boat as I am. I reviewed the document while I carry on with my normal work load. The report is lengthy and so detailed that even a seasoned expert and reviewer will have a tough time to meet the deadline of August 25, 1997. I am concerned that the time limitation given to reviewers may be at the expense of the accuracy and the credibility of the report. Editorial changes are required since the present version of the document needs clearly input and revisions.

Response: EPA has modified the document to improve presentation, address editorial concerns of the commenters, and to improve the presentation of the materials. The document is intended to be a repository of technical information and would not be expected to be used directly by the majority of drycleaners. EPA intends to develop a more concise version of the CTSA that can be used by a more general public to understand the general conclusions of the CTSA.

Comment #G-38: 1. The purpose of each chapter is clearly explained, sometimes at greater length than I felt was necessary.

Response: EPA has modified the CTSA to enhance readability and presentation.

Comment #G-39: 2. In general the text is clear and well presented. There are occasional lapses, such as in 1-10, third paragraph (insert 'in') and 3-44, sixth paragraph, line 2 (incomplete sentence) that additional editing will correct. To readers such as myself who are unfamiliar with EPA documentation, a glossary defining the initialized organizations would be helpful.

Response: EPA has modified the text of the CTSA based upon numerous editorial comments and has identified all initial uses of acronyms.

Comment #G-40: 3. The tables are generally clear and helpful (see below).

Response: No response is necessary.

Comment #G-41: 4. I found no inconsistencies between the tabular data and the text. Considering the number of tables I cannot, however, aver that no such inconsistencies exist.

Response Comment #G-41: No response is necessary.

Comment #G-42: 5. I am unaware of more current citations that could be added.

Response: No response is necessary.

Comment #G-43: 6. The literature cited appears to be appropriate and sufficient.

Response: No response is necessary.

Comment #G-44: When I was asked to serve as a peer reviewer, I tried to make it clear that my expertise was limited to ventilation and contaminant transport in buildings and that I would therefore need to restrict my review to those topics. After examining the report, I see no material related to those topics. Therefore I have no comments to make on the report.

Response: No response is necessary

Comment #G-45: I also have discussed the document with Dr. David Ozonoff and fully endorse the comments in his letter to you dated August 14, 1997. I have noted some of the same typographical and factual errors as Dr. Ozonoff but will not repeat them here.

Response: No response is necessary.

Comment #G-46: Each chapter clearly explains its purpose and is well laid out. Chapter 8 would be better titled Summary and Conclusion rather than "Evaluating Trade-off Issues". This chapter really summarizes what has been presented in the previous chapters and draws conclusions based on those statements.

Response: This chapter has been renamed "Trade-Off Issues".

Comment #G-47: For the most part the text is clear and well presented for the technically apt. Chapters 2-4 are written for scientists familiar with those fields. There are specific cases, as described below, where the point was confusing. Usually confusing occurs when the sentence contains a double negative. This situation was found in various places through the document. There is a lot of repetition in the document. The repetition is not bad as long as the intent is to be able to have each chapter be pulled individually from the document as a stand-alone work. There is an advantage to this since portions of the document will be of interest to risk-assessors only, portions to industrial hygienists primarily, and portions to the industry only. As the document stands, each of these groups could pull only the chapters of interest and not have to read the remainder of the document.

Response: The language in the CTSA has been modified to enhance readability. Many sections of the document are repeated in order to ensure that each chapter can be a stand-alone piece.

Comment #G-48: The tables and figures greatly enhance the presentation. The summary tables in Chapter 8 are the most valuable to the industry decision making.

Response: No response is necessary.

Comment #G-49: The greatest weakness of the document is its length. It is very time-consuming just to read the entire document, much less study it in sufficient depth to understand and use it. The greatest strength of the document is its completeness. It is a very good review of available literature and technology associated with the drying cleaning industry.

Response: The CTSA serves as a technical repository of information. EPA intends to develop a shortened version of the CTSA that condenses the findings of the CTSA and is more usable for a general audience.

Comment #G-50: Throughout the document there are words such as aqueous-based, solvent-based, PCE-based. These are not hyphenated in the document. These need to be hyphenated.

Response: EPA has made these editorial changes.

Comment #G-51: Personal communications are used as references numerous times through the document, i.e., Murphy in Chapter 1. Personal communications are useless references. I know that much of this document has been prepared with industry input, but actual references need to be sought wherever possible.

Response: EPA used published sources where possible and relied on personal communications only where information could not be found.

Comment #G-52: Throughout the document SLS is written as sodium laureth sulfate. SLS is sodium lauryl sulfate. This needs to be corrected through the entire document.

Response: EPA has removed this misleading abbreviation throughout; the correct compound is sodium laureth sulfate.

Comment #G-53: In portions of the document the compound sodium lauryl isethionate is named sodium laureth isethionate. This needs to be corrected. In the latter portions of the document the name is written correctly.

Response: This correction has been made.

Comment #G-54: Throughout the document the compound methyl 2-sulfolaurate, sodium salt needs to be changed to sodium methyl 2-sulfolaurate.

Response: The commenter provides a synonym for methyl 2-sulfolaurate, sodium salt. EPA has maintained its original presentation.

Comment #G-55: Gosselin, the 5th addition, provides some toxicological information about the compounds sodium methyl 2-sulfolaurate and sodium carbonate.

Response: EPA missed this reference in its literature search.

Comment #G-56: Once POTW is defined, then only the letters POTW should be used in the remainder of the document.

Response: EPA incorporated this change.

Comment #G-57: The preferred spelling for the past tense of model is modeled. This should be corrected throughout the document.

Response: This change has been made.

Comment #G-58: Wastewater is a single word (I think).

Response: This change has been made.

Comment #G-59: Microwave technology does not belong in this document. The purpose for including it is not clear, and the technology is too new for useful information to be derived.

Response: EPA removed the microwave technology from the document.

Comment #G-60: The CTSA contains a great amount of useful information that needs to be communicated to the cleaning industry.

Response: No response is necessary.

Comment #G-61: The overall impression of the CTSA is fair. It is the reviewers opinion that too much emphasis is placed on the health and environmental impacts of the different cleaning alternatives rather than the performance and cost, which will weigh much more heavily on the decision of a cleaner. In addition, the health and environmental information is very technical and does not seem to be at the level of the intended audience. It seems to be on the level of a toxicologist or a someone of a similar profession who is unlikely to be the trusted advisor for the typical cleaner who will be making these decisions. The reader is inundated with health and environmental information, making it difficult to make a comparison when this will probably not be the key factor in choosing alternative technologies. Performance and cost will be the prevailing factors in most situations.

Response: EPA intends the CTSA to be for a technical audience and is developing a shortened version of the CTSA more amenable for use by a broader audience.

Comment #G-62: Consideration should be given to compressing the hazard, release and exposure, and risk information and bringing it down to a level that meets the needs of the target audience. There is a lot of good information in these sections but it is buried under a lot of back-up information or detail that could be referenced or placed in the appendix.

Response: EPA intends the CTSA to be for a technical audience and is developing a shortened version of the CTSA more amenable for use by a broader audience.

Comment #G-63: The performance and cost sections are fairly thorough and provide good feedback. There could be a little more information on the case studies and points of contact for more information from the study locations would be a tremendous help.

Response: EPA has reviewed the comment and has not made adjustments to the presentation of case studies.

Comment #G-64: The document is very heavy with information on perchloroethylene, understandably so since it is by far the most widely used. However, more is not always best and there are some areas where the information can be trimmed and still provide enough information to provide a comparison. It does not have to be a clearinghouse on PCE to get the points across.

Response: The document has been modified to enhance readability. However, since PCE has been heavily studied relative to the other technologies, as noted by the commenter, it is not possible to entirely balance the amount of information presented on all technologies.

Comment #G-65: This document can very easily be adapted to meet the needs of different entities through small manuals, pamphlets, etc. on specific topics and will provide very useful information. The DfE committee is encouraged to provide these types of educational materials for a more targeted audience.

Response: EPA intends to develop a variety of materials from the information in the CTSA.

Comment #G-66: Chapters 2, 3 and 4 are very difficult to follow at times as they jump between human impacts to environmental impacts. It seems like it would be easier to follow if the health hazard, release, and exposure, and risk subject matter for humans was combined into one chapter and the environmental impacts in a separate chapter.

Response: EPA has reviewed the comment, however, continues to combine human health and environmental impacts in a single presentation.

Comment #G-67: As a technical assistance provider to small businesses, this reviewer felt that Chapters 5 and 6 were the heart of the matter and provided much useful information. A company is in business for no other reason than to make money. Most owners believe that environmental protection is important but it is not the bottom line. Therefore, the success of the business depends on the ability to turn a profit. Although environment and health issues can have an impact on the bottom line, there will be no bottom line if the customers do not come.

Chapters 7 also contained very useful information and Chapter 8 tied things up well, providing an adequate summary. There are no comments on the appendix or the reference list.

Response: EPA recognizes that businesses are concerned about the financial aspects of their business choices. However, the intent of the CTSA is to introduce the idea of additional costs, in the form of health and environmental effects, as additional considerations in the business decision. The CTSA discusses these additional considerations which may, in some ways, affect the financial aspects of a business through liability, regulatory compliance, and other ways.

Comment #G-68: There are several areas of specific concern mentioned in the review packet. many of the questions have been addressed in this section or the next. Quite a few of the concerns dealt with the validity of the estimates and assumptions for the hazard, release and exposure, and risk assessments. This is not this reviewers area of expertise and therefore no strong opinion was formed pertaining to these concerns.

Response: No response is necessary.

Comment #G-69: This document is an excellent review and summary of the issues related to selection of fabric cleaning technologies. It would benefit from a non-technical summary for workers, particularly those in the fabricare industry. Such a summary is mentioned on page 1-2, but not discussed in detail. I enclose a fact sheet which might be useful.

Response: EPA is developing a shortened, less technical version of the CTSA for use by a broader audience.

Comment #G-70: I have found that some misconceptions about processes in drycleaning have resulted in several sections which appear to be confusing and do not clearly represent the status of the industry.

Response: EPA has completed a peer review of the document to ensure that the CTSA represents the industry.

Comment #G-71: I appreciate the difficulty the authors have had in reviewing documents and trying to sort out old technology that has been totally replaced by new technology. The entire technical aspects of cleaning are changing drastically. While I was reviewing the document, I received a copy of a study recently published from Cornell University that indicates they have isolated a bacterium (apparently out of waste water treatment sludge) which removes the chlorine from perchloroethylene and converts perchloroethylene to the hydrocarbon ethylene, and the chlorine ends up being in the chloride form such as found in numerous inorganic materials such as salt. It would seem that whatever is released in the CTSA will become obsolete in the near future. However, if the CTSA is to be a credible reference document, it must not contain any inaccuracies when it is initially released. I did not find that to be the case, and became quite concerned about the accuracy of the text. In my role as a professor in a Ph.D. granting institution, I routinely review students' thesis and dissertation documents. If I received a thesis or dissertation for review in the state that the CTSA is currently in, I would advise the student that it must be rewritten and then resubmitted for review before they could schedule a committee meeting or oral defense. I am not certain that I found all of the errors that exist within the sections that I was able to review. Errors were numerous, and in some cases, very glaring in their nature. Given more time to conduct the review, I would like to have gotten into more detail and repeated the calculations involved in the modeling in chapter three. The numbers that were generated, in my mind, are instinctively in error. I sincerely regret that I was not allowed ample time to review the entire eight chapter document. I have read through the entire text and believe that my area of expertise is represented to a reasonable extent by the comments I was able to make.

Response: The calculations in chapter 3 have been checked. There were some rounding errors with a few of the numbers. These have been corrected. However, the results are not essentially different from the previous draft.

Comment #G-72: I am gravely concerned about the statement in your cover letter indicating the EPA is committing to getting the document out by September 1997. I do not see how the document can be converted from the form it is currently in to a final form in that period of time. I further believe quite strongly that releasing a CTSA that is not accurate will result in a CTSA that has no credibility.

Response: The commenter is correct that a longer timeframe is necessary to properly revise the CTSA and EPA has invested the time necessary.

Comment #G-73: General Comment A: With regard to solvent drycleaning, the document distinguishes between PCE (perchloroethylene) and PS (petroleum solvent) cleaning methods. PCE and PS does not adequately cover the solvents for drycleaning. There have been discussions in the industry regarding the possible use of other solvents such as Ryne®, esters, ethers, etc replacements for the current solvents. The character of these solvents is not clear since they are not currently available on the market. However, there is a major category that is on the market and is not covered in the CTSA. This category is synthetic hydrocarbon solvents (Exxon DF-2000). Some of the technology for this solvent is very similar to PS, but yet somewhat different. The designation petroleum solvent (PS) implies that the solvent is a distillation fraction from petroleum.

Different distillation fractions have different characteristics in terms of boiling points, flash points, odor, and composition.. The two fractions most commonly used in industry and clearly classified in the CTSA are Stoddard Solvent and I40F Solvent. The synthetic hydrocarbon category is different in that the material is synthesized rather than distilled from petroleum. It is my understanding that the material is a single component and not a mixture of components. This results in a more definite flash point, boiling point, and other characteristics rather than a range which is typical for petroleum solvent. The DF-2000 solvent is widely used within the industry, and the verbal reports I have heard from cleaners is a very high degree of success with the product. The CTSA cites references from Jim Shriner of Exxon, and I am surprised that a clearer distinction of the synthetic hydrocarbon DF-2000 is not included in the CTSA. I would suggest resolving this dilemma by replacing the PS (petroleum solvent) designation with HC (hydrocarbon). The HC designation could include both petroleum solvents and the synthetic hydrocarbons. Both are compounds of carbon and hydrogens and adequately defined by the term hydrocarbon. This would also make it necessary in the CTSA to include more lengthy discussions of the properties of synthetic hydrocarbons. In the U.S. this could clearly be typified by discussing the nature of the EXXON DF-2000 solvent. It is my understanding that the flash point is higher than 140°F, and the color and odor characteristics are a major improvement over the PS category of solvents.

Response: EPA has included information on DF-2000 and Rynex where appropriate.

Comment #G-74: General Comment B: I found the discussion of the machine technology of solvent cleaning confusing, and as a result, some of the tables misleading. There are many similarities between the basic design of machines with regard to cleaning, filtration, solvent recovery, and distillation that could be applied to both technologies. If one were to examine the tables alone (which is likely to occur if the CTSA becomes a reference document), the titles of categories can become very confusing. This is especially the case in solvent cleaning with the labels of uncontrolled, carbon absorber, and refrigerated. It took me some time and some studying of the document to realize that these were apparently classifications based upon the nature of the secondary vapor recovery device. For the benefit of the author, let me review the drycleaning technology as I believe it should be presented in the CTSA. This technology would apply to any solvent cleaning system. The discussion of a separate cleaning unit (washer) and dryer for transfer machines is very well done. One concern is regarding the discussion of dryers for transfer machines and the drying function of a dry to dry machine. It is my understanding that there are some older solvent cleaning machines in which the drying function is performed without any vapor recovery. This is probably an extremely small number for perchloroethylene due to the cost and odor that would be associated with the practice. It is likely that there are many hydrocarbon machines which dry by evaporating the hydrocarbon solvent and venting all of the evaporated solvent to the atmosphere I would anticipate practices such as this would be targeted for phase-out. All machines should be equipped with some type of condenser to recover the evaporated solvent. These condensers could be air cooled, tap water cooled, chilled water cooled, or refrigerated. An extensive option to a condenser as described in the CTSA could be a carbon bed used to capture the evaporated solvent. A condenser cooled by tap water consumes a substantial amount of water and could possibly lead to a discharge of solvent in the waste water stream due to leaks in the condenser coils. The efficiency of this technology depends upon the temperature of the tap water. In Texas in the summer time this is not a very practical system. The tap water condenser can be modified (chilled water condenser) by using cooling water that is recirculated from a refrigerated storage tank. This is very desirable technology in that the refrigerated water keeps any escaping solvent within the plant, reduces water consumption, and provides more efficient operation of the condenser by controlling the temperature of the water. A refrigerated coil

can be used as the condenser and would, perhaps, create some concern depending upon which refrigerant is used in the coil. Refrigerated coils can operate at lower temperatures. However, very low temperatures are not desirable. As the temperature of the vapor stream is lowered, the solvent condenses at a faster rate. Since the air across the condenser is recirculated back over a heater to the machine to provide the drying function, it becomes difficult to heat the chilled air warm enough to provide efficient evaporation. Therefore, too cold of a condenser coil results in very low drying rates. With the exception of fifth generation machines, a deodorizing cycle follows the drying cycle in which the last traces of solvent are vented from the machine. This venting gives rise to what I believe is the basis for the discussion currently held in the CTSA. Once the air is vented from the machine, there are methods to recover additional solvent vapor by the use of a secondary recovery device. This secondary recovery device could be a carbon absorber, a refrigerated unit, or no secondary device, what is referred to (with my objection) as uncontrolled. The term secondary vapor recovery device is well known within the industry and is included in terminology of the CTSA. I would propose that we use the term primary vapor recovery device for the condensers that are used as part of the drying operation. This is not commonly accepted terminology, but would allow us to distinguish the two types of vapor recovery. I believe the discussion of carbon absorber technology currently in the CTSA in some sections is discussing primary vapor recovery and other sections secondary vapor recovery. This is especially the case with the discussions related to how often it is necessary to strip the solvent from the carbon and the volume of water that is necessary. The volume of solvent going to a secondary carbon absorber should be a relatively small amount if the machine is equipped with a properly functioning refrigerated or chilled water condenser. For the author's information, it may be important to note that many of the refrigerated condensers on drycleaning machines use chilled water to cool the refrigeration compressor. Therefore, it can be confusing looking at a machine to know whether the chilled water is part of a refrigeration system or the condenser feed. In my experience, I have found chilled water condensers to be 1 very efficient, economical, and environmentally friendly method of recovering solvent during the drying operation.

I object to the terminology that is set forth in the CTSA for uncontrolled, refrigerated and carbon absorber categories. If the CTSA is to be a referenced document for operators, I believe it would be necessary to include a discussion of both primary and secondary condenser types and their function. I would consider the tern uncontrolled to refer to a dryer that has no vapor recovery and vents all of the solvent to the atmosphere.

Response: EPA agrees that the descriptions of controls for solvent process machinery were unclear and some terminology could be objectionable to some readers. In the updated CTSA, these descriptions have been clarified and objectionable terminology removed to the extent known.

Comment #G-75: General Comment C: I found the discussion and footnotes regarding azeotropic processes to be very misleading. By definition, an azeotrope is formed in the liquid phase and consists of a mixture that produces a lower boiling point Azeotropes are clearly formed with water and perchloroethylene. Because of the moisture that is added to the cleaning process from clothing, detergents, or intentionally added to improve cleaning, azeotropes are present. The azeotropes form in the drying cycle and, certainly, in the distillation operation. I have not tested the technology reported in the CTSA called solvation. It is my understanding in general discussions with people in the industry that this technology did not work and is no longer being sold. Certainly the explanation of this technology as presented in the CTSA does not make scientific sense. Since azeotropes have a lower boiling point, condenser recovery would be decreased, nor increased. Later in the CTSA the combinations of machine technology using this azeotropic technology is

overwhelming. The CTSA appears to recommend the solvation process. It is by opinion that releasing the document with an unproven and, perhaps, non-working technology having such a preponderance in the tables would drastically weaken the credibility of the CTSA among the cleaning industry.

Response: EPA acknowledges the lack of clarity on this issue, particularly on p. 1-11 of the peer review document. The explanation of this technology has been clarified and reduced in the CTSA. However, the commenter appears to conclude that the CTSA recommends the Solvation process because he or she perceives that it receives too much coverage. However, the extent of coverage in the CTSA does not correspond to an EPA recommendation. No recommendations are made in the CTSA; it is a comparative document. Also, the author of this CTSA section has no information to indicate that azeotropic processes do not work.

Comment #G-76: General Comment D: Throughout the CTSA not enough attention is given to the nature and the disposition of soils that are being removed from the garments. Since this is a primary role of the cleaning process, the impact of soils cannot be totally ignored. Granted, soil makeup would be a difficult concept to include in the modeling and projections. However, a general scenario regarding soils should be included. I think it important to note that the soils will most likely follow the route of the detergents and chemicals used in the process. Therefore, in wetcleaning the soil will be discharged into a POTW. In solvent cleaning, the soils will become part of the still bottoms or filter residue. In the case of potentially hazardous soils, these considerations certainly should not be ignored.

Response: The reviewer raises an interesting point. However, an evaluation of exposure to soils is beyond the scope of the CTSA.

Comment #G-77: General Comment E: The filtration technology is well written with regard to PCE systems. However, the systems described for PS systems are representative of a very old technology and do not include more current filtration systems. In actuality, a discussion of filtration systems in general could be applied to both PCE and PS (HC) technology. Bump filters and spin disc filters are available in both technologies. Likewise, canister filters are available for both technologies, and the canisters can include a combination of paper, carbon, and clay. Powder coatings can be applied in both technologies and increase filtration. However, the use of powder greatly increases the amount of muck or still bottoms that are produced, and this practice seems to be rapidly declining. The move in all solvent technology appears to be toward mesh filters which do not require coating and are not disposed of as solid waste.

Response: EPA agrees that the descriptions of filtration systems for PS systems in the peer review CTSA needed updating. The updated CTSA includes updated information on PS systems filtration.

Comment #G-78: General Comment F: In my opinion, the discussion on care labeling should appear earlier in the CTSA. Statements suggesting that manufacturers arbitrarily label items with dry clean only that could be washed is very misleading. In assigning care labels, manufacturers must indicate an acceptable method. The requirement of the care labeling rule to provide an acceptable method of care does not require that the care label will indicate the best method of care. There is a common practice known as low labeling in which manufacturers tend to indicate very cautious care instructions, apparently in an effort to avoid liability for damaged merchandise.

Not only is it possible that items labeled dry clean could be washed, it is also possible that items labeled hand wash in cold water could be machine washed. The FTC and the professional fabricare industry will most likely agree upon a wetcleaning definition that would distinguish professional wetcleaning from home care methods. It would also appear to be necessary co distinguish machine wetcleaning from something such as multi process wetcleaning. Manufacturers are not required to indicate all acceptable methods, but what they indicate on the label must be supported by a reasonable basis. The reasonable basis for a label can either be based upon a history of success with that technology for that particular garment with consideration of fiber, fabric, and garment construction variables or must be supported by test results. It is my anticipation that apparel manufacturers will be very reluctant to incur the added expense of testing to verify the appropriateness of a wetcleaning label. I have heard a broad range of estimates as to how this might affect the selling price of garments, especially if every variation of construction and color would have to be tested separately. At the present time, manufacturers of fine clothing, wool sweaters, suits, etc. recommend drycleaning based upon an historical (reasonable) basis. Under the current provisions of the care labeling rule, consumers or cleaners who use a method of cleaning other than the one recommended by the manufacturer assume liability for the products performance. For cleaners to process a large percentage in a wetcleaning process that are labeled "dry clean only" represents a substantial liability. One of the questions I have raised at meetings and have not had answered to my satisfaction is the legal aspects of where the liability falls. For example, if a machine manufacturer and/or a chemical company sell equipment and products to a cleaner that are intended to allow the cleaner to process dry clean only garments in a wetcleaning system, do the manufacturers of the equipment and chemicals, therefore, share in the liability for damaged garments?

Response: EPA has included a discussion of the Care Labeling Rule in its Regulatory Analysis chapter; however, it is not the purpose of the CTSA to address the legal aspects of liability relating to the requirements.

Comment #G-79: General Comment G: The CTSA indicates there is a wide range of reported success with regard to wetcleaning items. I have been present at numerous presentations where these studies have been reported and have been involved in discussions both formally and informally. Part of the discrepancy comes from how the calculations are done. In some of the studies the percent of items that are successfully wetcleaned are calculated based upon number of items wetcleaned compared to total number of items in the study. In almost every case, the items in the study include a mix of items labeled dry clean and items that have washing instructions. Therefore, the results are skewed based upon the mix of wash versus dry clean labels. In some of the projects, certain types of items were not accepted for cleaning and referred to traditional drycleaners for processing. One hundred percent of the items in a plant can be wetcleaned if the counter personnel only accept items that they are assured will satisfactorily wetclean. A more meaningful number comes from those studies in which the only items involved in the calculation are those labeled as dry clean or dry clean only. The number we should be interested in is what percentage of items labeled dry clean can be wetcleaned, not what percentage of items regardless of label can be wetcleaned.

Response: EPA reports the results of the performance studies; however, it is not within the scope of the document to critique these studies.

Comment #G-80: General Comment H: Again with the idea that the CTSA would provide a reference document and that tables and figures might be copied and used elsewhere, I believe we should be more complete in diagrams that show the over-all process for the PCE or HC cleaning machine. The exhibits shown are for transfer machines, and, hopefully, represent a technology that will be phased out in a timely manner. I believe it would be more appropriate to either replace these or include as additional exhibits schematics showing dry-to-dry machines with secondary vapor recovery devices. In light of the direction of technology, it seems appropriate to show the latest technology and then indicate what items in the technology are not present on older machines.

Response: In the updated CTSA, the more recent dry-to-dry machines used in drycleaning facilities have been included in the flow diagrams.

Comment #G-81: General Comment I: The references for drycleaning technology appear to be obviously lacking in that the training manuals used by the Neighborhood Cleaners Association (NCA), the International Fabricare Institute (IFI), the Southwest Drycleaning Association (SDA) and other such groups are not included. These training manuals provide a generic (nonvendor) source of information, and, in my opinion, are very objective.

Response: EPA requested these references but was only able to obtain one from IFI. The IFI reference was used extensively in updating information and replacing some personal references in the updated CTSA.

Comment #G-82: General Comment J: I understand the concept of the modeling calculations that were performed, and it initially appears that the assumptions are reasonable. However, the results are much different than I instinctively expected. I don't know if this represents a lack of insight on my part, or, perhaps, an error in calculations.

Response: The general population exposure calculations have been checked. There were some rounding errors, which have been corrected. However, the results are not essentially different from the previous draft.

Comment #G-83: General Comment K: The multi process wetcleaning project was Funded by EPA and, perhaps, is the reason it is covered so thoroughly in the CTSA. However, even within the CTSA the summary indicates that this procedure is no longer practiced, and that it is augmented with a machine wetcleaning process. In my mind, this no longer justifies malts process wetcleaning as another technology; just as the supplemental spotting that is done in laundering and drycleaning do not represent a complete technology.

Response: EPA has removed multiprocess wetcleaning from the CTSA as a technology alternative.

Comment #G-84: General Comment L: One of the scenarios that I thought was being pursued by EPA, but is apparently not part of the CTSA, is an analysis of the entire textile product chain. This would include environmental assessments of fiber production, yarn processing, dyeing finishing and the eventual recycling of used textiles. The cleaning step is only one process in a rather lengthy chain involving textiles for which an environmental impact analysis would be appropriate. The

other aspect is the fashion demands of the consumer. I am old enough to remember the fiasco of double knit polyester leisure suits in the 1970's. Many in the cleaning industry thought they would be put out of business, and, in fact, the cleaning industry declined. However, consumer rejection of the fiber and the fashion lead to a resurgence in cotton and wool fiber use. It is very simple to realize that if our fiber choices were limited to things such as polyester, that almost everything could be laundered or wetcleaned. However, the loss of fibers such as silks, wool, and other hair fibers would not be well accepted by today's consumer. Additionally, the eventual disposal of these fibers in solid waste requires another analysis as to the biodegradability of fibers such as polyester compared to protein fibers such as wool and silk.

Response: Coverage of the entire textile chain is outside of the scope of the CTSA; however, the Design for the Environment's Garment and Textile Care Program is active in this area.

Comment #G-85: Overall, I thought that the document was very good. I have focused my comments on health risk issues (my area of expertise) but do have some comments on other sections of the document.

Response: No response is necessary.

Comment #G-86: I do have one serious issue regarding the health risk assessment of PCE. The language in the document is quite inconsistent in assessing PCE, especially the carcinogenicity of this substance. I understand from later correspondence that EPA intends to modify the document to be more consistent with current EPA policy, other documents, etc. This should be done quite carefully and with careful review due to the many parts of this document that reference this information. I have tried to point out many of the problems with the current document but probably missed many others. I believe that the necessary revisions are more extensive than implied in the clarification issued on August 6.

Response: Revisions are, in fact, extensive in many parts of the CTSA and consistency of presentation has been addressed.

Comment #G-87: Another significant health issue overlooked in the report is the potential effect of PCE and solvents on children. Although the data are sparse (except for some reports on nursing mothers), there are good reasons to believe that children may be more susceptible to the neurotoxic and other health effects, especially given the exposures that may occur in some residences. EPA has recently set up an office dealing with environmental health and children. Some information on this issue should be included in the document.

I have organized by comments by chapter.

Response: The discussion of children's exposure has been expanded and has been coordinated with EPA's Office of Children's Health and the Office of Research and Development.

Comment #G-88: While the purpose of each chapter is summarized, I believe that the format encourages redundancy in the presentation. For example, rather than presenting data collection (with chemical and health information) followed by Risk, then Performance, then cost I would

suggest taking a technology and explaining all of the associated issues just once. In the current format the same information tends to be repeated in each chapter leading to reader burnout. Conclusions should be featured in boxes (or some other mechanism) to highlight them.

Response: EPA has reviewed the comment and made some changes to format. In general, however, the format has been maintained.

Comment #G-89: The quality of the collected material is generally good. However, the quantity seems to be overwhelming. The document needs to be severely pruned to highlight what is known. A significant portion of the document is dedicated to presenting caveats on the data, often several different times. One suggestion to increase clarity is to put the text and appendices in separate volumes and move much more of the chemistry and toxicity presentation to the appendices. The Executive Summary should be rewritten to contain the conclusions of the CTSA (see comments in Executive Summary review below).

Response: EPA has added more material to appendices to increase clarity. The Executive Summary has been rewritten to provide a better presentation of results.

Comment #G-90: The tables are often the crux of the report. However, within a chapter they should be thoroughly scrubbed to assure common units of measure. Fewer tables might help the reader. Several tables are really lists and belong in the appendices.

Response: EPA has moved some information to the appendix and has revised tables to use similar units of measurement (or explain differences).

Comment #G-91: I point out inconsistencies in text and table data below as they occur. One key problem seems to be that different chapters are written by different people with different background information (not unusual). This results in different values being reported for the same factor in different chapters. I have pointed these out where I have found them.

Response: EPA has addressed the specific comments.

Comment #G-92: New information is cited below, particularly with regard to CO_2 technologies where my primary expertise is.

Response: EPA has evaluated information provided by commenters and has moved discussion of CO_2 technologies to an Emerging Technologies chapter.

Comment #G-93: New references provided where appropriate.

Response: No response required.

Comment #G-94: Energy consumption should be a much stronger consideration and more consistently applied factor in the review. Energy costs translate directly to the bottom line of the

operator. Energy cost comparisons apply to a variety of dry-cleaning procedures: distillation energy, refrigeration condensers, aeration, adsorber regeneration, fugitive emission control fans, evaporators, etc. It is not clear to the reader that a systematic life-cycle cost evaluation has been applied as a part of the analysis.

Response: EPA has revised its estimates of energy consumption; however, as noted, a life-cycle assessment is outside of the scope of this document.

Comment #G-95: Several aspects of the description of PCE and PS cleaning are repeated from Section 1.2 increasing the length of the document without enhancing content. It might be advisable to craft one section on process, market, and technology rather than multiple sections.

Response: EPA has reviewed the comment, however has not adjusted the presentation of this information.

Comment #G-96: As a reader I found that there were some really repetitive concepts throughout the document. I would suggest using a "find" function in the word processing program and, after the first 5-6 mentions, deleting the rest. These include: release from transfer machines is higher than from dry-to-dry machines; the highest exposures are among drycleaning workers; poorly maintained machines leak; there is a fire risk from petroleum solvents; and dermal exposure occurs when working with solvents.

Response: The repetitive comments are needed to maintain some "independence" of one chapter or section from another. This repetition relays these facts to a reader without the reader's needing to read larger portions of the CTSA.

Comment #G-97: As you will observe, I believe the document needs major restructuring. The document could be much more useful if it were focused in a slightly different way., I would be glad to assist EPA by providing additional information if you decide to undertake a major rewrite.

Response: EPA has restructured the CTSA to enhance readability.

Comment #G-98: I do not believe EPA should publish the document as it is with only minor changes. If it comes out in its present form, it will be an embarrassment.

Response: EPA has invested the time necessary to revise the document.

Comment #G-99: At this stage, there are three technologies that cleaners use today. These include PERC, wetcleaning and PS. The document is fairly effective in portraying the very high risks to cleaners, the surrounding community and the environment from the use of PERC. I think the risk assessment portion of the document is very useful. The risk analysis of petroleum solvents performed here is not of great use because the issue of flammability is virtually ignored.

Response: A qualitative discussion of the issue of flammability has been included; however, quantitative assessment of flammability risk was not possible.

Comment #G-100: The document should be restructured to show that the use of PERC drycleaning poses a high risk. The risk of the other technologies should not be rigorously evaluated because either it is not actually treated (flammability of PS) or the document states there is not enough information to examine it (all other technologies). I would recommend that the document not try to analyze the detailed risk of all the other technologies, but rather present them as potential alternatives to PERC. Their problems should be discussed (PS is flammable, wetcleaning may have discharge issues, etc.).

Response: Because the CTSA is intended to provide comparative information, risks of alternatives to PCE processes have been included. However, comparisons of emerging technologies are not discussed due to the speculative nature of the data.

Comment #G-101: There should be two categories of alternatives. The first category should include wetcleaning (which is done today and equipment is available and sold) and petroleum solvents. Petroleum solvents of two types are available, the traditional solvents and the new higher flash solvents. The newer solvents are being used in the nitrogen inerted or vacuum equipment which significantly reduces the flammability risk of the process. The second category of alternatives should include carbon dioxide and wetcleaning variations (microwave dryers paired with wetcleaning and ultrasonics paired with wetcleaning). All of these options should be discussed in detail with regard to their advantages and disadvantages but a rigorous risk assessment on them should not be attempted. It is obvious that they pose less of a risk than PERC. That way, the document demonstrates that PERC poses a high risk and that there are other options available for cleaners.

Response: EPA has reviewed this comment and others regarding reorganization of the document and made appropriate revisions.

Comment #G-102: Site contamination is not evaluated extensively. This is the major reason drycleaners are having difficulty leasing facilities for PERC machines. It is also the major issue in the drycleaning community today because of the possibility that they will be required to pay for cleanup of their sites. It is the major reason drycleaners would switch to an alternative. It should be discussed in the document in more detail.

Response: An expanded discussion has been provided. Summaries of groundwater contamination in New York and California are discussed in the general-population exposure section, and the results of database searches (including ATSDR) is discussed in Appendix D.

In addition, EPA has identified these issues as part of its coverage of the Comprehensive Environmental Response, Compensation, and Liability Act.

Comment #G-103: The cost analysis should not be conducted for all the options it presently covers. I understand that it was necessary to cost out transfer machines and other PERC options because the operating costs of all possible cases needed to be compared. This is not the issue, however. The risks of using PERC should be presented, the alternatives should be discussed and then the cost analysis should be performed under the assumption that a cleaner is going to purchase a new system. The new system can be a dry-to-dry closed loop machine (the only real

system being offered today)n using PERC, it can be a machine wetcleaning process or it can be one of the new petroleum nitrogen inerted or vacuum machines. These options are the only ones that should be costed out in detail. Speculative costs (and they should be so defined) could also be given for the other processes like carbon dioxide.

Response: EPA has revised the machine options it has analyzed. Data on transfer machines have been maintained because they represent a baseline. Because information on the emerging technologies, such as CO_2, is speculative, these technologies have been moved to a chapter on emerging technologies.

Comment #G-104: The document is not useful for guidance as it is. If the document is restructured in the manner described above, it will actually be useful to cleaners who wish to evaluate different options. Picture the cleaner today with a very old transfer or dry-to-dry vented machine. The cleaner, every 15 years or so, purchases a new machine. The cleaner is probably aware of the problems with PERC machines in terms of landlords, site contamination and regulatory requirements. He/she might want to explore other options. The only two options available currently are machine wetcleaning and new petroleum machines that will be approved by fire departments. These are the options that they need to examine.

Response: EPA has restructured the CTSA to enhance the readability and presentation of the document. EPA intends to develop a short version of the CTSA that summarizes the results developed here, that is more suitable for use by the cleaner.

Comment #G-105: The cost analysis presented for PERC in the document contains many errors and is not credible. Anyone who knows the industry will know about these errors. The analysis should be redone before the document is released.

Response: EPA has revised portions of the cost estimates.

Comment #G-106: Overall, I enjoyed conducting the review, even though I tended to disagree with the general approach taken to evaluate the human health risks of the various technologies. On the other hand, I find the higher goals of the CTSA to be intriguing, and would be curious to see whether the approach works as intended.

Response: No response is necessary.

Comment #G-107: In a very basic sense, attempting to compare technologies on factors for which there are enormous informational gaps and uncertainties, usually due to the lack of scientifically valid data on key issues, seems to me to be tricky business. Although these gaps are frequently and appropriately noted, the true impact of just how much of the total picture is missing is not fairly addressed. Nevertheless, many of the conclusions drawn regarding health effect and related trade-offs (as in Chapter 8)might have been arrived at by more straightforward and intuitive means: given that several adverse health effects of PCE have been noted in both the human and animal literature (despite numerous limitations), avoidance/reduction of exposure seems prudent. By extension, then, those drycleaning systems generating less exposure are more desirable, and those

generating more should be modified. That some of these modifications are more or less cost-effective perhaps represents the most important bottom line.

Response: No response is necessary.

Comment #G-108: Because of the range of data gaps, an impression is given that choices can be made based on objective information, comparable across technologies. Although water-based techniques are likely to have some health concerns, they appear to be relatively minor (such as skin irritation), and for some chemical constituents, little is known of the possible health implications. How can the alternatives be compared in any detail, especially against substances which some believe to be carcinogenic? Greater simplicity and clarity of approach (especially with respect to human health effects) might produce a more credible and possibly more utilized document. For example, the document could be substantially compressed if the summaries were extended: a) summarize the alternative processes to be compared; b) summarize the substances used in each process; c) summarize the likelihood of human exposure to these substances under various realistic scenarios; d) summarize the human health effects, if any, relevant to the range of levels encountered; e) summarize the health and economic costs/benefits of modifying processes or equipment or converting to one or more alternative technologies. At any point, identify gaps in existing information, and provide reasonable means for estimating values. In contrast, the current document neither comprehensively and critically reviews the primary literature in any detail, nor synthesizes it adequately for a non-expert to understand the key issues. Also, the document occasionally details primary research (as in Chapter 5, Review of Performance Studies), yet possibly over-simplifies (or dismisses) other aspects (such as much of the human health information available, as in section 4.2.1). This inconsistency might be remedied by summarizing information only (or detailing more of it, which would create an even more unwieldy document).

Response: The CTSA has been revised, in text as well as in format, to try to make the information more useful to the reader. Section 4.2.1, for instance, has been removed so that there was no need to condense the health information of Chapter 2 or (now) Appendix C any further.

Comment #G-109: Heavy dependence is placed on modeling when data are deemed to be lacking or inadequate (especially risk models). In most cases, however, the models carry greater assumptions (usually not clearly stated) than proper synthesis of real data. Furthermore, the models frankly may be inappropriate, e.g., basing current exposure estimates on outdated compliance/enforcement data, and subsequent models for risk. Toxicological methods just do not appear to work here, either. Most epidemiological studies, despite the failure to control for even moderate confounding, will not be off by as much as one order of magnitude. If the human health data are largely avoided so as to avoid the current controversy surrounding the carcinogenicity of PCE, informed readers will detect this and discount the validity of the balance of the document. Appendix A contains a more objective and honest assessment (but less likely to be read by drycleaners) than the text (e.g., chapter 4). A good objective synthesis of the human health literature -- avoiding the carcinogenicity controversy -- would be valuable in the main text.

Response: EPA believes that the CTSA contains adequate caveats, relative to use of this data, including addressing the issue of representativeness. Also, newer data have been included in the updated CTSA. Compliance/enforcement (C/E) data are commonly used in EPA/OPPT exposure screening assessments, particularly when readily available sources of "representative" data cannot be found. A qualitative comparison of the two large data sets, PCE C/E data sets in Exhibit 4-5 and

IFI data sets in Exhibit 4-7, indicates that these sets are compare closely. None of the data sets can be directly compared since only limited information are available on each set. Also, the updated CTSA contains more data for comparing different factors affecting exposure. As noted earlier, the CTSA contains adequate caveats, such as the issue of representativeness, relative to use of data, and this applies to C/E data.

While some of the health hazard summaries have not been much changed, the revisions that have been made will clarify the ability to draw conclusions about the respective chemicals' effects.

Comment #G-110: It is unclear whether this is a one-time document, or the product of an ongoing process. Perhaps knowing that as information becomes available it will be synthesized into the document, some of the major informational gaps might be excused. (Is this what is meant by a "flexible format" in the Guidance to Reviewers?) How, and when will new information be incorporated? If this is a one-time document, however, does it not seem premature, given that the new technologies are emergent?

Response: At this time, EPA does not intend to develop a new CTSA to capture information that develops on processes in the future. Rather, the Design for the Environment's Garment and Textile Care Program will serve as a conduit by which much of this information can be disseminated.

Comment #G-111: The document needs to state its aims and objectives, as well as identify its target audience(s) at the beginning of the document, preferably Chapter 1 (fragments of its purpose are stated in the Executive Summary and Introduction to Chapter 8).

Response: EPA has revised language to clarify goals, objectives, and target audience.

Comment #G-112: Similarly, there is a lack of a general description of the organization or structure of the document. The current structure may benefit from some modification as well, as much of the document lays out (with varying degrees of detail and organization) a somewhat tedious collection of technical and background material, most of which has been summarized elsewhere. The truly unique and valuable aspect of the CTSA seems to me to be the creative synthesis of multiple dimensions for comparative purposes, under different scenarios and assumptions. While what is presented in Chapter 8 seems reasonable, it strikes me as a bit thin. I would think that the intended user is mostly interested in this synthesis, as this would be the part which informs important decision-making processes.

Response: EPA has modified the organization of the CTSA and has strengthened the presentation in Chapter 8 (now Chapter 10).

Comment #G-113: Numerous references to "personal communication with..." are cited in references which technically should only include materials generally available (see CBE Guidelines or other standard handbooks on scientific writing). Such "unofficial sources of information should be noted in the text or in footnotes. This standard probably has been established to avoid the appearance that this type of cited material has undergone the peer-review process to which other published material is subjected.

Response: EPA used published sources where possible and relied on personal communications only where information could not be found.

Comment #G-114: There are many redundancies in the text. Granted, most users of the document will not be reading it from cover to cover, but a tighter organization might allow a terser and more informative (less mechanical) document.

Response: EPA has reorganized the document; however, has maintained some redundancies in the chapters to assist readers who do not read the entire document

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Comment #G-115: Too many acronyms from too many fields are used. A comprehensive list of abbreviations (perhaps at the beginning of each chapter) would help any reader/user.

Response: EPA has attempted to clarify its use of acronyms throughout the document.

Comment #G-116: Although this is far from my field of expertise, why does the document not consider the potential for developing and using new fibers for clothing which would not require drycleaning? Apparently some are already on the market, and might constitute an important dimension in the process of deciding whether to modify cleaning technologies.

Response: Investigation into the possibility of developing new fibers for clothing is outside of the scope of the CTSA. Some aspects of this are being addressed by the Design for the Environment program's Garment and Textile Care Program.

Comment #G-117: The introductory paragraph of each chapter appears to describe well the preps of each chapter. However, very little is provided at the chapter level indicating how each chapter "fits" together, i.e., how the chapter contributes to the broader objectives of the CTSA. The title of Chapter 2, Data Collection, might be more accurately, "Sources of Information for the CTSA." Also, the introductory paragraph of this chapter, including the statement of purpose, do not necessarily describe "data collection."

Response: The language in the chapters has been clarified to assist the reader in understanding the relationship of each chapter to the others.

Comment #G-118: The text is generally clear and well presented. In fact, some chapters and sections are very well written: clear, interesting and informative. As mentioned elsewhere, however, a general introduction with a clear outline of objectives and central organizational or structural strategy for the CTSA would be most helpful. Because this is currently inadequate, Chapter 1 suffers most from a lack of clarity and logical flow. Perhaps recasting Section 1.1, adding statements of objectives and the organizational strategy would remedy this.

Response: Chapter 1 has been modified to more clearly state the objectives and describe the structure and intent of the document.

Comment #G-119: The tables are reasonable, and in most cases enhance the text. Some tables might be combined to reduce the number of tables and redundancies. The format of the tables is somewhat primitive, perhaps reflecting a draft stage of development. Spreadsheet-style tables with heavy (but unnecessary) grid lines also detract from the table's ability to present information hierarchically, or with various levels of detail. Little apparent effort has been made to utilize more effective graphical presentation or summaries of data: charts and graphs (and some of the few bar charts presented are unremarkable, e.g., exhibits 8-14 and 8-15). Many of the tables could be transformed into dramatic graphical presentations, with greater pedagogical and persuasive value. Although one might argue that the precise values presented in table cells are valuable, more critical communication (such as the broader purpose for the presentation) may be lost due to this detail. Finally, calling the tables and figures "exhibits" seems unusual, and conjures legal (and therefore unfriendly) connotations.

Response: EPA has reviewed the comment, however, generally has maintained the presentation of tables. The use of "Exhibit" in the CTSA is accurate and has been maintained.

Comment #G-120: The table and text appear to be compatible. See comment #3 above for comment on graphical alternatives.

Response: No response is necessary.

Comment #G-121: Dr. Salvatore DiNardi -- an industrial hygienist at the University of Massachusetts -- has conducted some important exposure monitoring work within the drycleaning industry, but perhaps this work is not published yet. Dr. DiNardi has employed video taping concurrently with real-time exposure monitoring to evaluate specific drycleaning tasks in various shops. Dr. DiNardi's data would seem to be an important contribution for the CTSA process.

Response: DiNardi did not respond to an EPA inquiry. However, the updated CTSA has incorporated information from a NIOSH study. NIOSH studied some factors, such as drycleaning worker tasks, which the commentator describes DiNardi as having investigated.

Comment #G-122: References generally appear adequate; however, see comments above under I-II pertaining to personal communication as references. One apparent deficit is inadequate reference to the human (epidemiological) literature; although the CTSA intends to provide a review-level treatment, better use of the available human data could be made. It is hard to believe that the entire epidemiological literature relevant to PCE is of no informational value, and that mouse and rat studies (which may not be relevant models for humans) are to be considered preferentially. This bias may ultimately compromise the validity and utility of the CTSA.

Response: It is unfortunate the commenter interpreted the use of rodent data to obtain a quantitation for the carcinogenic potential of PCE to indicate such data are preferred to human data. The epidemiological studies contribute substantially to the weight of evidence considered by the EPA and by IARC in their classifying PCE with respect to carcinogenicity, and we hope revisions in the text have made this clearer. The human studies, meanwhile, are insufficient to derive specific dose-response relationships or comparison values. In some cases, for instance, this is because of the fashion in which risk is provided in the study, in others because the exposures are

not well characterized. The Agency will be undertaking a full assessment of PCE under the auspices of the Office of Research and Development within about a year.

Comment #G-123: This reviewer finds the report, Cleaner Technologies Substitutes Assessment for Fabricare: Including Wet and Drycleaning Technologies (Peer Review Draft of July 1997), to be a useful, well-organized, and well-written document. It provides a good overview of alternative technologies for cleaning clothing and similar fabrics used by consumers. The technologies evaluated include drycleaning processes using the solvent perchloroethylene (PCE); drycleaning processes using petroleum distillates such as Stoddard solvent and a variant with lower flammability; and wetcleaning processes. The authors have compiled information that should be helpful to readers interested in understanding the fabric cleaning industry and the choices among alternative cleaner technologies that will be made as this industry evolves.

Response: No response is necessary.

Comment #G-124: While the strength of the document is that it provides a good introductory overview, the weaknesses of the document lie primarily in the level of depth at which various issues and policy implications have been investigated. In a number of areas, the authors could have gone deeper. These areas include: the extensive use of personal communications and old published references for information on the drycleaning industry; omission of references to other studies on exposure and risk from drycleaning using PCE; the lack of investigation on the feasibility of increased monitoring to assure proper maintenance of PCE-using equipment; and consideration of the health risks from PCE exposure using EPA's revised cancer risk guidelines in addition to the 1986 guidelines. These areas are discussed in more detail in the general comments and specific comments on the text in the sections that follow.

Response: Process description, release, and exposure information and estimates were investigated in more depth. As a result, the updated CTSA includes more and better information in these areas. However, it appears that the commenter has expectations for the CTSA that are beyond the purpose and intent for the CTSA. For some of these aspects, such as feasibility of increased monitoring in PCE facilities, the commenter's expectations will not be met.

Comment #G-125: General Comments: Strengths of the Report
This reviewer has carried out a number of investigations of risk from PCE in drycleaning and is generally familiar with the available information, although not at the level of detailed product offerings. Therefore, the assessment that the information provides a good overview is a strongly positive finding. The authors of the report have done a good job of assembling and integrating a considerable amount of information on established and alternative cleaning technologies. They have presented this information clearly, so that others can readily understand the choices in this industry, as these choices might be perceived by parties within the industry and by regulatory agencies with oversight responsibilities for the industry. The risk chapter and the supporting appendices A and C are generally well done, although more emphasis is needed on uncertainty with respect to carcinogenicity in the main text.

Response: Text on uncertainty has been clarified.

Comment #G-126: Weaknesses in the Report

The drycleaning industry and its potential competition from wetcleaning processes are not the sort of topics that generate a large volume of scholarly literature. Nonetheless, the industry is large in size, and it has been the subject for surveys and investigations by a variety of industry organizations and interested government agencies. This reviewer is concerned with the number of instances in which important information is referenced to old EPA reports or personal communications with one individual. These personal communications have the potential for significant bias, and they need careful review by other parties highly informed about the industry. While this reviewer is not well enough informed to dispute specific judgments, this reviewer is concerned about the lack of information from readily available sources, to be discussed below.

Several years ago, a large study was carried out in Southern California on uses of chlorinated solvents and alternatives to these uses by the Metropolitan Water District and the Environmental Defense Fund. K. Wolf was a principal investigator for a portion of this study, and one of her papers from 1992 is cited as reference 426. However, this reviewer finds no other references to this study. Copies of the summary volume and two technical support documents are attached. Further information is available from David Roe of the EDF's Oakland, California office, tel. 510-858-8808. (See letter from Mr. Roe, attached.) The CTSA authors might also wish to contact Katy Wolf, Institute for Research and Technical Assistance, Santo Monica, CA. Dr. Wolf remains active carrying out work on solvent exposure for various agencies in Southern California. (See, for example, her article in *Pollution Prevention Review,* summer 1995, pp. 25-38, attached).

EPA's Total Exposure Assessment Methodology (TEAM) studies are referenced in this report, such as USEPA 1986 referenced p. 3-42. This reviewer is not persuaded that the more recent investigations of outdoor and indoor air pollution carried out by the TEAM investigators have been comprehensively summarized. This reviewer recommends further review of the CTSA report by Dr. Edo Pellizzari; Research Triangle Institute; Dr. Lance Wallace, EPA; and Dr. Wayne Ott, EPA. The extensive publications of these three leaders in the TEAM research effort are not apparent in the CTSA report references. Several such references are included in the Thompson and Evans article, discussed below.

[Roe, D. 1997. Letter from D. Roe (Environmental Defense Fund) to W. North (Decision Focus, Inc.) dated August 20, 1997. Thompson, K.M., and J. S. Evans, 1997. The value of improved National Exposure information for perchloroethylene (Perc): A case study for drycleaners. Risk Analysis. 17:253-271.]

Response: Published sources have been used to the extent possible to replace personal communication references, and personal references and other unpublished sources have been minimized. The newest references found have been used; however, the use of older EPA reports could not be eliminated.

The general-population exposure section has been revised to provide a better description of the TEAM study. The CTSA has undergone extensive peer review by 36 reviewers recommended by various stakeholders. EPA sees no need for further review of the document.

EPA used published sources where possible and relied on personal communications only where information could not be found. The intention of EPA's peer review was to assist in evaluating the validity of information, including that provided through personal communications. EPA reviewed comments that provided additional references and incorporated information accordingly.

Comment #G-127: An Important Missing Reference

Kimberly M. Thompson and John Evan published "The Value of Improved National Exposure Information for Perchloroethylene (Perc): A Case Study for Drycleaners" in *Risk Analysis*, Vol. 17, pp. 253-271, April 1997 (attached). Not only is this article not referenced in the report, but also other important references in this article are missing from the references in the CTSA report. While this article is focused mainly on the use of probabilistic methodology, its sources of information and its conclusions on the high value of better information on the carcinogenicity of PCE definitely need to be reflected in the current report.

Response: This article has been examined and referenced in the CTSA. A detailed discussion of its conclusions is beyond the scope of the CTSA.

Comment #G-128: Microbial Contamination: Does This Issue Need Exploration?
The evaluation of processes involving water-based cleaning examined a number of chemicals used in such processes, but there was no discussion of potential microbial contamination. This reviewer has listened to presentations at professional society meetings on the difficult of controlling microbial populations in recycled water containing grease and other microbial nutrients. Microbial contamination does not seem to be a significant issue in home washers and dryers, where water is not recycled and flushing with hot water and detergents is frequently done. Nonetheless, this reviewer would like to be assured that in the wet processes being considered as alternatives to drycleaning, build-up of microbial populations has been carefully considered, and that microbial contamination poses at most inconsequential risks to human health and the environment.

Response: EPA was unable to find information on microbial contamination in the wetcleaning process.

Comment #G-129: Implications for Policy: Better Monitoring is Needed for Indoor PCE Exposures

The report correctly notes the importance of high levels of PCE that have been observed in the small number of observations in residential areas in, or immediately adjacent to, buildings with drycleaning machinery using PCE. The work of Judy Schrieber and colleagues from the NY State Department of Health (NYSDOH) is perhaps the best known of such data sets. The implication of these data, correctly noted in the report on pages 3-26, 3-31 to 3-39, 4-21 to 4-23, 4-31 to 4-32, and 7-13 to 7-21 is that high human exposure to PCE and consequent risk can result from situations in which PCE is released within buildings by leaks from machines that are defective or poorly maintained, or from poor practices in which fumes from solvent-soaked fabrics are released into indoor air.

Better inspection and maintenance are needed to avoid exposure of workers and nearby residents to the high PCE levels that result from these substandard practices. While EPA may not have statutory authority to carry out monitoring and enforcement, EPA does have activities aimed at a better understanding of high risk situations posed by indoor air pollutants. PCE exposure from defective equipment and poor operating practices seems clearly within EPA's charter for developing better information no potential health risks. EPA's TEAM investigators have developed considerable skill in adapting available air monitoring equipment to provide low-cost, portable equipment for real-time indoor air monitoring. New air monitoring equipment using infrared absorption allows measurements to be immediately available at the monitoring location, rather requiring a delay of many hours or days for gas chromatography of samples taken at field locations. A set of

descriptive information on one such monitor was forwarded to this reviewer by Dr. Wayne Ott, and is included in the attachments. Dr. Ott can be contacted for further information c/o Department of Statistics, Stanford University, Stanford, CA, and by telephone at 650-364-1430.

This reviewer recommends the addition of a section on indoor air monitoring of PCE, including the costs for inspection of PCE levels. This discussion should be placed in Chapter 7 and briefly summarized in the Executive Summary. Air monitoring inspections might be carried out under industry sponsorship by certified inspectors to assure workers and nearby residents that PCE levels are not excessive. Alternatively, inspections might be carried out by state or local air quality or health agencies. The capability to carry out such inspections at affordable costs should facilitate identification, and sanctions to force corrective action, of those drycleaning establishments who poor maintenance and operating practices result in high PCE exposures for workers and co-located residents.

Response: The inclusion of indoor air monitoring information for worker exposure is not within the scope of the CTSA. It is not the purpose of the CTSA to provide recommendations for increased monitoring of PCE levels.

Comment #G-130: The report switches from exposure measurements in parts per million (ppm) (e.g., Chapter 1) to mg/m^3 (Chapters 3,4). Using micrograms (μg) in these chapters as done in Appendix C would avoid forcing readers to count zeros. The reader should be given an explanation and a conversion table. Exhibit 3-9 includes both ppm and mg/m^3, but readers may have difficulty finding this. Abbreviations should be introduced when used. "ppm" is used on p.1-11, top, without explanation that ppm means parts per million.

Response: Worker exposure sections contain units in both ppm and mg/m^3. The abbreviation "ppm" is written out in its first occurrence in each chapter. Also, the concentration shown on p. 1-11 is not an exposure measurement as are the others noted in this comment; rather, this concentration is an approximate concentration within the machine.

Comment #G-131: Chapters 5-8. No comments

Response: No response is necessary.

Comment #G-132: In response to your request as a peer reviewer of the Cleaner Technologies Substitutes Assessment for Fabricare: Including Dry and Wet Cleaning Technologies, I found the material very in-depth, and felt some to be biased to their product and studies conducted. I believe results would be better understood in parts per million, as opposed to milligrams per cubic meter or milligrams per liter.

Response: EPA has reviewed the comment and will continue to present information in terms of milligrams per cubic meter and milligrams per liter.

Comment #G-133: My assessments are listed and my views are that I believe 100 ppm TWA (time weighted average) is a very safe exposure and risk assessment for PCE, even though in ".....", we have found 25 ppm for an 8 hour TWA to be easily achievable with the modern drycleaner

units, an I believe that there will be a need for the present cleaning technology and the future proposed cleaning technology.

Response: This is a statement of opinion and does not appear to have implications for specific sections of the CTSA. No changes have been made.

Comment #G-134: Overall, the CTSA document is an impressive piece of work. The document carefully walks the reader through the history of the commercial cleaner industry, including the myriad of equipment and operational procedures, and delineates the potential points of solvent releases into the environment. As a reviewer, I will comment primarily on sections of the report that I believe could be improved or that were unclear to me. However, the document as a whole is very comprehensive and well written.

Response: No response is necessary.

Comment #G-135: Each chapter is clearly explained. The text was generally clear and well-presented. In general, tables and figures were clear (see below for some suggestions). I did not find any inconsistencies in data presented in the tables and text. I did find one minor inconsistency in nomenclature (see below). I am not aware of additional sources of information that could be used in this report. Overall, the document seemed to be extremely well-referenced.

Response: No response is necessary.

Comment #G-136: **Discussion of Wet Cleaning Performance**

Wetcleaning is inaccurately portrayed in the CTSA as a substitute or alternative for drycleaning with solvents. Informal discussions between NIOSH researchers and drycleaning industry representatives, equipment manufacturers, and shop owners, over the past four years, have indicated that only a percentage of garments currently being cleaned by drycleaning could be effectively cleaned with wetcleaning technology. For example, garments made of wool, silk, and rayon cannot safely be immersed in water because of possible garment damage from fiber shrinkage or bleeding of dyes. For these reasons, we suggest that the term "substitute" in this context be changed to "supplement."

Response: EPA has reviewed the comment and continues to use the term substitute and acknowledges that wetcleaning may not be a complete substitute for drycleaning.

Comment #G-137: **Safety and Other Hazards**

A great deal of effort has been made to present information concerning the health risks associated with exposure to perc. However, the document does not adequately address other risks that may be presented by perc or potential alternatives or substitutes. Of particular concern is the lack of information concerning safety hazards. On the first page of Chapter 1, the CTSA states that "Small companies rarely have the time or resources to gather information . . . to choose safer or lower risk chemicals, work practices, or technologies." If a drycleaning shop owner makes a decision regarding which process to use based on risk, safety hazards also need to be considered.

Specific to the drycleaning industry, the potential for fire or explosion from petroleum-based solvents should be more thoroughly addressed in this document, particularly for the traditional petroleum-based solvents used in the U.S., Stoddard solvent and mineral spirits.

Other hazards not addressed include the ergonomic risks associated with wetcleaning operations, which are often more labor intensive than drycleaning (e.g., garment pressing has been identified by NIOSH as presenting a significant ergonomic risk) [Earnest et al. 1995; 1997]; the safety hazards associated with the use of high-pressure systems for cleaning with liquid CO_2; and the environmental risks associated with dumping large quantities of contaminated wastewater during wetcleaning.

[Earnest GS, Spencer AB, Smith SS, McGlothlin JD [1995]. In-depth survey report: Perchloroethylene exposures and ergonomic risk factors n commercial drycleaners at Tuchman Cleaners, Carmel, Indiana. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, ECTB Report No. 201-19a.

Earnest GS, Spencer AB, Smith SS, Heitbrink WA, Mickelsen RL, McGlothlin JD, Ewers LM [1997]. Technical report: Control of health and safety hazards in commercial drycleaners: Chemical exposures, fire hazards, and ergonomics. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.]

Response: The CTSA has been modified to include some information on safety issues such as ergonomics and fire hazard.

Comment #G-138: Overall, I believe that the CTSA has failed to complete its goal of providing "information that can be used by cleaners to assist them in making informed technology choices that incorporate environmental concerns along with more typical considerations of cost and performance." There are several reasons for this. First, the document is overly long and technical, complex, has organizational problems, and is thus difficult to follow. Even with years of post-graduate education, I had some difficulties in understanding parts of the document. I can say with certainty that there are few commercial drycleaners that will read this document and even fewer that will understand it (especially given the large percentage of non-native English speakers in the industry). If the audience of this document consists of commercial drycleaners, then that audience will not be reached with this document. Given the length and technical complexity of this document, the audience would appear to be trade organization technical staff and technical staff of chemical and machine manufacturing companies. Though the fact that this is a document for the technically informed is mentioned on page ES-1, as written the CTSA is still too complex except for those with advanced training and education in the sciences, economics, and engineering. This technical complexity is often offset by obvious statements of fact (controlled technologies lead to less exposure than uncontrolled) which are unnecessary. Unless the EPA provides a shortened version of the CTSA in fact sheet form, with easy to understand language and conclusions, this document will serve little purpose for individual drycleaners.

Response: EPA is developing a shortened version of the CTSA that is more appropriate for a broader audience, including commercial drycleaners.

Comment #G-139: Secondly, the CTSA only provides raw summary information for drycleaners with little analysis and reaches no conclusions on the viability of alternative methods. Drycleaners will be looking for insight from EPA about where the Agency sees the future direction of regulation and technologies. These people, with little time or technical resources, want the bottom line: will

PCE hurt me or the environment; will PCE technology put me at an economic disadvantage in the future; are the alternative technologies viable in the short and long term with adequate performance. EPA has avoided making any recommendations or drawing conclusions in this document through the careful use of language to minimize the impact of information provided. For example, EPA never once states in this document that the only way to prevent risk to humans and the environment from the use of PCE in drycleaning is to eliminate the use of PCE. While a simplified argument, this is the type of conclusion that individual drycleaners need and expect. Additionally, EPA fails to rank technologies when there are clearly some technologies that are superior from a human health and environmental point of view.

Response: EPA does not rank or recommend specific technologies because to do so would overlook the specific situations faced by the individual drycleaner. Rather, EPA summarizes information relevant to the individual's decision, that will allow the individual to tailor any decision to the particulars of the individual's situation. EPA intends to develop a shortened version of the CTSA that will support individuals in this process.

Comment #G-140: Finally, the CTSA is too heavily focused on different PCE options. Analyzing 13 different options for PCE technologies legitimizes the continued use of PCE technology and minimizes the important environmental benefits of some of the truly cleaner substitutes. As an expert in pollution prevention, I can assure you that a large percentage of the options considered for PCE are not true pollution prevention. Many of these could be considered "end-of-the-pipe" controls. EPA has chosen to follow the format of a risk assessment in this CTSA; however, while the document has the appearance of a risk assessment of PCE and alternative PCE technologies, it should be noted that this document is not a risk assessment, but rather an assessment of cleaner technology substitutes.

Response: Significant numbers of cleaners currently use PCE technologies. Complete adoption of alternative technologies can require significant resources, and many cleaners may not be able to undertake such an action, particularly in the short-run. EPA provides information on several PCE options to demonstrate that cleaners can take reasonable steps that may help to reduce PCE emissions. While many of these alternatives may not represent true pollution prevention measures, they do result in reduced emissions. Reductions in solvent emissions is one of the goals of the industry, in addition to pollution prevention.

Comment #G-141: There is a clear hierarchy of pollution prevention that has not been mentioned or followed in this document (i.e., product reformulation and chemical substitution as most aggressive and improved operations/maintenance and recycling as least aggressive. For many in the pollution prevention field, the choice of wetcleaning (provided that further development of the technology occurs) over drycleaning is simple and an effective risk reduction measure. This is a conclusion of the work currently being carried out by UCLA in their Pollution Prevention in the Garment Care Industry Project. The pollution prevention/technology chapter of the CTSA is thus inadequate if indeed its purpose is an comprehensive analysis of pollution prevention options.

Response: The purpose of this chapter (Chapter 7) is not a comprehensive analysis of pollution prevention options. Rather, its purpose is to identify opportunities within processes which may result in pollution prevention and/or risk reduction. This purpose has been more explicitly stated in the introduction to the chapter, and the pollution prevention opportunities language has been reduced to prevent misconceptions regarding this purpose.

Comment #G-142: Also, an integral part of design for the environment is to consider the life cycle impacts of a particular technology or product. EPA has failed to do so in this document. If EPA had done so, the agency would have likely determined that the production of PCE is potentially an important source of dioxin generation, release of toxic substances in the workplace, and release of persistent organic pollutants to the environment. The disposal of PCE still bottoms and filters through incineration will also generate dioxin. Also, a life cycle assessment would have analyzed the full costs of different cleaning technologies (energy, pollution, health, etc.). By considering the life cycle of PCE, PS, and alternative technologies, the alternative technologies would likely be considered even more preferable.

Response: Life cycle analysis is outside of the scope of the CTSA.

Comment #G-143: EPA needs to be clearer in this document about its exact purpose. It fluctuates from being a risk assessment, to an alternative technologies assessment, to a regulatory requirements summary. It cannot be all of these (at least in the main document) and still serve its purpose of improving environmental decision-making within drycleaners. A useful format would be to describe the technologies (current and alternative) and provide a process characterization, as in chapter 1; then provide technical, economic, and environmental/health and safety analyses, as in chapters 5, 6, and 3 and 4; and then to summarize the trade offs as in chapter 8. If this is an analysis of cleaner technologies, a full materials accounting of each technology is needed. This would help the reader to better understand how the chemicals are being used in the process, what are the emissions, and what are the options for reducing pollution. Given the substantial differences in technologies there is really no way (and really no need) to analyze them via single risk numbers. A hazard summary is sufficient when comparing vastly different technologies. It is true that risk assessment is useful in comparing similar risks, as is the case with the different variations of PCE technologies.

Response: In order to improve environmental decision making by drycleaners, EPA believes it is necessary to provide information on alternative processes, risks, and regulatory requirements, among other information. EPA has modified the document to enhance its presentation of material and readability.

EPA agrees that single risk numbers should not stand alone in this kind of decision process. Hazard summaries alone, however, may be somewhat inscrutable without an exposure context.

Comment #G-144: There is an excessive use of conditional language in the document that undermines the assessment. For example, the authors often state that "PCE may pose a potential risk". This is something akin to a double negative. These types of conditional statements tend to underestimate the real hazard in the reader's mind. The excessive attempt to note all of the uncertainties in the document also undermines the assessment. The uncertainties found in this assessment are the same uncertainties and limitations found in every assessment of this type. This should be duly noted. Also, the authors consistently identify uncertainties which could possibly lead to an overestimate of risks. What about those that could lead to an underestimate of risk? These are more important for public health and are often more prevalent than those that overestimate risk.

Response: The discussions of uncertainty have been revised, with more attention paid to any factors that affect uncertainty, including those that could lead to an underestimate of risk.

Comment #G-145: It would appear that every effort has been made to identify every possible hazard associated with the detergents and other chemicals used in wetcleaning alternatives. There is no need to go overboard on wetcleaning hazards, if they do not exist. EPA needs to be clearer about the potential risks from these technologies, which are minimal. Also, EPA needs to note that the detergents can be replaced with biodegradable, bio-based ones, something that cannot occur with PCE technologies.

Response: A typical hazard assessment will present a variety of effects that a chemical may cause. The risk assessment, which combines hazard and exposure information, will provide an indication of whether or not those effects are likely to occur. This approach is consistently applied for all chemicals, including those in detergents, in the CTSA. EPA has also included information on biodegradability of detergent chemicals.

Comment #G-146: Editing is necessary both to write the document in a more user friendly manner and to eliminate repetition. Many chapters repeat information from earlier chapters. Eliminating repetition could substantially reduce the size of the document. There are many places throughout the document where a table is mentioned on one page and it doesn't appear for another 3 or 4 pages, often times confusing he reader. Tables should be located on the same or following page from where they are mentioned. More bolding, underlining, and italicizing of key points and findings is needed in the document so that these points stand out from the text. Boxing of key findings may also achieve this goal of highlighting. A separate glossary of key terms and abbreviations would be extremely helpful so that the reader does not have to continuously go backwards in the text to find this information. Citations need to be added in numerous places in the text in each chapter.

Response: EPA has modified the document to enhance its presentation of material and readability.

Comment #G-147: As you can see, I have considerable concern about many aspects of this document. The bulk of my concern lies with technical errors in the description of drycleaning and wetcleaning processes. In order to retain its credibility with the industry, it is essential that these errors be corrected before the document is released. I shall submit these comments on specific items to you over the next week.

Response: No response is necessary.

Comment #G-148: It is repeatedly stated that the CTSA document is intended to be used as a tool whereby drycleaners can make informed decisions on various technological alternatives. First, and most important, the size and complexity of this document virtually precludes any such use by the industry itself. To suggest otherwise implies a level of sophistication that simply does not exist in the industry, in the United States, or elsewhere for that matter. I believe I may be the only drycleaner reviewing the document. If this is the case, I think it is reasonable to predict that I will be the only drycleaner who ever reads the document in its entirety. A document of this complexity simply will not be used by the industry as intended. In fairness, it is implied in several places that

the document might be useful as a reference tool for groups connected with or interested in the industry. As such, information in the document could be made more "user friendly" for consumption by the industry itself. This may be true to some degree but we then have to contend with the "filtering factor."

This document says many, many things about many different subjects. All of it is no doubt presented with the best of intentions but as you will see in many of my later comments, there are a vast number of technical inaccuracies. Even assuming that all of these inaccuracies are corrected, lack of information on many of the technologies precludes parallel treatment of the various options. This problem virtually guarantees that groups inside and outside the industry will take bits and pieces of the vast amounts of information presented and use them in ways that the agency has not anticipated and does not really intend them to be used.

Response: EPA is developing a short version of the CTSA that will be more appropriate for a broader audience, and has developed the CTSA to serve as technical background for that document. EPA has also made modifications to address inaccuracies identified by commenters.

Comment #G-149: The technical inaccuracies in the document demonstrate a shocking lack of knowledge of textile care processes on the part of those preparing the document. This is particularly true in light of the length of time the document has been in preparation and what I suspect are the vast amount of money spent preparing it. There is already a great deal of anticipation amongst cleaners about what this document might contain. In order to maintain its credibility with the industry, the agency cannot release a document that is so badly flawed technically. I will be submitting detailed comments on what I perceive to be the technical problems over the next week or so.

The writers of the document have tended to take single source comments on various technologies and treat these comments as valid information in many places in the document. Many of these comments are not verified, and although they are well referenced (some of them may even have been made by me) they are often used later on for if/then sorts of scenarios. This practice is the source of many of the problems with the document. There is nothing particularly wrong with soliciting comments from various sources of expertise, but if this information is to be used later on to develop important concepts in the document, it must be verified better than it has been in many cases.

Response: EPA has incorporated commenters' suggestions, particularly where they address inaccuracies.

Comment #G-150: The only technology that is really dealt with thoroughly is PCE drycleaning. Obviously, there is more information available about this technology than any of the other alternatives. This imbalance presents problem, however. There is so much said about perc that the effect is overwhelming. The risk data, although reasonably well qualified in the document is clearly subject to misuse and misinterpretation. It is far too complex to be of any use whatsoever to a drycleaner trying to make a decision about technology. Further, a plethora of perc technologies are presented many of which were never really common and some of which haven't been available for many years. This adds to the confusing nature of the document. I think that the consistent mention of transfer technology almost implies that the agency considers it acceptable for future use.

Response: As the commenter states, the volume of information on PCE in the CTSA is a reflection on the amount of information that is available on the technology. EPA has attempted to convey this throughout the CTSA and has moved emerging technologies to their own chapter so that these technologies, with relatively little information, are not directly compared to the existing technologies. The assessment of risk in the CTSA is developed in order to suggest potential concerns with the use of the technologies, in order that they may be compared on the basis of what is currently known. While EPA has modified the PCE machine configurations included in the CTSA, the transfer technology remains to serve as a baseline from which improvements in control technologies can be compared.

Comment #G-151: Petroleum solvent technology is dealt with very poorly and in many cases, conflicting messages are presented. The issue of aquatic toxicity is initially presented as a serious concern then repeatedly dismissed as a relatively trivial issue. In general, the document recognizes that both aqueous and non-aqueous technologies will be used for the foreseeable future in a "textile care spectra" type of environment. Given (I think) that the agency would like to see less perchloroethylene used by the industry and given that other technologies such as liquid carbon dioxide are not well developed as yet, petroleum solvent seems to be a good alternative or at least transitional non-aqueous technology. It must, therefore, be dealt with in more detail and in a more forthright manner. Just as an example of how poorly it is dealt with in the document, carbon adsorption is repeatedly presented as a solvent reclamation alternative for this technology. I could be wrong, but to the best of my knowledge, there was only ever one experimental installation of this type in California some years ago. The vast amounts of carbon required precluded financial viability and the experiment was abandoned. We should note that the document indicates that no cost data exists for this technology. There is a good reason for the lack of data. The technology doesn't exist!

Response: EPA has corrected some errors (including carbon adsorption) and has researched for new information on these technologies. However, little new information on these technologies are available. The new information found has been included in the updated CTSA. The CTSA is a comparative document and is not intended to make judgements such as the one regarding petroleum solvents suggested by the commenter.

Comment #G-152: Machine wetcleaning may well be an extremely viable alternative, but the document does not deal with it well because of lack of data. As an example, cost data are presented for the Greener Cleaner project in Chicago which among other things indicate wage costs that are roughly double industry standards for a well operated plant. There could be many reasons for this disparity but regardless, anyone reading this section will dismiss wetcleaning out of hand as a result of this data because it confirms the stereotypic fear that the industry has of wetcleaning. As a matter of interest, our findings in Hamilton indicate that a dedicated wetcleaning plant can be operated in a manner that is competitive with drycleaning.

Much more research is needed in this area. I have a lurking fear that we will never realize the full potential of the wetcleaning alternative because of improperly conceived and operated research projects.

Response: EPA has not included study results on costs directly into its cost assessment.

Comment #G-153: Although the focus on multiprocess wetcleaning is somewhat limited in the document, I feel that it should be toned down even further. There is an indication in Chapter One that the technology is not in use in the United States at the present time. Some of the Environment Canada data in Chapter Five indicates that "steam cleaning" is completely ineffective for removing soil (University of Guelph data Exhibit 5-17). These techniques (multiprocess wetcleaning cannot be called a technology) have not been accepted by the industry because of the absolute lack of the type of inherent process control that is embodied in drycleaning or machine wetcleaning. I do not think that the overall credibility of the document is enhanced by repeated references to these techniques.

Response: Multiprocess wetcleaning is no longer included as a technology alternative in the CTSA.

Comment #G-154: The industry is clearly in a period of change. One of the purported purposes of the CTSA document is to be a tool to assist in the decision making process that accompanies change. Clearly, in order to finance necessary changes, the overall financial viability of the industry must be maintained. Because of the vast amounts of data and its varied nature, there is some danger that the agency could inadvertently harm the industry financially by releasing the document in its present form. As was mentioned above, the risk data in the document is reasonably well qualified, but those qualifications often disappear when data is extracted from documents such as this. The agency must be very careful of this phenomenon and the potential it has to harm the industry financially. In seeking to assist in the process of change, the agency could be harming it.

Response: Multiprocess wetcleaning is no longer included as a technology alternative in the CTSA.

Comment #G-155: The most troublesome aspect of this document to me is the apparently lack of purpose and direction. Granted, there is a stated purpose with respect to the document serving as an information source but as we have already noted, this goal is hardly met. The document does raise a great deal of potentially valid concern about the quantity of perchloroethylene that is used by the industry. It would be most helpful in terms of direction if there was some sort of clear statement that one of the major goals of the document is to assist the industry in reducing the amount of PCE that it uses in the United States. In contrast, the document seems to circumvent this issue by presenting massive amounts of data on all sort of different technologies in the faint hope that someone might draw some sort of conclusion from it. Environmental agencies in other jurisdictions have set out to reduce the amount of PCE consumed by the drycleaning industry and done so very successfully. Germany is an excellent example of a jurisdiction which has had considerable success in reducing the amount PCE that the industry consumed. There are many aspects of the German model which probably do not apply in the U.S. but there are other aspects of it which certainly do apply. The Canadian S.O.P. model is another example of a consultative process undertaken by regulators and the industry to reduce the amount of PCE consumed. The most important thing about both of these models is that reduction targets and time lines were set. I think that this document is an ideal tool to help start a broader consultative with the industry in the United States which has not existed to this point. In its current form, this document simply does not do that. In fact, I think it actually confounds the process more than it is already confounded. In summary, I think that a great deal more work is required on this document as well as a complete rethinking of its purpose before it can be released.

Response: EPA has noted that this CTSA arose out of a desire by industry to reduce emissions of PCE.

Comment #G-156, General: The identity of the authors and their academic degrees and certifications should be disclosed. The extent of the role of Abt Associates should be clarified, including Abt staff other than the principal author mentioned on page (iii).

Response: Staff involved in the development of the CTSA have been acknowledged. The role of Abt Associates has been in the preparation of the document and research under the direction of EPA staff.

Comment #G-157: Usability: Overall, the presentation lacks focus. The identity of the "users" mentioned in the executive summary is unclear -- certainly engineers or buyers of equipment could not be expected to interpret the health effects information in the manner presented. The executive summary doesn't summarize. Individual chapters lack a clearly delineated summary with key points. The health hazard sections fail to draw clear conclusions. No conclusion is drawn whether any reduction in exposure is needed from existing transfer machines or any other type of equipment.

Response: EPA has revised the Executive Summary to improve its presentation of information.

Comment #G-158: The document has the form and tone of a criteria document or preamble to a regulation. The authors should clarify where the conclusions on health risk are essential quotations from prior EPA documents, and where they are extending previous analyses with additional information.

Response: EPA has made modifications to the document that assist the reader in understanding if conclusions result from prior EPA work and where previous analyses have been extended.

Comment #G-159: The information on uses and releases is valuable and less problematic.

Response: No response is necessary.

Comment #G-160: Conclusions: Health effects descriptions in this document are confusing and in my view biased against human health risks. Buried within, Chart 4-31 clearly states that existing exposures pose unacceptable risks.

Response: EPA has revised the document to make conclusions clearer.

Comment #G-161: As an introductory chapter, it is too long and addresses too many topics. I suggested in the general comments section that this chapter could be broken down into several chapters. The first chapter could be dedicated to the general missions and goals of EPA's DfE program, which should then be completed with specific goals and objectives concerning the

drycleaning industry. It would be desirable to have clearer statements of EPA's objectives concerning the future of the drycleaning industry.

Response: EPA has modified the Introduction to improve its presentation of information.

Comment #G-162: Although EPA has clearly stated that the CTSA report is not intended as a guidance document enabling a small business person to make decisions, EPA could state preferences about the options within or between each textile care technology. For example, does EPA see a future for PCE cleaning if an appropriate pollution prevention technology described in this report is implemented? If yes, what are acceptable solvent consumption limits? What is EPA's position on the emerging alternative technologies and how will they be integrated into EPA's strategic objectives?

Drycleaners are waiting for this information. I don't think they will use the information in this document without more specific guidance from EPA. Because of their limited financial resources, they are reluctant to invest in any pollution prevention technologies or in new alternative technology without the "blessing" of government agencies with regulatory authority.

Response: It is not the purpose of the CTSA to develop recommendations on solvent use or technologies.

Comment #G-163: I offer a few concluding remarks:

- The document contains many useful information which will encourage serious the search for more environmentally friendly textile care methods.
- The document is not very user friendly and often very repetitive.
- There are many factual deficiencies which need to be corrected or clarified.
- This document focuses too much on old and outdated technologies.
- Inferences are often drawn from anecdotal personal communication which weakens the credibility of this report.
- The report can be shortened by deleting "filler-data" which do not add to the objectives of this report.
- A condensed version should be prepared for educational purposes.
- The need for future research and demonstrations should be clearly stated.
- Every effort should be made to communicate risk associated with PCE in an unbiased and factual way.
- This document should identify the environmentally preferred methods for textile care within each and among the existing or emerging technologies.

Finally, I urge that the document is not released to meet a set deadline. Time consuming major revisions are required to make this document a valuable and informative tool for responsible and informed societal and business decisions.

Response: EPA has modified the document by reorganizing it to enhance presentation, removing technologies that do not appropriately belong, and addressing inaccuracies. The updated CTSA has reduced the amount of information on "old and outdated technologies." A shortened version of the document for use by a broader audience, is currently under development. It is not the purpose of the document to make recommendations on research or the preferred technologies.

Comment #G-164: Clearly a lot of work went into the preparation of the CTSA document. However, there are three major issues that need to be addressed before the document can be an accurate and informative resource for people making informed choices about drycleaning methods.

(1) We recognize that the CTSA is not meant to be a detailed summary of the toxicity of PCE, however, the CTSA does not contain an up-to-date summary of the metabolic and toxicological information on PCE. Specifically, it is missing summary statements of the results from numerous recent human studies showing effects of PCE exposures. This weakens the risk characterization of PCE because the omitted recent articles contain important data that bear directly on the risk assessment and characterization of PCE. For example, recent epidemiological studies of drycleaning workers have consistently found an association between exposure to PCE and central nervous system, kidney, and liver effects. In addition, a recent epidemiological study of residents of apartments located near drycleaning facilities reported an association between exposure to PCE and central nervous system effects.

Overall, these data increase concern over the potential human health effects of exposure to low levels of PCE in air, and are essential data for any individual using the CTSA to assist them in making informed choices about cleaning technologies. Our technical comments suggest where these articles could be discussed, and we have enclosed copies of the relevant articles. We recommend that they be incorporated in the CTSA.

(2) The section on risk characterization is very difficult to understand. Some of these difficulties stem from the inherent complexity of the subject, but some are due to the way the material is organized, analyzed and presented. Our technical comments illustrate some of the problems of organization and presentation.

From our perspective, the major point of this section should be that there are sufficient data to indicate that the levels of risk associated with occupational and residential exposure to PCE are substantially elevated. It should also indicate that these risks may be difficult to detect in the population given the complexity of human exposures. These messages are difficult to perceive in the current draft. The Final Report of the Presidential/Congressional Commission of Risk Assessment and Risk Management entitled 'Framework for Environmental Health Risk Management' contains useful information on risk characterization and should be consulted during preparation of the final draft.

(3) The CTSA analyses indicate that adults living in residences co-located with a drycleaning facility may be at risk from PCE in air. Presumably, these adults are part of families with infants and children, who would also be at risk. However, the CTSA fails to comprehensively assess the health risks to children. For example, the CTSA does not adequately discuss and does not incorporate the special characteristics of children (other than the oral exposures of breast fed infants) into the non-cancer or cancer risk assessments. Children have relatively greater exposures than adults at the same air level and may be more sensitive to the effects of PCE than adults. US EPA's own policy on evaluating health risks to children specifically states that the Agency will develop a separate assessment of risk to infants and children or state clearly why this is not done. Therefore, we strongly recommend a more comprehensive discussion and assessment of the risks PCE poses to infants and children. Such an analysis is essential to accurately describe the potential health effects of PCE to individuals making informed choices about drycleaning methods.

In addition, the CTSA does not adequately address the health risks to other potentially sensitive subgroups, such as pregnant women, the infirm, and the elderly. Efforts to better characterize their exposures and risk would improve the quality of the CTSA.

Response: Some more recently published work relating to metabolism has been included, as has some of the neurotoxicity literature. This particular comment did not include specific citations,

however. The CTSA has been extensively revised to make its risk characterization more readable and to include discussion of special populations including children.

Comment #G-165: I have few comments to be made. On the whole I found the document easily readable and understandable. The document provided an excellent education on the technical aspects of clothes cleaning, the underlying assumptions and methods of risk assessment, and a clear discussion on the economic and other trade offs for the current alternatives. It is both detailed and organized in such a way as to allow policy makers and others to utilize the recommendations and conclusions without a full reading of the entire work.

Response: No response is necessary.

Comment #G-166: Finally, there is a major criticism concerning the evaluation of the potential human and environmental toxicity of PCE. I believe that it is necessary to take into account the potential Dioxin generation by this chlorinated solvent. This requires at least a several page addition concerning the environmental and human impacts of dioxin and the amounts potentially produced by the use of PCE. The document, I am afraid, is incomplete without this, especially the cost benefit evaluations.

You may view this as unnecessary due to the cost of alternatives being equal or less and their toxicity being clearly less - but it should not be ignored.

Unless I have missed the section dealing with Dioxin, clearly a decision has been made at some level not to deal with the issue. If this is the case the reasoning for such a decision and its ramifications should be included. This would be consistent with the tone and the highly objective scholarly approach to the rest of the analysis.

Response: The evaluation of dioxin, as it relates to PCE, is more appropriate for a life cycle analysis and is not within the scope of the CTSA.

Comment #G-167: While this document contains a wealth of information, the degree of details, length, scientific and technical references may be too advanced for the intended audience. (Based on page ES-1, citing that "small cleaners who may have limited time or resources to compare cleaning technologies.") Even though "technically informed owners and decision makers" are also cited as the target audience, the size of this document may discourage many from picking it up. My first and foremost recommendation is to scale down the CTSA to a more manageable size.

Response: EPA is developing a condensed version of the CTSA more appropriate for less technical audiences.

Comment #G-168: I would also suggest changing the outline - chapter numbering format. Through our program here in ..., we have surveyed businesses and found that they see this type of numbering system (like 4.2.2) to be confusing, intimidating and difficult to use. I'd suggest using a more typical outline format (with page numbers that flow in chronological order) such as: I. Chapter Title

A. Sub Title

1.
2.
3.
    a.
    b.

B. Sub Title

1.
    a.
    b.
2.

Response: EPA has reviewed the comment; however has decided not to change the numbering system.

Comment #G-169: I would suggest a change to the layout of the document. Rather than separate chapters on risk, releases, performance measures, economics, etc., I would suggest chapters on each dry or wetcleaning method, with subchapters to include each of the above mentioned topics. I think this document could be useful for a cleaner or potential new cleaner that wanted to find out about cleaning alternatives. However, the information on alternative cleaning methods is scattered throughout the document. If I'm a drycleaner thinking of switching to wetcleaning, I would like to see all the information on wetcleaning in one area. I could then turn to that chapter and see all the regulations, exposure information, risk, performance measures and tradeoffs as they relate to wetcleaning. As the document is currently laid out, I have to flip through each chapter and find the wetcleaning section, thus taking up a great deal more of my time.

Response: Based upon this, and many other comments on presentation, EPA has reformatted the document to enhance the presentation of information.

Comment #G-170: The CTSA is inconsistent in several grammatical issues throughout the entire document.

- NUMBERS: Journalism style books state that numbers one through nine should be written out and numbers 10 and over can use their numeric form. (Except when numbers are used to start a sentence, then they should be written out.) This is a problem throughout each chapter and will drive people with any kind of editing experience insane.
- EIGHT HR: The use of the term "Eight Hour" is listed as "eight-hour" (page 3-28), "8-hr" (page 3-24) and eight-hr. Pick one term and stick with it.
- CONVERSIONS: Most of the numbers are given in both metrics and pounds or other units. In some cases, just the metric number is given (i.e., page 3-4, 11.3 kg of clothes - what is this in pounds? Another example in Chapter 2 - almost all temperatures in the Chemical Properties and Information charts are only listed in Celsius.)

Response: EPA has incorporated these comments.

Comment #G-171: As I read through the document, a recurring theme was how little good attention seemed to be paid to uncertainty. I see this as a serious problem. There are many short paragraphs about uncertainty, full of adjectives such as "major", "key", "important", "significant", etc. Yet, I was left wondering, "Well, just how uncertain are these risk estimates?" This question

is important. The audience for this document will want to know the answer to it. The new EPA guidance on risk characterization and their provisional cancer risk assessment guidelines emphasize it, and Abt Associates has answered it before in its quantitative risk assessment for particulate matter, at least to a far greater degree than was done in this document. I would much prefer to see uncertainty treated in a manner that would permit the reader to appreciate how different the risk estimates could be if various plausible alternative approaches, interpretations, models, assumptions, etc. were used instead of the preferred ones.

Response: It is important to give some feeling for the fact and magnitude of uncertainty and variability as possible. Some uncertainties also bear public health weight, relating to their perceived consequence and historical consideration and not to their size. It may be that this comment was obliquely requesting a quantitative uncertainty analysis (sometimes more restrictively termed a Monte Carlo analysis). Such an analysis is beyond the scope of a CTSA, which is a screening level document. It could increase the CTSA's mass without assisting the reader through the central considerations of choice; we hope the enlarged and revised discussion of uncertainty in the Risk Chapter and of uncertainty and variability in the Exposure chapter are helpful to this commenter.

Comment #G-172: The goal of the CTSA project, laying out balanced information about alternative cleaning technologies in a systematic way to promote risk-reducing decisions, is laudable and important. The report is clearly written. The framework is reasonable and potentially quite useful. Unfortunately, the use of hazard information in the framework is woefully inadequate.

Response: EPA has reviewed the use of hazard information and finds it to be sufficient for its purpose.

Comment #G-173: The critical failure is a strict reliance on approved regulatory evaluations and numbers. This leads to an implicit assumption that lack of official information equals a lack of risk. Meaningful comparison and trading off of risks requires comparable types of information across the cleaning technology options. Clearly there are different levels of information available for different chemical compounds but we must remember that limited or unavailable data for a particular hazard does not mean that there is no information about hazard potential. The information on some compounds may be more uncertain, but it is not nonexistent.

The lack of available data problem was handled very nicely in the sections on environmental hazard, in particular all of section 2.3. This section illustrates nicely the role that quantitative structure activity relationships (QSAR) can play in filling key information gaps. The same techniques should be used, when necessary, in the evaluation of human health risks. There are available QSAR relationships for many human health endpoints including carcinogenic potential[1], maximum tolerated dose (which can be used to estimate carcinogenic potency)[2], developmental or teratogenic potential[3], LOAELs[4] and many others[5]. Crude, but useful, methods also exist for estimating regulatory-type numbers like reference doses from commonly available toxicological data[6]. Explicit expert judgment should also be used to derive needed toxicity values. There should be no empty cells in Exhibit 2-3. Of course, there is more uncertainty to values generated with QSAR or expert judgment but the critical point is that the types of comparisons advocated by this document (which I support completely) require that lack of direct data not lead to a bias against well tested compounds.

[1]e.g., Enslein, K., Borgstedt, H.H., Tomb, M.E., Blake, B.W., and Hart, J.B. (1987) A Structure-Activity Prediction Model of Carcinogenicity Based on NCI/NTP Assays and Food Additives. Toxicology and Industrial Health 3:267-287.

[2]Gombar, V.K., Enslein, K., Hart, J.B., Blake, B.W., and Borgstedt, H.H. (1991) Estimation of Maximum Tolerated dose for Long-Term Bioassays form Acute Lethal Dose and Structure by QSAR. Risk Analysis 11:509-517 addresses the MTD and many papers exist for estimating potency from MTD such as Travis, C.C., Pack, S.A.R., Saulsbury, A.W., and Yambert, M.W. (1990) Prediction of Carcinogenic Potency from Toxicological Data. Mutation Research 241:21-36 and Zeise, L., Crouch, E.A.C. and Wilson, R. (1984). Use of acute toxicity to estimate carcinogenic risk. Risk Analysis 4:187-199.
[3]e.g., Gombar, V.K., Enslein, K., and Blake, B.W. (1995). Assessment of developmental toxicity potential of chemicals by quantitative structure-toxicity relationship models. Chemosphere 31:2499-2510.
[4]Mumtaz, M.M., Knauf, L.A., Reisman, D.J., Periano, W.B., DeRosa, C.T., Gombar, V.K., Enslein, K., Carter, J.R., Blake, B.W., Huque, K.I., and Ramanujam, V.M.S. (1995) Assessment of effect levels of chemicals from quantitative structure-activity relationship (QSAR) models. I. Chronic lowest-observed-adverse-effect level (LOAEL). Toxicology Letters 79:131-143.
[5]Klopman, G., and Rosenkranz, H.S. (1995) Toxicity Estimation by Chemical Substructure Analysis: The Tox II Program. Toxicology Letters 79:145-155.
[6]Layton, D.W., Mallon, B.J., Rosenblatt, D.H., and Small, M.J. (1987) Deriving Allowable Daily Intakes for Systemic Toxicants Lacking Chronic Toxicity Data. Regulatory Toxicology and Pharmacology 7:96-112 and Gaylor, D.W., and Gold, L.S. (1995) Quick Estimate of the Regulatory Virtually Safe Dose Based on the Maximum Tolerated Dose for Rodent Bioassays. Regulatory Toxicology and Pharmacology 22:57-63.

Response: In some cases no studies have been reported in a wide variety of data bases. EPA interpreted that to indicate such studies have not been done. The eco approach is standard for that field. The exhibit identified by the commenter has been substantially revised.

Comment #G-174: The report does an admirable job of identifying potential sources of uncertainty in estimates of harm from different technologies. The language used to describe the uncertainties, however, is confusing. For example, on page 4-27, in a discussion of PCE groundwater concentrations across the country, it is stated that lack of knowledge of variability in concentrations is a large uncertainty. Lack of this knowledge does make the uncertainty prominent but it may not be large in the quantitative sense. That is, if the range of actual concentrations is 0 to 6 ppb, that is a relatively small uncertainty compared to a range of 0 to 500 ppb. Discussions of uncertainty must distinguish between large uncertainty due to lack of knowledge and uncertainty that may be large quantitatively. This distinction is an important factor behind calls for uncertainty to be quantified, not just described with adjectives like large, considerable, or small.

Response: EPA has taken this distinction regarding language into account in the revised CTSA.

Executive Summary

Comment #ES-1: Section on costs: This section should give the year dollars being used. In addition, the numbers reported here represent private costs (e.g., they don't include external costs).

Response: EPA has incorporated this change.

Comment #ES-2: I would vote for putting a couple of tables in the ES that provide a quantitative overview of the results. I'm thinking of the summary tables for costs and for risks. Otherwise, the executive will have to plow through the whole thing to get some quantitative information. Generally, I'd say try to cut some of the words, and let a couple of tables do more of the talking.

Response: EPA has included more tables in the Executive Summary to improve presentation of information.

Comment #ES-3: An executive summary is supposed to summarize the main findings and conclusions contained in a document. However, the CTSA Executive Summary only summarizes what the Assessment attempts to accomplish. It generally does not present findings in the full document. This is an important problem considering the length and complexity of the document – readers will not be able to gain a clear impression of the results of the Assessment through the Executive Summary. As a result, the Executive Summary should contain more relevant data and perhaps some summary tables from the full document.

Response: The Executive Summary has been rewritten to increase the amount of data presented.

Comment #ES-4: The Executive Summary begins (paragraph two) by stating that the CTSA is intended to provide information that can be used by cleaners to assist them in making informed technology choices regarding cleaning methods. However, although the assessment provides technical information on a variety of cleaning methods, the CTSA offers no guidance on the technical information presented. In my opinion, a person reading the CTSA would not be able to make a more informed decision regarding cleaning methods and risks. In part, this is due to the lack of a summary and conclusion section in the CTSA which might have provided some indication of the Agency's position on or interpretation of the technical materials that were presented in the CTSA.

The Executive Summary itself does not summarize the information provided in the CTSA, but states what the CTSA will undertake (conduct exposure assessment, characterize risks, assess costs, performance and tradeoffs). In the conclusion section, no conclusions are given, only that the CTSA is designed to contain information to help cleaners. Furthermore, it states that 'rankings of the overall cleaning technologies are not made and will be left to those using the information that it contains'. In my opinion, the Executive Summary does not provide adequate information about the contents of the CTSA nor does it provide useful guidance for cleaners seeking information about cleaning technologies. Also, given the detail provided in the text on PCE toxicity and health effects, more information should be provided in the Executive Summary (page ES-3, bottom).

Response: EPA intends the CTSA to compile technical information on the trade-offs associated with alternative cleaning technologies. EPA expects that materials will be developed using this information that will be more appropriate for use by a broad audience. Currently, EPA is developing a shortened version of the CTSA that summarizes the information found in this more comprehensive document. EPA has also revised this CTSA to include more summary material, and rewritten the Executive Summary to strengthen the presentation of results.

Comment #ES-5: p. ES-1, executive summary and box on p.1-6: For reasons discussed earlier, I don't think that the current organization will be as helpful to small cleaners as the structure suggested above. I am concerned about the statement "It will be used by EPA and stakeholders to develop information products suitable for a broader audience" because the CTSA itself "is not intended to be a rigorous level assessment," because it currently does not fully convey the sources and implications of uncertainty, and because it does not adequately address all of the risks. I would be very concerned about other products based on this one failing to convey all of the issues.

Response: EPA has revised the CTSA to improve the presentation of material. Revisions include reorganization of chapters and revisions that clarify uncertainties. EPA has also revised its risk information and included additional information on risks, including those related to children's health and flammability.

Comment #ES-6: p. ES-1: This document is far too complicated for cleaners to read. The text should not say it "can be used by cleaners to assist them in making informed technology choices."

Response: EPA believes that the information contained in the CTSA will be useful to cleaners; however, acknowledges that the CTSA itself is highly technical and may not be easily read by cleaners. This is intentional, as the CTSA is meant to be a source of technical information and serve as the basis for development of user-friendly information products. EPA is developing a shortened version of the CTSA, containing the general results from this document, that is more suitable for use by cleaners and others.

Comment #ES-7: p. ES-1: In describing the purpose of the CTSA (p. ES-1), EPA notes that this document is part of an effort to assist small cleaners who have limited time to evaluate technologies. As previously noted, this document does not serve that purpose. Also, there is a obvious omission of the importance of educating the consumer (the public) on the hazards, costs, and benefits of various technologies. Ultimately, the informed consumer will have an important role in encouraging the development of safer technologies.

Response: EPA believes that the information contained in the CTSA will be useful to cleaners; however, acknowledges that the CTSA itself is highly technical and may not be easily read by cleaners. This is intentional, as the CTSA is meant to be a source of technical information and serve as the basis for development of user-friendly information products. EPA is developing a shortened version of the CTSA, containing the general results from this document, that is more suitable for use by cleaners and others.

Comment #ES-8: p. ES-1, third paragraph, line 2: intended <u>to</u> be...

Response: The language has been revised so that this comment is no longer relevant.

Comment #ES-9: p. ES-1, third paragraph, line 6: Replace first sentence with *However, these case study scenarios may not be representative or generalizable of common practices.*

Response: EPA has included this change.

Comment #ES-10: p. ES-1, first paragraph: The stated objective of the Cleaner Technologies Substitutes Assessment is to aid the dry-cleaner in assessing the relative merits of several alternatives to perchloroethylene (PCE) or petroleum solvent (PS) dry-cleaning methods. One of my first observations is that the overall document may be too large to be effectively used by the normal dry-cleaning operator. There is a great deal of material that is redundant from section to section that could be eliminated. The daunting size of the document could be alleviated by a concise, informative Executive Summary. However, the Executive Summary does not summarize results. It serves as a review of the table of contents and the mission of the authors. The ES should include a section of conclusions with the statement that the interested reader can explore the broader document for more specifics on individual approaches.

Response: EPA believes that the information contained in the CTSA will be useful to cleaners, however, acknowledges that the CTSA itself is highly technical and may not be easily read by cleaners. This is intentional, as the CTSA is meant to be a source of technical information. EPA is developing a shortened version of the CTSA, containing the general results from this document, that is more suitable for use by the cleaner and others. The Executive Summary has been rewritten to improve the summary of information.

Comment #ES-11: p. ES-1, second paragraph: Only place stating goal.

Response: EPA has included reference to the goal of the CTSA in several places.

Comment #ES-12: p. ES-1, third paragraph, last 2 Lines: Strike *reasonable to*, so as to read *It is expected that...*, replace *may vary* with *will vary*.

Response: EPA has not included these editorial changes.

Comment #ES-13: p. ES-2: No equipment is available for use with liquid carbon dioxide. There is virtually no information on the technology for this reason. Indeed, throughout the document, the authors state that there is no information available. A better approach to dealing with this technology would be to put it in a different category and say it is not being evaluated because there is not yet any equipment to evaluate. Call it an emerging technology.

The same holds true for the ultrasonic cleaning technology. Ultrasonics are widely used in the industrial cleaning sector. It is an old well-known method of mechanical action that is used with water-based cleaners. It is not a separate technology as the document classifies it. It is more like a sub-category of water-based cleaning, like multiprocess wetcleaning or machine wetcleaning.

Again because no information is available on it, the document should mention it, call it an emerging technology and not evaluate it because no data for such an evaluation are yet available.

The document refers to two model detergent formulations but never really discussed them in any detail, gives a reason for why they were selected, or provides an MSDS for them.

Response: EPA has revised the CTSA to include ultrasonic and liquid CO_2 cleaning as emerging technologies and moved discussion of them to a new chapter. Multiprocess wetcleaning has been removed from the CTSA as a process alternative. EPA has also included language to clarify the reason for selecting the example detergent formulations.

Comment #ES-14: Comment ES-42, p. ES-2: The Design for the Environment Program is Described. It should be noted that Design for Environment (DfE) in its strictest sense is "an engineering design initiative that promotes environmentally sound decisions at every step of the production process." DfE includes consideration of product design, packaging design, life cycle analysis, and process redesign. In essence, DfE is about designing safe substitutes (from the product or service design phase) for potentially hazardous production processes.

Response: EPA agrees that Design for the Environment is well described by the comment. However, in the CTSA, EPA is describing its own Design for the Environment Program. EPA has included language to clarify this and to reflect the comment.

Comment #ES-15: p. ES-3: Under Project Considerations EPA notes that "the overwhelming majority of the analysis addresses existing technologies" and "no studies were specifically conducted as part of this document." These limitations should be made more explicit throughout the document as the reader will be prone to think that there is a bias towards existing technologies given the present format of the document. EPA could have at least conducted interviews with some of the approximately 40 cleaners using wetcleaning methods (according to Greenpeace) to gain better insight into the wetcleaning process.

Response: EPA has included language that assists the reader in understanding what information is reported in the CTSA and what information was developed by EPA for the CTSA. EPA has also included language to stress that certain technologies are more extensively covered in the document, because the amount of information available on them exceeds the amount for other technologies.

Comment #ES-16: p. ES-3, paragraph at bottom: I believe that some mention of the controversy regarding PCE's classification belongs here. In addition, you should note that while the EPA 1991 final version maintains EPA's position on B2 classification, it also notes that its Science Advisory Board did not fully agree. Also, note that IARC classified PCE as a 2A, but drycleaning with PCE as 2B. See Thompson (1997) page 109. I am concerned that if these are not written well, the CTSA will alienate those readers that it seeks to inform.

Response: EPA has removed specific reference to PCE's cancer classification from the revised Executive Summary, however, the commenter's point is addressed with language elsewhere in the document (Appendix C).

Comment #ES-17: p. ES-3, last paragraph: This has been addressed in the follow-up memorandum from Battelle, and it is my understanding that the classification of PCE is as yet undetermined, but is somewhere between a possible human carcinogen and a probable human carcinogen.

Response: EPA has removed specific reference to PCE's cancer classification from the revised Executive Summary, however, the commenter's point is addressed with language elsewhere in the document (Appendix C).

Comment #ES-18: p. ES-3, Project Considerations, bullet 2, line 3: Strike *Certain risks, such as* so as to read *"The very serious* risk of fire..."

Response: This table has been removed from the CTSA so the comment is no longer applicable.

Comment #ES-19: p. ES-3, first paragraph, lines 4-5: Identify the specific endpoints. *Other effects such as*...is not particularly informative.

Response: The Peer Review copy of the CTSA, and the current one, both list the "other endpoints" of concern: the nervous system and liver and kidney effects.

Comment #ES-20: p. ES-3, second bullet, third sentence; ES-5, third (new) paragraph, line 4-5, and then in corresponding sections of the main text. It is regrettable that more information is not provided on the risk of fire and explosion from flammable solvents in drycleaning. Perhaps historical information from the early part of the century prior to the use of PCE might be provided.

Response: EPA includes discussion on the fire hazards associated with certain hydrocarbons. Risks were not quantitatively assessed.

Comment #ES-21: p. ES-3: Project considerations belong in the introduction of the project in the main text. It is confusing here and derails the train of the presentation. It should be labeled as project limitations defining what was left out and why. It says that resources, energy, and consumer acceptance are not factored into the evaluation when these are three extremely important considerations to the target audience. However, later in the document each of these factors is covered to one degree or another. Customer acceptance is certainly reflected in the claims and customer satisfaction data presented on the different technology demonstration projects. Energy use is calculated for the control part of some processes and for the entire process in other cases.

Response: EPA has removed the "Project Considerations" table from the document.

Comment #ES-22: p. ES-4, petroleum solvents: Refer to general comment A [Comment #G-73] regarding the classification of petroleum solvents which excludes the synthetic hydrocarbons. What does moderately heated mean? The flammability depends upon the flash point. I feel somewhat misinformed. I was not aware that petroleum solvents were ranked as high concern for environmental hazard. In fact, the trend of the industry to move towards petroleum and the synthetic hydrocarbons instead of PCE was being driven, I thought, almost totally by environmental concerns.

Response: EPA has clarified the discussion of flammability as it relates to flashpoint in the CTSA. EPA has reviewed its analysis and still assigns a high environmental hazard potential to hydrocarbon solvents. However, given EPA's assumptions about releases of these chemicals, the CTSA estimates a low risk of toxicity to aquatic species from these chemicals.

Comment #ES-23: p. ES-4, first paragraph: In addition, Petroleum Solvents (PS) may also be toxic by aspiration. There is no mention of this toxic effect anywhere in the document. Consumer Product Safety Commission (CPSC) would require household products containing more than 10% PS to be labeled: DANGER

Response: Aspiration may be a key toxicological feature of HCs, which are volatile liquids. EPA did only look at Stoddard solvent, for which the aspiration data are more speculative.

Comment #ES-24: p. ES-4, second paragraph: The chemical mixtures are described as proprietary. Are Materials Safety Data Sheets (MSDS) available from the manufacturers? If so they could be appended to the document to give the reader an idea of safety considerations.

Response: EPA based its example formulation on information from several proprietary formulations. MSDSs were not provided to the Agency.

Comment #ES-25: p. ES-4, third paragraph: There is an extensive literature on microwave safety hazards. While the units intended for drying will likely be sealed units there is an ES&H concern particularly for pregnant women.

Response: The microwave technology has been removed from the CTSA.

Comment #ES-26: p. ES-4, third paragraph: The short summary on microwaves is misleading. Some reference to "at high levels" should be added to the first sentence.

Response: The microwave technology has been removed from the CTSA.

Comment #ES-27: p. ES-4, fourth paragraph: The NESHAP for Drycleaners plays a major role in the operation and financial burden of a PCE drycleaner and deserves to be mentioned here. The implications of the NESHAP apply to the majority of drycleaners. In addition, states may have other requirements. For example, Illinois is in the process of establishing a clean-up fund specifically for drycleaners that will be funded by cleaners. The regulatory impacts of PCE cleaning can be a major burden to small business owners and this paragraph gives no indication of that.

Response: In the Executive Summary, EPA has noted that the NESHAP may affect PCE drycleaners. Additional information on the NESHAP is included in the body of the CTSA.

Comment #ES-28: p. ES-4, second paragraph, last sentence: This sentence is misleading. Some of the individual components of the wetcleaning products can be medium to high risk but the mixtures as used pose a relatively low risk to the environment. It is not a fair comparison to PCE as a moderate risk (ES-3, P1, LL) unless stated that some of the individual components of wetcleaning products could be medium to high.

Response: This text has been removed from the CTSA. EPA has revised language to clarify the difference between the hazards that are associated with chemicals and the risks that they may pose in usage as well as between information on individual chemicals and on their existence in mixtures. Thus, while several of the wetcleaning chemicals have been demonstrated to cause effects in laboratory studies, the risk analysis concludes that there are no expected health risks to the general population from the wetcleaning example formulations, that there may be risks to aquatic organisms, and that risk estimates could not be made for workers.

Comment #ES-29: p. ES-4, middle of second paragraph: I think it is called the "digestive tract".

Response: This statement has been revised in the CTSA, so that the comment no longer applies.

Comment #ES-30: p. ES-4, first paragraph: The statement "PS are ranked high concern for environmental hazard" is not terribly consistent with what is written later in the document. Specifically, see page 4-41.

Response: EPA has reviewed the document to ensure consistency.

Comment #ES-31: p. ES-4, first and second paragraphs: Criteria for high/medium/low concern not apparent.

Response: EPA has revised the Executive Summary and removed this information. Criteria for high/medium/low concern for aquatic toxicity are included in the hazard discussion in Chapter 3 of the final CTSA.

Comment #ES-32: p. ES-4, paragraph 1, line 5: Fire hazards are also *an important consideration*...

Response: EPA has included information identifying fire hazard as a consideration when using certain hydrocarbon solvents.

Comment #ES-33: p. ES-4, third paragraph, line 1: *High intensity microwave* radiation can affect... .

Response: The microwave technology has been removed from the CTSA.

Comment #ES-34: p. ES-5, fourth paragraph: Although the document says that fire hazard considerations are not a factor in the evaluation, the issue is discussed several times (see ES4, paragraph 1) - I believe that operational issues such as this should be thoroughly examined but that the discussion should occur only once. The section on safety hazards 2.1.2 is appropriate and indeed discusses fire hazard at length.

Response: EPA has revised the document to ensure consistency among chapters. Fire hazard has been included in the document.

Comment #ES-35: p. ES-5, fifth paragraph: In this paragraph, it is stated that wetcleaning information is provided on a per formulation basis rather than a per constituent basis. This provides a much better indication of the relative risk compared to other technologies which backs up the previous comment.

Response: No response required.

Comment #ES-36: p. ES-5, first through fifth paragraphs: Assumes reader knows what a model is...what is intended audience, and is the terminology used appropriate (for a non-technical reader)?

Response: EPA has revised the language in the CTSA to improve the presentation of the material. However, the CTSA is intended for a technical audience, expected to be familiar with what a model is.

Comment #ES-37: p. ES-5, fourth paragraph: It is stated that use of PCE is greater than PS. It should be noted that this is the situation in the US but the reverse is true in major markets such as Japan.

Response: EPA has not included discussion of markets outside of the United States which may not be comparable for cultural, legal, and other reasons.

Comment #ES-38: p. ES-5, first paragraph: Indoor air contamination associated with the release of PCE (and petroleum solvents) from drycleaned clothes have been (or should be) assessed and included in this paragraph.

Response: EPA has included discussion on exposure to PCE in indoor air of co-located residences in its Release and Exposure chapter. Information was not available to discuss indoor air contamination and hydrocarbon solvents.

Comment #ES-39: p. ES-5, second paragraph: The dual exposure to nursing infants in co-located apartments from inhalation and ingestion exposure should be mentioned in the executive summary.

Response: Inhalation and ingestion exposures to infants are discussed in the exposure chapter.

Comment #ES-40: Comment ES-46, p. ES-5, fourth paragraph: It is important to note that there are various alternative bio-based and biodegradable detergents that can be used. It is possible to make safer detergents, which are additions to the cleaning process, while it is not possible to make safer PCE which is integral to the process.

Response: In its chapter on hazard, EPA has stated that certain attributes of detergents are preferable to others from an environmental standpoint. These attributes include biodegradability.

Comment #ES-41: p. ES-5, last paragraph: This question, again, regards the classification status and the cancer risk of PCE. In chapter 3 I must admit I have some difficulty following the modeling's approaches to assess cancer risk. I find some of the conclusions and some of the technology rankings surprising.

Response: The classification status of PCE is no longer included in the Executive Summary and has been clarified elsewhere in the revised CTSA (Appendix C).

Comment #ES-42: p. ES-5, Risk Characterization, line 2: "Two approaches, a *linearized* multistage..."

Response: To be accurate, the phrase should be a "linearized multistage procedure;"this is a somewhat awkward phrase in its current construction. The language has been changed from "a linear multistage modeling approach" to "an approach that assumes a linear relationship at low doses" in the document.

Comment #ES-43: p. ES-5, third paragraph: "Exposures from controlled PS technologies are estimated to be lower than those from uncontrolled PS processes." Statements like this, which occur throughout the document are often unnecessary as they are obvious.

Response: EPA has reviewed language and removed statements that appear to be unnecessary.

Comment #ES-44: p. ES-5, second paragraph: No mention is made of cumulative exposures to multiple toxic chemicals. Those co-located residents for example, may also be co-located with an auto body shop or print shop which will also lead to potential exposures. If only considering exposure to PCE, risk may be underestimated.

Response: EPA agrees that this issue can be an important one. However, it is beyond the scope of the CTSA to perform a quantitative assessment of risk from exposure to multiple toxic chemicals.

Comment #ES-45: p. ES-6, fifth paragraph, line 5: this CTSA. ...

Response: The comment is unclear. No response.

Comment #ES-46: p. ES-6: Top of page "those with the highest risks of cancer are workers, followed by co-located residents, and nursing infants of mothers exposed to PCE." This statement is potentially quite misleading to the intended audience. The data supporting those three categories are very different, and any such summary statement needs to be much more carefully stated.

Response: EPA has removed this language from the Executive Summary and clarified its conclusions regarding estimated risks.

Comment #ES-47: p. ES-6, first paragraph: Please provide specific risk numbers, along with a description of their relevance.

Response: EPA has developed some quantitative estimates and described their relevance in the Risk chapter.

Comment #ES-48: p. ES-6, third paragraph: Why are social/environmental costs not included in the cost estimate?

Response: EPA's chapter on costs focuses on the private costs of the technologies. Social/environmental costs are considered qualitatively in the Trade-Off Considerations chapter.

Comment #ES-49: p. ES-6, fourth paragraph: Statement that "the historic and continuing use of PCE and PS reflects the dependable and established performance attributes of these solvents." This is conjecture and should be omitted. The comment in the next sentence about results suggesting that "many garments can be effectively wet cleaned." The general conclusions reached in performance testing are that <u>most</u> garments can be effectively wetcleaned and that technology innovation and experience.

Response: These statements have been removed from the revised Executive Summary.

Comment #ES-50: p. ES-6: At the bottom of the page, the document indicates that the customer is the final arbiter for judging the cleaning and cost-effectiveness of a process option. I do not think this is entirely true. Other factors, like whether it is practical to use, whether drycleaners can afford to buy and operate equipment play into the decision. This is why the customer satisfaction studies on wetcleaning have not led to a wholesale conversion from PERC to wetcleaning.

Response: EPA agrees that many factors play into decisions regarding the performance and cost-effectiveness of a process option. This language has been removed from the Executive Summary.

Comment #ES-51: p. ES-6, fourth paragraph: Costs should include energy costs beyond the control system which represent a trivial percentage of the total. Such factors could be critical to a comparison. For example, the new CO_2 cleaning machines do not include a drying cycle to drive PCE into the filters. This results in decreased operating time on each cleaning cycle and an energy

savings of roughly 50% over a PCE machine. Yet when compared on energy for controls the systems would appear equivalent.

Response: EPA has revised the cost estimates for PCE and hydrocarbons to include the costs of energy for dry-to-dry machines. Costs for energy for the liquid CO_2 technology have been removed from the document due to their speculative nature.

Comment #ES-52: p. ES-6, fifth paragraph, line 1: remove...(should) include...

Response: This language has been removed from the document.

Comment #ES-53: p. ES-6: Switch the *Costs* and *Performance* paragraphs to match the outline of the document.

Response: EPA has reorganized the Executive Summary to better mirror the document's overall organization.

Comment #ES-54: p. ES-6, third paragraph, sentence 1: Potential environmental risks were identified for PCE and wetcleaning. Shouldn't PS be included here?

Response: EPA identified potential environmental risks from PCE and certain components of the sample wetcleaning detergent formulation. Although EPA identifies the hydrocarbons as a potential aquatic hazard, projected releases are negligible and the estimated risk is therefore, not a concern.

Comment #ES-55: p. ES-6, fifth paragraph: The review says performance is extremely important to operators but that it is not measured. IFI cleaning standards exist and the systems should be compared head-to-head on cleaning efficiency. Given that this was not done uniformly (a good DFE project by the way), this paragraph should be eliminated. It is a very long paragraph that does not impart any really useful information to the reader. Further, given that chapter 5 includes performance data analysis this reference is confusing.

Response: EPA did not conduct cleaning performance studies specifically for this CTSA. As noted by the commenter, however, the results of cleaning performance studies are included in the Performance chapter. The Executive Summary has been modified and it continues to summarize performance factors identified in these studies.

Comment #ES-56: p. ES-6, 2nd line: This should say "infants of mothers occupationally exposed."

Response: EPA has revised the language in the Executive Summary and this editorial comment is no longer applicable.

Comment #ES-57: p. ES-6, lines 4-5: I strongly recommend that the ratios be reversed so as to be consistent with the MOE analysis of cancer. Divide the relevant toxicity comparison levels by the

estimated exposures. It will be less confusing than having different indices going in different directions.

Response: Many reviewers felt that the use of both the MOE and the HQ for non-cancer risks was confusing, since the indices go in opposite directions. Both approaches, however, do have currency in the field. Therefore, EPA chose to restrict the CTSA to only one, the HQ approach, to describe the non-cancer risks. Extensive revisions were also made to clarify the text and tables of the risk chapter (chapter 5) and to better define and explain the use of the MOE for cancer.

Comment #ES-58: p. ES-7: A cost-benefit analysis, as suggested here, is much different than a trade-off analysis. Dr. Nicholas Ashford, MIT (Ashford, 1991) describes trade-off analysis as a much more comprehensive assessment than a cost-benefit analysis which attempts to reduce diverse factors into a single monetary value. In the same paragraph, EPA notes that because of the prevalence of PCE and PS dray cleaning facilities, the CTSA offers comparisons of technologies using the same solvents. Please note that once drycleaners invest in control technologies involving PCE or PS, the chances of them switching to alternative, non solvent technologies will be greatly reduced. Cost effectiveness analysis comparing PCE and PS options is not necessary nor recommendable in this light. If EPA wishes to complete cost effectiveness analysis, if should also do this analysis based on a goal of solvent elimination. As previously noted, the continued focus and analysis of technologies involving PCE and PS legitimizes their continued use.

[Ashford, N. and C. Caldart. 1991. Technology, Law, and the Working Environment. New York: Van Nostrand Reinhold.]

Response: In the CTSA, EPA considers a cost-benefit analysis as one approach to comparing the trade-offs among alternatives. EPA continues to include cost-effectiveness analysis as another approach for evaluating trade-offs and applies this to alternative machine configurations for PCE and hydrocarbons. These are provided to offer alternatives to those cleaners interested in reducing solvent emissions who may not be able to adopt alternative technologies, particularly in the short run.

Comment #ES-59: p. ES-7: Conclusion sounds like it should be in the introduction.

Response: EPA has revised the conclusions found in the Executive Summary.

Comment #ES-60: p. ES-7, second paragraph: By not completing technology rankings, EPA will be considered to have implicitly chosen the status quo, PCE and PS technologies. Drycleaners will expect that EPA rank the various technologies, given that individual drycleaners will be unable to do this on this own, due to the complexity of this document. EPA's statement that "judgments on whether one cleaning technology is better than another need to be made by individual cleaners in responding to their customers' preferences" is naive and misguided. First, the public is not even a target of this document and thus will have no preference at this point of one technology over another, and second, there are clearly technologies that are environmentally preferable to others – the identification and dissemination of those technologies should be an important goal of this document. Adequate information is available at this point to make at least tentative rankings of the most environmentally friendly options.

Response: It is not the intent of CTSA's to provide recommendations or rankings of technologies. EPA strongly maintains that CTSA's are sources of technical information that support decision making by individuals based upon their own circumstances. EPA disagrees that this approach endorses maintenance of the status quo and in fact, believes that it provides information that will allow cleaners to move away from the status quo, if desired. While certain technologies may be more environmentally preferable, EPA does not believe that the CTSA can be a prescriptive document. EPA is developing a condensed version of the CTSA that is not as technical that can be used by cleaners to make their technology choices.

Comment #ES-61: p. ES-7, Conclusions, lines 7-8: While I understand the authors' reluctance to become involved in the decision making, it would be extremely useful to provide some exemplary rankings of the overall cleaning technologies just for illustrative purposes. Caveat them to death if you want, but don't leave it completely up to people who know far less about the big picture and are just struggling to wade through this massive tome and find out what applies to their specific situation?

Response: It is not the intent of CTSA's to provide recommendations or rankings of technologies. EPA strongly maintains that CTSA's are sources of technical information that support decision making by individuals based upon their own circumstances. EPA does not believe that the CTSA should be a prescriptive document. EPA is developing a condensed version of the CTSA that is not as technical that can be used by cleaners to make their technology choices

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Comment #ES-62: p. ES-7, first paragraph: Releases don't equal exposure. To say that they reflect exposure is inaccurate. At best they enable exposure but don't tell us anything about extent.

Response: EPA has not stated that releases equal exposure, but has stated that they are used as a surrogate for exposure in the CTSA. EPA believes this to be reasonable given that releases play a significant role in the amount of chemical to which individuals are exposed.

Chapter 1

Comment #1-1: The descriptions appear to me to be accurate and adequate.

Response: No response necessary.

Comment #1-2: To my knowledge, the technologies have been properly categorized.

Response: No response necessary.

Comment #1-3: To my knowledge, the proper primary equipment and operations are included.

Response: No response necessary.

Comment #1-4: I have no expert knowledge of the processes described.

Response: No response necessary.

Comment #1-5: Chapter one does set the stage for the comparative evaluations that follow.

Response: No response necessary.

Comment #1-6: No specific comments. The use of diagrams to help explain different methodologies was very helpful.

Response: No response necessary.

Comment #1-7: The document overview reinforces the need to revise the executive summary. The first two sections that the viewer reads are almost the same. The document overview on 1-3 could be put into the introduction on 1-1 - too much description!

Response: The sections mentioned in the reviewers comments have been revised in the new draft.

Comment #1-8: Q-5: Cleaning volume figures are from 1991 and solvent consumption figures are from 1996. Volume figures should be updated (get it from trade associations IFI and NCA-I). Solvent consumption figures are used in later chapters for release estimates. I recommend that PCE consumption figures are shown for several years, i.e., for all years from 1991 to 1996. Any emission inferences drawn should refer to the annual consumption and volume numbers.

Response: EPA has updated the cleaning volume figures (provided they do not affect the size of the model facility which was based on the 1991 numbers) with information from either IFI or NCA-I. EPA release estimates are based on the PCE consumptions figures.

Comment #1-9: Q-4: References to volumes of articles cleaned in Exhibits 1-8 and 1-9 in PCE and Petroleum Solvents are different. Text states 85% PCE and 15% petroleum solvents. Volume numbers given in 1-8 and 1-9 don't correlate or are not adequately explained.

Response: EPA has revised its estimates on volume of clothes.

Comment #1-10: Q-3: Process flow charts are useful, but they need to be revised. Also, it does not make sense to use a transfer machine flow chart to represent PCE drycleaning technology since the majority of the machines are dry-to-dry machines. Place flow-charts immediately after the text (CO2 chart).

Response: In the updated CTSA, the more recent dry-to-dry machines used in drycleaning facilities have been included in the flow diagrams. Also, to the extent possible, flow diagrams are placed immediately after the text.

Comment #1-11: Q-6: References are generally relevant. Several references are personal communications. It would be desirable to minimize them in favor of published documents.

Response: EPA tries to use published sources when they are available. However, in order to provide certain market profile or equipment information, it is often necessary to use information from personal communications. In the updated CTSA, several published documents have replaced a number of personal communications from the peer review CTSA.

Comment #1-12: Q-2: Section 1.1 is fine, but the other sections need technical corrections and major revisions. Many segments are too long and could be condensed without losing the communication objectives. Breaking it down into several chapters will be more reader friendly.

Response: EPA has revised the document to assist readability. The updated CTSA has corrected technical errors, revised and clarified information on processes to the extent possible.

Comment #1-13: Are the descriptions accurate & adequate? There were some areas that I thought needed improvement. Included in comments.

Response: No response necessary.

Comment #1-14: Do the technologies appear to have been properly categorized... There were some areas that I thought needed improvement. Included in comments.

Response: No response required.

Comment #1-15: Finally, for CO_2, the CTSA needs to address the problems associated with increasing emissions of CO_2 to the atmosphere using such a system and the potential for its

contribution to global warming. In addition, accidental releases of CO_2 could also pose some risks, although these appear to be unlikely given that people will be gasping for air if exposed to high levels (i.e., unlike CO they will be able to detect a problem).

Response: Given the developmental status of the liquid CO_2 cleaning process, EPA believes that it is not appropriate to address issues relating to emissions or accidental releases of CO_2 from the process.

Comment #1-16: Q-1: For an introductory chapter, it is too long. Section 1.1: Project Background should be the only one in this chapter. Section 1.2: Overview of Clothes Cleaning, Section 1.3 Drycleaning Industry Market Profile and Section 1.4: Comparison of German, Japanese, Canadian and United States Market (Section 1.5) should be separate chapters following the introductory chapter.

Response: EPA has revised the document to assist readability.

Comment #1-17: The information compiled to create the drycleaning industry market profile appears to be reasonably complete. The information is not particularly complex and its presentation could be simplified, however. Exhibits 1-8, 1-9 and 1-11 would be more useful with column totals and percentages. On page 1-27, it is stated that 42% of the PCE produced is used by drycleaners. I would like to see this figure presented so that I could relate it to exhibit 1-10. Also, I would like to know what percentage of domestically consumed PCE that is used by drycleaners if this information is available.

Response: The Agency has revised the information on PCE consumption and volume of clothes cleaned to update the presentation.

Comment #1-18: Chapter 1, as stated above, does not completely "set the stage" for the comparative evaluation which should follow. Whether these comparative evaluations are accomplished constitutes another issue, which has been discussed above in brief as well.

Response: EPA has revised the document to assist readability.

Comment #1-19: Process Descriptions: I have no comments here.

Response: No response necessary.

Comment #1-20: The chapter does explain its purpose fairly clearly. The rationale for comparing the German, Japanese, Canadian and US markets is unclear, however.

Response: EPA has removed the discussion of the German, Japanese, and Canadian markets.

Comment #1-21: Chapter one does a marginal job in setting the stage for the comparative analysis. Sections 1.3-1.5 are not exceptionally useful in setting the stage for the document, if

indeed the idea is to compare technologies. This could be relegated to an appendix as it is still important in terms of the stages of development of the various technologies. The chapter needs to better explain why each of the proceeding seven chapters is important to the analysis, not just that they are included in this analysis. Also, each section in this chapter needs some description of its importance, perhaps at the beginning of the chapter (this is true for each of the other chapters).

Response: EPA has revised the document to assist readability.

Comment #1-22: The proper primary equipment and operations appear to be included. In terms of process characterization, it would be useful to include both emissions from products (clothes), environmental emissions from muck and water, and other hazards (e.g., transport, production of chemicals coming into the process). The descriptions appear to be accurate.

Response: The issue of release sources in the cleaning facilities is covered in Chapter 4 of the revised CTSA.

Comment #1-23: 1. Does chapter one help set the stage for the comparative evaluation to follow? Chapter one is generally well done in the sense that it has good process and industry profile descriptions. It could be further improved if it set the stage better for relevant health hazard analyses--emphasizing a goal (not now addressed in the current document) to provide some population aggregate indices of exposure and health harm. That is, how many person-mg/m^3 of perchloroethylene exposure do we expect at present for workers, residents of apartments co-located with drycleaning establishments, and the general population via outdoor ambient air and indoor air affected by indoor emissions from drycleaned clothes? Under current cancer risk estimates what is a best-estimate and plausible upper limit estimate of the annual numbers of cancers that might be induced? How much might these be changed by (a) use of the best PCE machine configurations currently available, or (b) the most extensive practicable use of alternative technologies, and how much extra would these cost society as a whole (if anything)? I believe these would be better, more helpful questions for EPA to spend its resources on than the current focus of the document to be a "repository" of information that others might put to some ill-defined use in making education materials.

Response: The commenter suggests a change in the goal of the document. EPA maintains the goal of the CTSA to serve as a repository of information that can be used to assist drycleaners in making choices among clothes cleaning technologies. The focus of the document is to develop information that can be used to assist individual small businesses in making technology choices by identifying important considerations. The evaluation of aggregated social costs are not expected to be as useful to the individual decision maker in selecting among technologies. Therefore, the CTSA gives an indication of the potential risks to specific populations and from particular technologies that should be considerations for the individual decision maker, pointing out that these risks are costs to society.

Comment #1-24: Proper primary equipment and operations information are included. However, the process flow charts should reflect modern technology. For example, Exhibit 1-2 should be replaced with a drawing of the most advanced PCE technology, i.e., a generation 4 or 5 machines flow chart. The same holds true for petroleum solvent cleaning technology (Exhibit 1-4). There should be a flow chart for the new petroleum machine with dry-to-dry technology and safety features.

Here are some specific comments:

Response: In the updated CTSA, the more recent dry-to-dry machines used in drycleaning facilities have been included in the flow diagrams. However, configuration-specific safety features in PS machines were not included since the diagrams are to apply generally to various configurations.

Comment #1-25: The proper primary equipment & operations were included.

Response: No response is necessary.

Comment #1-26: Does chapter one help set the stage... Yes. The arrangement was good but there were inconsistencies between like data from one chapter to another.

Response: EPA has revised this chapter and others to establish data consistency.

Comment #1-27: Other Technologies: Ultrasonic Cleaning and Microwave Drying. No comments because of insufficient information.

Response: No response necessary.

Comment #1-28: Carbon Dioxide Processes. To most people, the use of carbon dioxide as a cleaning medium for textiles is difficult to grasp. Process information released by the advocates of this potential alternative to PCE cleaning are sketchy and market driven. The two commercial companies are understandably reluctant to release proprietary information about process details. But there is a need for objective assessment of this technology. The enclosed report by Wentz ("Textile Cleaning with Carbon Dioxide," Street's, 1995) provides a frame of reference for information needed by drycleaners.

Since this technology is still in its infancy, caution is advised to draw premature conclusions and projections about the viability of this technology.

Response: Because of the developmental nature of this technology, it is no longer compared to existing technologies. EPA, however, continues to report information on the technology in Chapter 11.

Comment #1-29: Machine Wet Cleaning. EPA's demonstration site in Chicago (CNT) generated useful information. The technology used there should be summarized in Chapter 1. Drycleaners should know about the process variations practiced in the professional wetcleaning arena. Of particular interest is the water consumption and the rules and regulations about waste water discharge into the sewer. Many drycleaners argue that wetcleaning is not a viable complement to drycleaning in areas where water is scarce or expensive. A discussion of these issues would be helpful.

Response: Machine wetcleaning process variations are discussed generically in the revised CTSA. The CTSA also provides information on many Federal regulations governing specific technologies

and conveys the need for individual cleaners to closely examine State and other requirements related to a technology choice. While water scarcity may be a consideration for individual cleaners, EPA has not found information to discuss this issue.

Comment #1-30: Multiprocess Wet Cleaning. As stated earlier, the industry considers this technology as nonviable. The references to this labor-intensive "technology" should be limited to its historic role within the DfE project.

Response: The multiprocess wetcleaning technology has not been included as a process alternative in the revised CTSA.

Comment #1-31: Petroleum Solvent Processes. The old petroleum technology is overemphasized. Drycleaners are interested in the function and performance of the new petroleum technology since it is offered as a viable alternative to PCE drycleaning. The CTSA report should assess the new petroleum solvent technology (controlled petroleum solvent processes) which is not done adequately in the existing draft document. Cost, performance, emission and exposure information should be made available to American drycleaners in an objective way. The National Fire Protection Agency (NFPA) is in the process of reviewing the petroleum drycleaning standard (NFPA-32). EPA's participation in this process is desirable.

The new technology balances the three variables: fuel, oxygen and source of ignition. A proper control of these variables virtually eliminates the fire and explosion hazard as demonstrated under practical conditions in more than 1000 drycleaning plants in Germany. Furthermore, the new dry-to-dry petroleum machines which use well defined linear or branched hydrocarbons without aromatics, minimize the emission of the solvent dramatically. Therefore, the burden on the environment and the exposure of the worker is significantly lower than with the traditional petroleum systems. Case studies in the USA should be undertaken to verify the performance of this new technology.

Response: Involvement in the National Fire Protection Association's petroleum drycleaning standard and in case studies on the new petroleum technologies is not within the scope of this CTSA.

EPA searched for new information on function, emissions, and exposure for new PS technologies, and found very little. To the extent available, new information is presented in the revised CTSA.

Comment #1-32: The descriptions are not always accurate or adequate. For example, the statement on p. 1-7, last paragraph: "The drycleaning process was developed to control fabric shrinkage" is incorrect. Drycleaning gained commercial significance because oily and fatty-type of soils are better removed with organic solvents than with water. Shrinkage prevention evolved as colloidal moisture management in organic solvents was understood and implemented.

Response: The drycleaning process developed in response to several garment cleaning needs. Simpler, more accurate, and more adequate descriptions have been incorporated into the updated CTSA.

Comment #1-33: The purpose of this chapter should be to provide an overview of the different types of drycleaning processes, a snapshot of the processes used in current United States market, as well as compare the US market profile to market profiles in other countries where drycleaners have implemented different types of pollution prevention strategies. I found this chapter somewhat confusing. I think its clarity could be improved by removing statistics that describe the US drycleaning industry as a whole from the section on clothes cleaning process descriptions. The information that describes the industry as a whole is better suited to the market profile section. As it stands, the figures that attempt to describe the drycleaning industry as a whole that are presented in the cleaning process section appear incomplete. Specifically, on page 1-8, the sentence that states that PCE is used in 80% of all drycleaning facilities and accounts for 60% of the total drycleaning volume should be removed and presented in the market profile section in a clear, concise manner. Currently, this information is repeated and expanded upon in the market profile section. Exhibit 1-3 also belongs in the market profile section because it provides a descriptive information on the industry as a whole -- it does not describe a drycleaning process. Also, Exhibit 1-3 would be more useful if columns and rows were totaled and percentages were included in the table.

Response: EPA has reviewed the organization and modified aspects of the formatting of the document, including removing statistics on the industry as a whole. EPA has also removed Exhibit 1-3 from the revised CTSA.

Comment #1-34: Microwave Drying. This technology is not a cleaning technology. It utilizes electromagnetic radiation as energy source for removing water from textiles. EPRI's research at NCSU and elsewhere suggest that more work is needed before a clear feasibility statement can be made.

Response: EPA has not included the microwave technology in the revised CTSA.

Comment #1-35: Ultrasonic Cleaning. Existing information are derived from laboratory experiments which do not resemble the challenge this technology will face under commercial conditions. To state that the primary benefits of this process is in-line continuous processing is premature and unproven. In addition, there is insufficient evidence to show that ultrasonic cleaning will work for textiles. The scientific literature on this subject matter is scant, but what is published does not justify the overwhelming optimism expressed in this section of the document.

Response: EPA removed the statement on primary benefits from the discussion on ultrasonics. The discussion does not address feasibility issues. The information has been edited for clarification and conciseness in the updated CTSA and due to the developmental nature of the process, it has been included in an Emerging Technologies chapter.

Comment #1-36: Carbon Dioxide Process. The two equipment options described are not sufficient to make an informed decision about the commercial feasibility of this horizon technology. This is not surprising since field experience is lacking. What is clear, however, is that some of the claims made are not substantiated or dead wrong. For example, it is clearly irresponsible to state that carbon dioxide provides solvent power similar to trichloroethylene. This is simply not true. A cautious and objective assessment should be made here. Future developments will bring the answers, and claims will be either proven or disproven. Any unfounded ecstasy expressed today

has the potential to erode the credibility of this document.

Response: Feasibility of liquid CO_2 process is not an issue discussed in the process descriptions. Regarding the statement on solvent power. This statement was removed from the CTSA. EPA cannot determine what other claims in this section the commentator perceives as unsubstantiated or wrong. To the extent possible, developer "claims" were removed from this section.

Comment #1-37: Wet Cleaning. Early on, EPA's almost exclusive focus on the "multiprocessor wet cleaning" as a substitute for drycleaning was not taken seriously by the industry. It is now clear that this "new technology" is not a viable commercial alternative. However, the automated professional wetcleaning technology which emerged thereafter has indeed the potential to become an integral part of the day-to-day fabricare industry. The CTSA report talks only about the Miele-Kreussler system. CNT has prepared an updated summary of vendors in the USA. Their summary listing of wetcleaning equipment available to American drycleaners should be incorporated in this report.

Response: Multiprocess wetcleaning is no longer considered as a technology alternative in the CTSA with respect to machine wetcleaning. Miele/Kreussler provided the first description for this section, and there are no significant differences in various MWC systems that need to be addressed in the CTSA. The general factors common to all MWC systems are discussed in the CTSA.

Comment #1-38: Because of fire hazard, smog formation potential and toxicity (aromatic components), petroleum solvent have been largely replaced by PCE. There are still pockets of higher petroleum use for drycleaning (i.e., Texas, Oklahoma), but they use traditional petroleum solvents and outdated transfer technology. The new petroleum technology, developed in Germany, is making inroads in the USA as manifested during the Clean >97 show.

This new technology uses refined linear or branched saturated hydrocarbon solvents with narrow boiling ranges and high flashpoints. Their evaporation rate is lower than that of traditional petroleum solvents, so that fugitive emission is considerably lower than with the traditional solvents. The new machines uses predominantly dry-to-dry technology with nitrogen or vacuum control technology. Extensive field experience exists in Germany, where over 1000 machines are installed in mostly co-residential areas. The National Fire Protection Agency (NFPA) is in the process of reviewing the drycleaning standard NFPA-32. Their drycleaning committee is currently assessing the safety of the new petroleum technology and is considering a revision of the standard.

Drycleaners are interested in this new petroleum technology. They are waiting for position statements from NFPA as well as from EPA. The CTSA document should contain more specific information on this new technology rather than focusing on the old petroleum technology. Again, a clearer statement from EPA concerning the agency's assessment of this technology is needed.

Response: EPA has searched for new information on these technologies and included the little information available from the literature and other sources. It is not, however, the purpose of the CTSA to make a "position statement" on technologies.

Comment #1-39: There is too much emphasis on old technology. The NESHAP (1993) regulation no longer allows the installation of new PCE transfer machines. Therefore, it is sufficient to

describe them from a historic perspective and highlight their significant PCE emission potential. The industry's move towards dry-to-dry machines reduced PCE consumption and exposure significantly during the past decade. For example, PCE consumption in the drycleaning industry dropped from 365 million lbs. in 1981 to 151 million lbs. In 1994, a reduction of 214 million lbs. or 59% (Source: TCATA-Ernst & Young surveys).

The industry developed a series of pollution prevention technologies and maintenance programs which are listed in the document. But again, there is too much emphasize on "transient"" technology. For example, the "azeotropic technology" is clearly overemphasized. Historic mentioning may be appropriate. The fact that the last units were sold in 1982 (Footnote, p. 3-7) and that the company (Solvation) does no longer exist does not give drycleaners the opportunity to consider it as a pollution prevention technology. So, what is the purpose of highlighting it in this document?

A clear statement about the best performing PCE technology with EPA's position on it would clarify the confusion many drycleaners have about the future of PCE drycleaning.

Response: The commenter apparently interpreted amount of coverage to be emphasis. The amount of coverage in this document is generally a function of available information. To reduce this misinterpretation, the CTSA contains a statement regarding volume and coverage, and coverage on old technologies has been reduced.

Comment #1-40: p. 1-1, second paragraph: Section 1.1 should include a summary of the findings of other EPA (and other reports) written to date on the issue of pollution prevention in the drycleaning industry. For example, EPA document EPA/600/R-94/178, The Product Side of Pollution Prevention, contains a section on drycleaning that is not mentioned in the CTSA. It concluded that safe substitute approaches to reducing the use of PCE include: reducing the use of water-sensitive fabrics and garments that require drycleaning modifying the process to eliminate or reduce the use of organic solvents; and substituting a safe solvent for PCE. This document notes that PS is not a safe substitute for PCE.

Response: EPA has reviewed the document and mentioned it, as appropriate in the revised CTSA. EPA believes that the context in which substitutes are considered in EPA document EPA/600/R-94/178 differs from the CTSA because it is limited to reducing releases of chemicals with toxic properties. The CTSA, however, provides information on the risks of substitutions. This difference is explained in the CTSA.

Comment #1-41: p. 1-1: Section 1.1 should include a summary of the findings of other EPA (and other reports) written to date on the issue of pollution prevention in the drycleaning industry. For example, EPA document EPA/600/R-94/178, The Product Side of Pollution Prevention, contains a section on drycleaning that is not mentioned in the CTSA. It concluded that safe substitute approaches to reducing the use of PCE include: reducing the use of water-sensitive fabrics and garments that require drycleaning modifying the process to eliminate or reduce the use of organic solvents; and substituting a safe solvent for PCE. This document notes that PS is not a safe substitute for PCE.

Response: See response to comment 1-40.

Comment #1-42: Section 1.1.1, third paragraph: HSIA = Halogenated Solvents Industry Alliance.

Response: The Agency has corrected the acronym.

Comment #1-43: p. 1-1, list of stakeholders: These need to be verified, I thought that the NY Dept. Of Health was involved (via Judy Schreiber), and the Halogenated Solvents Industry Alliance (HSIA) is improperly listed. Also the last full sentence on the page begs the questions, "What about the trade associations, particularly since they are involved as stakeholders in the paragraph above?" How does EPA intend to disseminate this information? Will it be sent out to all U.S. drycleaners, made available to trade associations?

Response: EPA has corrected the stakeholder list, which does include trade associations. The CTSA and related documents will be available to the public through EPA's Pollution Prevention Information Clearinghouse.

Comment #1-44: p. 1-1, Section 1.1.1, second paragraph: I believe Halogenated Solvents Industries of America should read Halogenated Solvents Industry Alliance.

Response: The Agency has corrected the error.

Comment #1-45: p. 1-1: History - change second paragraph to New York Department of Environmental Conservation.

Response: The Agency has corrected the error.

Comment #1-46: p. 1-1: HSIA is the Halogenated Solvents Industry Alliance.

Response: The Agency has corrected the error.

Comment #1-47: p. 1-1: The project background history section in Chapter 1, p. 1-1 does not list the Fabricare Legislative and Regulatory Education (FLARE) organization as stakeholder. Please add.

Response: EPA has included FLARE.

Comment #1-48: p. 1-2, Section 1.1.1, fourth paragraph: Multi-process wetcleaning cannot be described as a technology. It is only a series of techniques.

Response: The CTSA no longer includes multi-process wetcleaning as a process alternative.

Comment #1-49: p. 1-3, second paragraph: The review leaves out industrial and coin-op markets

which is understandable given the relative market sizes. However, industry trends suggest the elimination of "mom and pop" shops in favor of larger, centralized operations. This trend makes the exclusion of industrial operations risky.

Response: The focus of the CTSA is on the commercial clothes cleaning sector. Evaluation of the industrial and coin-op markets are outside of the scope of the CTSA.

Comment #1-50: p. 1-3, last paragraph: Please refer to the general statement D regarding the lack of consideration given to the nature and disposition of soils that are being removed from the garments.

Response: No action required. This issue is covered in comment referenced.

Comment #1-51: p. 1-3, second paragraph: First time PCE is mentioned in this chapter, it should be spelled out (i.e., Perchloroethylene (PCE)).

Response: EPA has made this revision.

Comment #1-52: p. 1-3, second paragraph: "...apply to specific clothes cleaning technologies (not technology)." Why doesn't the report provide information on pollution prevention opportunities for the industry as a whole, not just ones that are technology specific.

Response: Pollution prevention (P2) analysis for the entire industry is not within the scope of this CTSA. The CTSA is intended to give some information where data gaps exist, to disseminate information, and to assist in making gross comparisons within and between technologies.

Comment #1-53: p. 1-3, fourth paragraph: 2nd sentence is confusing as written. It would be better written: "For the aqueous-based technology, multi-process wetcleaning, model formulations containing chemicals common to detergents and cleansers are used as the basis for release estimates."

Response: EPA has revised the CTSA to enhance readability. In addition, multi-process wetcleaning is no longer presented as a process alternative.

Comment #1-54: p. 1-4, Exhibit 1-1: The shaded boxes are hard to read.

Response: EPA has revised the document to enhance readability.

Comment #1-55: p. 1-4, Exhibit 1-1: The explanation of what is meant by the shaded boxes should be included on this page. Currently, this is not explained until Page 1-8.

Response: EPA has revised the document to enhance readability. Exhibit 1-1 is no longer part of the document.

Comment #1-56: p. 1-4, Exhibit 1-1: Exhibit 1-1 categorizes the clothes cleaning alternatives into Drycleaning Substitute and **Wet** Cleaning substitutes and the subcategories existing, newly available and under development. This is a logical categorization which should be adhered to in the text. It would be desirable to state that cleaning of the current textiles on the market requires both, non-aqueous ("dry") and aqueous ("wet") cleaning technologies.

Response: EPA has revised the document to better distinguish between its descriptions of drycleaning and wetcleaning. These descriptions have been adhered to throughout the CTSA. The CTSA has also been revised to include emerging technologies in a separate chapter because it is not possible to present them on a comparative basis with existing technologies.

Comment #1-57: p. 1-4: Please refer to the general comment A [Comment #G-73] regarding the PS classification as opposed to HC classification and the need to include synthetic hydrocarbons such as Exxon's DF-2000. I am not sure whether this would fall under the existing category or the newly available category. DF-2000 has been used in the industry for several years, but I do not have actual consumption data and would suggest you contact Jim Shriner of Exxon regarding the extent of DF-2000 use in the industry. Under wetcleaning substitutes, I do not believe professional laundering should be included in this CTSA as an option to drycleaning. If professional laundering is included, the CTSA needs to be probably doubled in scope due to all of the issues with regard to industrial laundering and the classifications of soils in waste water based upon the nature of the soils. This is probably well beyond the scope of this CTSA. See also my general comment K regarding multi process wetcleaning. I am under the impression that this is no longer practiced as evaluated in the original EPA project.

Response: Where information allows, EPA has included Exxon's DF-2000 in the CTSA. Professional laundering is not considered as an alternative to drycleaning. Multi-process wetcleaning has also been removed as an alternative process to drycleaning.

Comment #1-58: p. 1-4: Controlled petroleum solvents should not be considered a drycleaning substitute, as it is merely an addition to the PS production process (though it obviously reduces risk in PS solvent cleaning) Throughout the rest of the document, Controlled PS should be considered in the same section as PS and not with the alternative technologies section so as to avoid confusion. As noted above, even controlled PS is not a safe (or cost-effective for that matter) substitute for PCE.

Response: The conventional and controlled PS process information and assessments have been combined in the CTSA.

Comment #1-59: p. 1-4: The text reference for Exhibit 1-1 doesn't come until page 1-8. I had to look around for quite a while to find this and it should be relocated.

Response: EPA has revised the document to enhance readability. Exhibit 1-1 is not included in the revised CTSA.

Comment #1-60: p. 1-4: This figure is not called out in the text until well after it appears. This is

true throughout the document. In all cases, the figures should be discussed before they appear in the text. It is jarring to come upon a figure or table before it is introduced.

Response: The Agency has reformatted and re-organized this section of the document.

Comment #1-61: p. 1-4: No reference to Exhibit 1-1.

Response: The Agency has reformatted and re-organized this section of the document. This exhibit no longer is included in the CTSA.

Comment #1-62: p. 1-5, second paragraph: I don't understand the 100% release estimate assumption. The review purposely leaves out two market segments and then says information on the entire market is not available. It would be better to report release estimates (by technology) on what is known and leave it at that.

Response: The assumption was not clear and has been clarified in the updated CTSA.

Comment #1-63: p. 1-5: The document indicates that release estimates were developed by assuming 100% of the market was represented by carbon dioxide cleaning but, in fact, no analysis for this technology was ever presented. Again, I think it should be said up front that this technology is emerging and that no equipment is yet available to purchase. No cleaners are using the technology so no data can be presented.

Response: EPA has included liquid CO_2 as an emerging technology. Due to the developmental status of the technology no data are available on releases for this technology, so none are.

Comment #1-64: p. 1-5, fourth full paragraph: This paragraph indicates that the CTSA presents quantitative estimates when data allow. Thus, the document is implicitly biased toward those risks that are more well-characterized. By ignoring the less-known risks, decisions based on this lopsided information could lead to unexpected consequences. Also, why is the emphasis only on individual risk, what about population risks? This should be discussed here.

Response: The presentation of quantitative estimates of risks of certain chemicals does not imply that any other chemicals are less "risky". The presentation of material in the CTSA has been revised to clearly indicate that the health risk between the various technologies can only give a "ballpark" type of comparison. Quality comparisons are made in the CTSA. Individual risks were the only estimates developed for the CTSA.

Comment #1-65: p. 1-5, fifth paragraph: Why is it not the intent of the project to derive conclusions about the suitability of alternatives? Isn't that the whole rationale for a DfE program?

Response: The intent of the CTSA is to provide general information on technology alternatives that can support the individual cleaner's decisions regarding the suitability of a process alternatives. This supports DfE's goals while allowing individuals to adjust information and make judgements based upon the specifics of their situation. The CTSA, therefore, is not meant to prescribe,

however, to provide the basis from which cleaners can become informed.

Comment #1-66: p. 1-6, Box: The box says that the document is not a tool to allow the small business owner to make a decision. Yet the opening paragraph of the introduction states "The assessment is intended to provide information that can be used by cleaners to assist them in making informed technology choices....." and states that it is intended to specifically "assist small cleaners." Which is it? I firmly believe that it should attempt to be the latter. It doesn't really matter if all factors could not be considered. There should be an up-front statement that because the data was assembled from a variety of sources and different studies, there are bound to be some gaps. I have provided a table at the end of this review to help identify these gaps. The text often goes to wordy extremes to justify or explain what everyone intrinsically recognizes: this is a big job, done to the best of abilities, but there are some gaps.

Response: EPA has clarified the goal of the document to make clear that the document is written for the technical reader, not necessarily for cleaner. The information in the document, however, is meant to be used by cleaners to assist them in making technology choices. The manner in which the information will be conveyed to the cleaner is primarily through more user-friendly products than the CTSA.

Comment #1-67: p. 1-6, first paragraph: Cost information from performance evaluations not included in cost analysis. The text says that cleaners can use what information is provided but, again, the box on 1-6 says they can't.

Response: The cost data in the performance studies represent data on machine configurations and operations that differ from the "model" plants used in the cost analysis. Therefore, cost information from the performance studies was used to inform the cost estimates, however, was not the direct source for them.

Comment #1-68: p. 1-6, first paragraph: Why are social costs of various technologies not included? Are they considered of little importance.

Response: EPA discusses social costs in Chapter 10 of the CTSA. They are discussed qualitatively to provide the reader with an understanding of how the choice of a particular process may impose costs on society, and, in particular, what those costs are (e.g., health risks).

Comment #1-69: p. 1-6: The box on how to use this document should go at the beginning of this section. 2nd paragraph of the box, no comma is needed after "in this project". Why are the public and workers, those potentially at greatest risk not included as "other readers" in this document. If these stakeholders are at greatest risk from PCE, shouldn't they be one of the primary targets of this document? Also, last sentence in the box, "can be useful when working with cleaners toward technology that might reduce risks or pollution." There is no doubt that machine wetcleaning will reduce risks and pollution.

Response: EPA has revised the document to enhance readability. EPA has not explicitly identified the general public and workers as "other readers" because of the technical nature of the document. EPA has stated, however, that information contained in the CTSA will be of interest to a broad

audience and expects it to be conveyed through sources such as the shortened version of the document currently under development.

Comment #1-70: p. 1-6 Box: How to Use This Document **COME BACK TO THIS**

Response: No response needed.

Comment #1-71: p. 1-6: The document states "After reviewing these more targeted information products, clothes cleaners may choose to return to the CTSA to obtain more technical details..." No cleaner will ever read this document.

Response: The commenter provides no basis to support this claim. EPA has made no changes.

Comment #1-72: p. 1-6, first full paragraph: If the goal of the CTSA is to help cleaners evaluate strategies for risk and pollution prevention, then they need to be able to look at the incremental costs and benefits of strategies that might be available to them. In particular, the options, costs, and benefits are different for different types of facilities. An owner of a shop with a PCE transfer machine can either buy control device for it (and should have already done so under the NESHAP), buy a dry-to-dry machine (with RC control to satisfy the NESHAP), buy a PS machine (if zoning permits), or buy a wetcleaning system. However, a person wishing to open a new shop can not buy a new PCE transfer machine (because of the NESHAP) and his or her decision is very different since the person incurs all of the equipment costs associated with start-up. In addition, the exposures and risks related to any facility will depend on the amount of clothes cleaned, the type of machine used, the control device used, the numbers and types of workers, the distribution of the population around the source, etc. A small PCE shop in a rural area in Maine poses a lower overall population risk than a similar shop in Manhattan, simply due to the population density.

Response: EPA, where possible, has provided information that shows the relative incremental costs of switching from one PCE or HC machine configuration to another PCE or HC machine configuration. EPA specifically notes that the costs presented are relative and that individual factors, such as machine used, numbers of workers, and others would affect the actual costs that would be faced by a cleaner. The CTSA notes that individual factors will also affect exposures. Therefore, the CTSA does not provide measures of incremental costs for specific operations. The intent of the material developed is to demonstrate the potential risks and costs associated with alternative technologies and to provide general information that is useful for comparing those technologies. As stated in the CTSA, the information is meant to provide background from which individual cleaners can begin to assess the specifics of their own situation.

Comment #1-73: p. 1-7, last paragraph: I believe it is necessary at this point to define some terms so there is no misunderstanding as to what the term dry means throughout the CTSA. The author of this paragraph apparently takes the definition of wet to be anything liquid. In strict chemical terminology, wet would refer to aqueous processes involving solutions of water. The point is well taken that the term drycleaning may suggest to consumers that no liquid is involved, and a clarification of these terms is probably necessary. Again, the absence of synthetic hydrocarbons disturbs me in numerous sections throughout the document.

Response: EPA has clarified the term "dry" throughout the document, and has included synthetic hydrocarbons where information allows.

Comment #1-74: p. 1-7, section 1.2.1: Definition (?) of Clothes Cleaning - Portrait, Description, Clothes Cleaning Background, etc. seem more appropriate.

Response: The Agency has edited and reorganized the document to clarify the presentation. This includes changes to section titles, where appropriate.

Comment #1-75: p. 1-7, second paragraph: "some garments can be damaged if washed in traditional water-based machines (should replace damaged if washed in water).

Response: EPA has incorporated this change.

Comment #1-76: p. 1-7, section 1.2: This section could be greatly improved if it provided some historical context for how the industry has developed and variable it is now. The last paragraph on the page is somewhat inaccurate. Drycleaning developed over a century ago to prolong garment life and initially consumers had to wait for long periods of time before garments were returned to them clean. Prior to the development of drycleaning, garment cleaning was even more difficult (see Thompson, 1997). Transfer machines were developed first with petroleum-based solvents, because they allowed cleaners to reduce fire hazards by placing the hot dryer far away from the flammable solvent in the washer. When chlorinated solvents were introduced, the possibility of the dry-to-dry machine was recognized, but they were not the "standard technology." I think it is important to recognize that the industry has a long history of changing solvents and technologies and that any snapshot at a point in time will reflect a mixture of these. While EPA might disagree with this, I think the industry has gone a long way in reducing its consumption of PCE and while it can and should go farther, it should be given credit for the accomplishments that have been made.

Response: EPA has incorporated language within the CTSA to help clarify this point.

Comment #1-77: p. 1-7, section on evaluation of trade-off issues: This section promises more than the CTSA can currently deliver. In order to consider external costs, one must estimate the externalities and value them. To address the externalities, the CTSA needs to consider population risks, not individual risks. As noted above, this will mean including exposure and risk estimates to groups of the population not currently included in the CTSA (see Thompson and Evans, 1997 for an analysis that relies on social costs). I believe this section should say that it points out possible sources of externalities (i.e., societal exposures resulting from drycleaners) but that the trade-offs are not characterized. In addition, it is important to recognize that making trade-offs requires or implies value judgments.

Response: The trade-off chapter identifies factors that are important considerations for the cleaner selecting among processes. The CTSA appropriately identifies some of these considerations as externalities, however does not, as the commenter alludes, value these externalities. EPA acknowledges that valuation of social costs requires additional work, however, it is not in the scope of the CTSA.

Although no specific changes have been made in this paragraph, the exposure and risk chapters have been revised to discuss implications for special populations. It is true the CTSA opens by describing that DfE projects include "encouraging business to ... incorporate environmental concerns into decision-making processes" and closes by trying to convey the concepts of a social cost/benefit analysis. The evaluation, however, is acknowledged to be difficult and focuses on private (rather than external) costs, evaluated qualitatively. These costs are ones that each business owner or manager can visualize, being at micro level.

To appropriately estimate population risk, accurate, detailed, and site-specific information is required for all of the release sites. This information is used in the environmental modeling. Uncertainties in locations, releases, and the conditions of releases (including stack heights and duration of release) create uncertainties in the modeled concentrations. These uncertainties can lead to significant inaccuracies in the results.

It is possible to model population risk as Thompson and Evans (1997) have done. However, as stated above, numerous assumptions are required to perform this modeling. There are so many uncertainties involved when estimates or default values are used for missing data that people could be unnecessarily alarmed (or reassured) if estimates of population risk were provided.

The National Research Council book Science and Judgment in Risk Assessment quotes the Risk Assessment Council's 1991 Guidance: "Information about individual exposure and risk is important to communicating the results of a risk assessment...Population risk refers to an assessment of the extent of harm for the population as a whole. In theory, it can be calculated by summing the individuals for all individuals within the subject population. This task, of course, requires a great deal more information than is often available." (pp. 368-371).

Additionally, because the information in the CTSA is intended for the individual business decision maker, it is not clear that a quantitative presentation of population risk, including appropriate caveats of the uncertainties will be clear and more useful than the discussion of the social costs associated with risks, as currently presented in the CTSA.

Comment #1-78: A good description of the processes is given on pages 1-7 and 1-8. It might be more clear to differentiate these as solvent-based and aqueous-based.

Response: The Agency has edited and reorganized the document.

Comment #1-79: p. 1-7, third paragraph: People chose drycleaning because not because it is cost effective, but because it essentially is the only choice when hiring someone else to wash clothing. Store prices for wetcleaning are very similar.

Response: EPA has removed this language.

Comment #1-80: p. 1-7, Section 1.2.1, third paragraph: This paragraph is very poorly written. Drycleaning actually evolved as a process to deal with garments and other textile items that would not process well in water. The statement "Drycleaning chemicals are chosen for their ability to dissolve organic materials that soil fabrics "is very simplistic and ignores other important issues such as flammability."

Response: This language has been revised. EPA believes that by including process, risk, performance, and cost information, the CTSA adequately covers issues relevant to chemical selection.

Comment #1-81: p. 1-7, Section 1.2.1, second paragraph: The description of the finishing process is very shallow and should include things such as reshaping, restoring dimensions, etc. The rearranging of shoulder pads, although important, cannot really be considered a major part of the finishing process.

Response: EPA has not provided extensive discussion on finishing because it is not a focus of the CTSA.

Comment #1-82: p. 1-7: The text should read that the production of TCA and CFC-113 were banned on January 1, 1996--not use. In fact, at least some drycleaners are still using CFC-113. The ban is worldwide except for developing countries, not just in the U.S.

It is not clear why the document focuses on conventional petroleum solvents and 140 F solvent but does not describe the new petroleum solvents/equipment. It is appropriate to leave the new technologies out of the evaluation if carbon dioxide is also left out. At least, there are actual machines in operation in the field in the case of the new petroleum technologies whereas there are not for the carbon dioxide technology.

Response: EPA has removed language discussing TCA and CFC-113 from this section. A general discussion of Clean Air Act requirements that mentions CFCs is included in Chapter 8. EPA has included information, where possible, on synthetic hydrocarbons.

Comment #1-83: p. 1-7, first paragraph on the top of the page: The word "art" is missing from "state of the art technology."

Response: EPA has incorporated this change.

Comment #1-84: p. 1-8, first full paragraph: Since multiprocess wetcleaning is not commercially practiced, it should not be included here as an alternative, even as "representing the two ends of the wetcleaning spectrum." I believe that it is much better to talk about wetcleaning and its evolution (which should briefly discuss multiprocess wetcleaning) as a coherent whole. In particular, I think that the CTSA is really about professional fabricare processing technologies which includes cleaning, drying, and finishing. (If the finishing process is the same for all technologies, then it doesn't have to be included since comparisons will not be different.) In this sense, ultrasound techniques and microwave drying represent process modifications for wetcleaning in the same sense that refrigerated condensers do for PCE machines. I think that the CTSA should strive to be as concise as possible without leaving out any important information. Thus, while EPA sponsored some of the multiprocess wetcleaning work and therefore has a motivation for including it, it should not be included equally with machine wetcleaning unless it is a viable alternative.

Response: EPA has not included multi-process wetcleaning as an alternative cleaning process. Those processes that are under development have been included in a separate chapter so that they

are not directly compared to established technologies.

Comment #1-85: p. 1-8, last paragraph: The words "discarded" in the 4th line and "articles" in the 6th line sound funny. Discarded sounds like they throw it away in the trash, and previous sections talked about garments or clothes.

Response: The wording has been changed in the revised CTSA.

Comment #1-86: p. 1-8: Filtration and distillation are primarily done for performance reasons, not recycling reasons. They are necessary for getting clean clothing.

Response: The issues of performance, as it pertains to this comment, and recycling are essentially the same in this instance. Filtration and distillation are not needed for performance if the solvent were only used in a "once-through" cycle after which solvent containing soils, detergent, etc, were disposed. But in order to restore solvent to usable quality, the solvent is filtered and recycled. The wording has been changed in the updated CTSA to show both issues.

Comment #1-87: p. 1-8, second paragraph: The text indicated that multiprocess wetcleaning is not longer used. Why then include the comparison in the text. This just pads the size of an overly large document. On page 1-8 a discussion of different methods begins. This needs to be made consistent. If coin-op and industrial processes are left out because of market size, what is the justification for this section?

Response: EPA has not included multi-process wetcleaning as an alternative process, in the revised CTSA.

Comment #1-88: p. 1-8, third paragraph, line 4: easy to distill <u>for reuse</u>

Response: The wording has been changed in the CTSA.

Comment #1-89: p. 1-8, first paragraph: Spell out CO2 (i.e., carbon dioxide CO2))

Response: EPA has revised the document to enhance readability.

Comment #1-90: p. 1-8: Although it is explained later in the document, on page 1-8 there needs to be a brief description of multiprocess wetcleaning and dedicated machine wetcleaning. The other processes are defined on this page.

Response: EPA has reedited the CTSA and incorporated this comment.

Comment #1-91: p. 1-8, second paragraph: EPA states that certain aqueous based processes "may be potential substitutes for drycleaning." This type of language (a double conditional -

may/potential) undermines the potential for these alternatives. Certain aqueous based processes, such as machine wetcleaning, are currently being economically employed at various establishments. So these "are" substitutes.

Response: EPA has reedited the CTSA and incorporated this comment.

Comment #1-92: p. 1-8 through 1-15: The process description of PERC drycleaning is not clear and contains many errors. The entire text should be rewritten. A good guide would be to summarize the data presented in the California Air Resources Board (CARB) technical support document, one of the references called out in the CTSA. Pages II-3 through II-029 of the reference provide a very good summary of the drycleaning process. I am also enclosing another reference entitled "Controlling Dry Cleaner Discharges in Wastewater" that should be helpful in summarizing the process. I wrote pages 3 through 24.

The CTSA does not convey the point that there are really three types of machines that are significantly different from one another in their emissions characteristics. The first type is the transfer machine with or without controls. The second type is the dry-to-dry vented machine with or without controls. The third type is the dry-to-dry closed loop machine. The CARP report presents data on mileage that shows the different characteristics of these three types of machines. The NESHAP background document does not draw a distinction between dry-to-dry closed loop machines with a control device and a dry-to-dry vented machine with a control device. The NESHAP authors failed to understand that the emission characteristics of the two machine types are entirely different. This is emphasized by the CARB data. Indeed, virtually all equipment people and others in the drycleaning industry understand that emissions are much higher from a dry-to-dry vented machine with a control device than from a dry-to-dry closed loop machine.

Response: The descriptions of machine types and controls for solvent process machinery have been updated and clarified in the CTSA. NESHAP language which may result in misunderstandings has been minimized.

Comment #1-93: p. 1-8, third paragraph: Note that while PCE is relatively inexpensive, if one considers the full economic costs, including externalities, the price would likely be much higher.

Response: This comment is not appropriate to the context of this process equipment description section. Data were not complete enough to derive quantitative estimates of social costs. The CTSA qualitatively discusses the social costs associated with exposure to and release of PCE to emphasize the next for their consideration when making technology choices.

Comment #1-94: p. 1-8, Section 1.2.1, fourth paragraph: The statement "Certain aqueous based processes can be used on most garments" is somewhat of an overstatement at this point in time. The word "many" should be substituted for the word "most."

Response: The experience of several wetcleaning demonstration projects has shown that aqueous based processes can be used on most garments.

Comment #1-95: p. 1-8: Clothes Cleaning Process Descriptions. It would be more descriptive to

explain the 4 generations of perc, or PCE drycleaning, e.g., from transfer (1st generation) to integral carbon adsorber refrigerated condenser (4th generation) see ... 6/94 paper enclosed which contains an illustrative table explaining the 4 generations of perc drycleaning machines.

[Lauber, J.D. and Pallante, G. 1994, State-of-the-art technologies for multi-media pollution control in the Drycleaning Industry, Presented at the Seventh Annual Pollution Prevention Conference, June 5, 1994, Albany, NY.]

Response: The descriptions of machine types and controls (including "generational" terminology) for solvent process machinery have been updated and clarified in the CTSA.

Comment #1-96: p. 1-8, second paragraph: In this paragraph the term wet is defined as aqueous based cleaning, where the previous paragraph on page 1-7 would suggest that wet is appropriate to any liquid since it is stated that drycleaning is a misnomer. Later in this paragraph is the statement that the multi process wetcleaning is no longer practiced in the commercial field. I would question on that basis why it is included as part of the CTSA. Likewise, in the later paragraphs on the page, the discussion of the washing machine and drying machine need to be clarified. Within the industry a washer is a machine that uses water, while a dryer commonly refers to an evaporation unit for either removing water of solvent; confusing, but this is the nature of the way the terms are commonly used in the industry. In the last paragraph I believe the opening sentence probably is a misstatement. To my knowledge, from the time PCE was first introduced to the industry, cleaners have been concerned about solvent mileage and tried to increase the recovery of the solvent. Filtration and distillation were available prior to PCE being introduced as a solvent. All of the statements, distillation, etc., could be made for both PCE and HC or PS systems. I would suggest a general discussion of transfer units, drying devices, primary and secondary vapor recovery devices and filters be approached without regard to solvent, and solvents can be dealt with on their own in another section.

Response: EPA has clarified the distinction between wet and drycleaning. Multiprocess wetcleaning is no longer included as a technology alternative in the CTSA. EPA did not organize its discussion of equipment without regard to solvent, because such a discussion was deemed too difficult to write and to read.

Comment #1-97: p. 1-9, Exhibit 1-2: The dashed line box around the machine should be labeled for clarity. Also, the diagram implies that all of the PCE in the storage tank might be sent to the still.

Response: The dashed line has been removed. This diagram is a simplified flow diagram and is not intended to give a complete picture of the process. Details, such as the amount of PCE pumped from the tank to the still, are not intended to be diagramed.

Comment #1-98: p. 1-9: Add, PCE process vent emissions <u>from vented first and second generation machines</u> are potentially the largest source of drycleaning emissions.

Response: Agree. This suggestion would have been implemented. However, the rewriting of this section eliminated the sentence to which this addition was suggested.

Comment #1-99: p. 1-9: See my general comment B [Comment #G-74] regarding the classification of machines. The classification that follows later in the section is based upon the secondary vapor recovery units, which are not even shown on the diagram. Additionally, I would repeat my general concern that there needs to be more diagrams so that new technology is presented. Regarding the last paragraph, as indicated in my general discussion, I would consider there to be more than three technologies to recover PCE, PS, or HC; namely, air cooled condensers, tap water cooled condensers, chill water condensers, refrigeration condensers, and carbon absorbers.

Response: The descriptions of machine types and controls for solvent process machinery have been updated and clarified in the CTSA. Diagrams of newer machines have been added and recovery technologies expanded.

Comment #1-100: p. 1-9, first paragraph: Statement that new equipment loses less PCE per cycle than older equipment is logical but undocumented. A table of average loss of PCE per cycle by machine type would be an invaluable addition. This data is presented elsewhere in the document but should be summarized here.

Response: This wording has been improved in the CTSA. However, the section on process equipment is not intended to summarize findings on releases from "model facilities".

Comment #1-101: p. 1-9: It is common knowledge that the Bureau of Census data underestimate the actual number of drycleaning facilities. Some drycleaners do not pay income taxes so they are not recorded in the statistics. The estimate of 27,100 facilities is likely a significant underestimate of the actual number of facilities. CARP did a very thorough estimate of the cry cleaning facilities in California during their rulemaking for the California regulation. There are between 4,000 and 5,000 processing drycleaning facilities in California. Assuming that population determines number of drycleaning facilities and that California has about 11 percent of the U.S. Populations, this suggests that the real nationwide number of drycleaning facilities is between about 36,000 and 45,000.

Response: The national statistics for the industry, to which this comment refers, have been removed from the equipment section. However, this and other similar comments have been addressed. The number of drycleaning facilities has been updated elsewhere in the CTSA.

Comment #1-102: p. 1-9, Section on Process Vent Emissions and Control Options: This whole section is very poorly written from a technical standpoint. The descriptions of recovery technologies do not coincide with descriptions normally used in the industry. This whole section needs to be re-written.

Response: The descriptions of machine types and controls (including "generational" terminology) for solvent process machinery have been updated and clarified in the CTSA.

Comment #1-103: p. 1-9, Exhibit 1-2: There are inaccuracies in this flow diagram. The direct vent to air comes from the Vapour Reclaimer, not the tumbler. There is also a liquid PCE stream from the Dryer to the PCE Storage Tank.

Response: This diagram has been revised to present the process more accurately.

Comment #1-104: p. 1-9: It is my understanding from J. Levine at NCA, that there are approximately 34k PCE plants currently operating.

Response: Based on a different comment (1-33), the national statistics for the industry, to which this comment refers, have been removed from this equipment section. However, this and other similar comments have been addressed. The number of drycleaning facilities has been updated elsewhere in the CTSA.

Comment #1-105: p. 1-9, second paragraph: Information on control options, according to the logic of the document, should go in Chapter 7. This chapter should present only a process characterization. Also, what about door opening and transfer and other fugitive emissions as a large source of drycleaning emissions? Technologies to recover PCE from process vents can reduce but will never prevent PCE's release. No current technology can do that.

Response: The process description headers and the title to Chapter 7 misrepresent the intent of the process description sections and the flow of the CTSA. The headers have been changed to clarify that these sections cover process equipment. Chapter 7 has been retitled and moved to indicate the contents are for environmental improvements. Control options are considered to be process equipment, thus requiring a place in the equipment characterization. The fugitives issue is touched upon in the equipment discussion and covered in more detail in the release section. The language regarding "reduce" vs. "prevent" has been corrected.

Comment #1-106: p. 1-9; 1-26: A NIOSH review of the American Business Directory for 1995 found slightly different results for the number of facilities [Earnest et al., forthcoming]. The attached table presents the results of this review.

[Earnest S, Ewers L, Ruder A [forthcoming]. The drycleaning campaign: Communicating risks to improve exposure control and address other health and safety issues in the dry-cleaning industry. Phase two: Evaluation of retrofit engineering controls to reduce perchloroethylene exposure, using real-time monitoring and breath sampling. Draft protocol, 1996. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health.]

Response: Based on a different comment (1-33), the national statistics for the industry, to which this comment refers, have been removed from this equipment section. However, this and other similar comments have been addressed. The number of drycleaning facilities has been updated elsewhere in the CTSA.

Comment #1-107: p. 1-10, last paragraph: There appears to be a typographical error at the end of the second line where the word *"on"* in font of the word "all" seems to be omitted. Regardless of the typographical error, I am not sure the statement is true. I don't believe refrigerated condensers are installed on all new machines. I would certainly hate to think that chilled water condensers are no longer allowed, as these seem to be extremely efficient.

Response: This wording has been changed to fix typographical errors. However, wording regarding refrigerated condensers has not been changed because the PCE drycleaning NESHAP

requires all new machines to have refrigerated condensers or the equivalent.

Comment #1-108: p. 1-10, first paragraph: I take strong exception to the phrase *machines with water condensers alone are commonly referred to a "uncontrolled machines."* This is the first time I have heard this terminology. In my mind, an uncontrolled machine would be a machine that has absolutely no condenser. I believe there are a very small number of these in existence using PCE and a larger number in existence using PS. I also disagree with the statement that all machines with carbon absorbers have water condensers. Any primary condenser could be combined with any secondary condenser.

Response: This terminology has been removed from the CTSA. The statement linking adsorbers and water condensers has been removed, and the related language has been improved and clarified.

Comment #1-109: p. 1-10, Exhibit 3: Table leave coin-op machines out yet it is a bigger market segment than the industrial. Text refers to three market segments yet elsewhere says that coin-op and industrial are not part of the analysis. Industrial cleaning represents 22% of volume and coin-op represents 9% of establishments. Neither of these are small enough to warrant exclusion. Consistency should be the order of the day. Pick one and stick with it.

Response: Industrial and coin-operated market segments are not within the scope of the CTSA. Tables referencing these segments have been removed.

Comment #1-110: p. 1-10, third paragraph: "and are installed on (add on) all new machines."

Response: Rewriting this section has removed this typographical error.

Comment #1-111: p. 1-10, last paragraph, line 2: Insert "on" after "installed"

Response: Rewriting this section has removed this typographical error.

Comment #1-112: p. 1-10: The CARE 8/27/93 Technical Support Document for the California Proposed Airborne Toxic Control Measure, has a more complete description of carbon adsorber operation noted on page II-12 of this document, i.e., desorption at 3 pounds of clothes for every pound of carbon in the adsorber; and after breakthrough that about a half gallon of perc per 100 pounds of clothes, can be emitted to the atmosphere. Also note the indication of operational problems due to steam channeling during desorption of carbon adsorbers.

Carbon adsorbers should also be mentioned here for other applications, in addition to those of 1st and 2nd generation PCE equipment, i.e., for use in azeotropic control systems with door fans, for 3rd generation refrigerated condenser machines, and integral carbon adsorbers for 4th generation PCE refrigerated condenser dry-to-non-vented machines.

Response: This equipment section is not intended to cover specifics of adsorber maintenance. Regarding other adsorber applications. These other adsorber applications have been addressed

more specifically elsewhere in the text.

Comment #1-113: p. 1-10: Again the discussion fails to distinguish between dry-to-dry closed loop and dry-to-dry vented machines. At this stage about one-third of the machines in the nation are transfer, one-third are dry-to-dry vented and one-third are dry-to-dry closed loop.

There is no aeration cycle in a dry-to-dry closed loop machine.

Carbon adsorbers cannot be retrofitted onto a dry-to-dry closed loop machine unless secondary control is being added.

Response: The descriptions of machine types and controls (including "generational" terminology and carbon adsorption options) for solvent process machinery have been updated and clarified in the CTSA.

Comment #1-114: p. 1-10, Exhibit 1-3: It is important to note the large number of transfer machines with no control that currently exist. This represents a significant risk to workers and the public, as noted in chapter 4. This information on numbers of types of machines should be repeated later in the risk chapter

Response: Information on the number of machines is relevant to worker risk and not to the equipment description section. Based on a different comment (1-33), the national statistics for the industry, to which this comment refers, including Exhibit 1-3, has been removed from the equipment section. Also, new (post-PCE drycleaning NESHAP) data on numbers of machines with various controls were not found, and the old data are not expected to reasonably represent current numbers.

Comment #1-115: p. 1-10, Exhibit 1-3: A better title to the last column would be "No control (water condensers alone)".

Response: This clarification is appropriate and has been made throughout the text. However, based on a different comment (1-33), the national statistics for the industry, to which this comment refers, have been removed from the equipment section, including Exhibit 1-3.

Comment #1-116: p. 1-10, third paragraph: Refrigerated condensers are not an alternative to carbon adsorbers. A refrigerated condenser liquefies PCE vapors during the drying cycle while a carbon adsorber removes PCE vapors during the aeration cycle or in emission streams.

Response: The descriptions of controls for solvent process machinery have been clarified in the CTSA.

Comment #1-117: p. 1-10, third paragraph, line 2: ...installed <u>on</u> all...

Response: Rewriting this section has removed this typographical error.

Comment #1-118: p. 1-10 and throughout: The draft needs to consider the status quo post NESHAP. In particular, since the NESHAP has led a number of drycleaners to upgrade their equipment, the profile of the industry pre-NESHAP differs from the post-NESHAP. The CTSA needs to be looking at the industry now and it should be very clear about what drycleaners are legally allowed and required to do. I suspect that if it is not clear, then it might serve to confuse drycleaners and it will invite criticisms from the industry that one group at EPA does not know what the other group is doing.

Response: This process equipment description section refers directly to the PCE drycleaning NESHAP information in Chapters 8 and 9 to promote clarity. Some text will also be revised to improve clarity on this issue. However, the CTSA is not intended to lay out all legal requirements in detail. This intention is stated in the updated CTSA, which recommends other EPA documents for more information on NESHAP requirements and compliance.

Comment #1-119: p. 1-10, Exhibit 1-3: Surely there should be more up-to-date information on the estimated number of PCE machines by type and control than EPA's NESHAP background document of 1991.

Response: More updated information on numbers of PCE machines by type were not found. However, based on a different comment (1-33), the national statistics for the industry, including Exhibit 1-3, to which this comment refers, have been removed from the equipment section. EPA has updated its estimate of number of PCE machines elsewhere in the CTSA.

Comment #1-120: p. 1-11, fifth paragraph: add Fugitive emissions can also occur when the door to the drycleaning machine is opened, and/or from machine and system leaks.

Response: The equipment section was revised to focus more on the equipment. This comment is more relevant to releases and exposures, and its point is made in those sections.

Comment #1-121: p. 1-11, fourth paragraph: the Solvation azeotropic process can be better described as using water to humidify the PCE vapors during the aeration or drying cycle, to displace and extract more PCE from the garments for recovery by condensation. A door fan vented to a small carbon adsorber further controls residual PCE emissions when the machine door is opened. Such azeotropic controls are normally used with first and second generation drycleaning equipment.

Response: EPA acknowledges the lack of clarity on this issue in the peer review CTSA, particularly on p. 1-11. The explanation of this technology has been clarified and reduced (because it is not commonly used) in the CTSA.

Comment #1-122: p. 1-11, last paragraph: What are "significant amounts?" There are several issues in this paragraph that are important. For optimal processing, clothes of similar types should be cleaned together. If mixtures of fabric types are used, then some clothes will not be dry completely when they are removed (or other clothes will be damaged by excess drying). Cleaners may place an inappropriate garment in a load in order to satisfy a consumer's demand for fast cleaning or mix loads if insufficient amounts of different types are received. I believe that the tone

regarding "pressing staff demanding clothes to press, or when employees want to complete their work and go home" is not helpful. In addition, this section should emphasize the need to eliminate social expectations for "one-hour cleaning" so that cleaners can properly process clothes.

Response: This section has been rewritten and refocused to increase clarity. This section has been rewritten and refocused on the equipment, and changing the social expectations noted by the commentator is not relevant to this section.

Comment #1-123: p. 1-11, third paragraph: add after vented solid and liquid waste storage units, if the carbon adsorber is connected to a properly designed and operated multi-point local exhaust system.

Response: This clarification would have been made. However, this sentence is no longer part of the section since this section was rewritten.

Comment #1-124: p. 1-11, fifth paragraph: Only minute PCE amounts remain in garments after proper drying, less than 0.05% (depends on structure and type of textile).

Response: EPA agrees regarding the point, although the percentage cited by the commentator was not researched. However, this issue is no longer covered since this section was rewritten.

Comment #1-125: p. 1-11, third paragraph: The azeotrope definition is incorrect and the term is used improperly: An azeotrope is a mixture of liquids which boils at a constant temperature lower than that of its components and the vapor composition remains constant as long as all components are present in the liquid mixture. For example, PCE (BP: 121 C) and water (BP: 100 C) forms an azeotrope which boils at 87.1 C. The vapor mixture is 84.1 wt.% PCE and 15.9 wt.% water. These are not the conditions under which the "azeotropic technology" is explained to function. As stated earlier, this "technology" is old and no longer available. It should be dropped.

Response: Technologies which are less common, but still exist are still mentioned in the CTSA, but are not covered to as large a degree. Others were dropped. EPA acknowledges the lack of clarity on azeotropic technology, particularly on p. 1-11. The explanation of this technology has been clarified and reduced in the CTSA.

Comment #1-126: p. 1-11, first paragaph: add that the equilibrium saturated vapor pressure of PCE at 45 F is about 8500 ppm in a 3rd generation refrigerated condenser machine, vs. 300 ppm for a 4th generation system with an integral carbon adsorber.

Response: EPA interprets the comment to mean that in a third generation machine the PCE concentration in the drum is 8500 ppm, the saturation vapor pressure of PCE in air at 45F, while in a fourth generation machine (which, by definition, has an integral carbon adsorber), the PCE concentration in the drum is 300 ppm. This point has been reflected in the CTSA text.

Comment #1-127: p. 1-11, fourth paragraph: The solvation process is discussed in general comment C [Comment #G-75]. Azeotropic processes are not unique to the solvation process, and I

do not follow the physical chemistry logic of the statement that the dryer condenser can remove more of the PCE using this technology.

Response: EPA acknowledges the lack of clarity on this azeotropic issue, particularly on p. 1-11. The explanation of this technology has been clarified and reduced in the CTSA.

Comment #1-128: p. 1-11, third paragraph: "Then the air stream flows to a carbon bed which may remove most of the remaining PCE before emitting the air stream." This is incorrect. The small carbon device attached to the Solvation unit is a once through door fan, which does not work. It is not a part of the process vent control.

Response: EPA acknowledges the lack of clarity on this azeotropic issue, particularly on p. 1-11. The explanation of this technology has been clarified and reduced in the CTSA.

Comment #1-129: p. 1-11: The figure 10,000 ppm seems high. It is my understanding that some of the fifth generation PC machines are claiming less than 50 ppm.

Response: The 10,000 ppm number is an upper bound for machines with refrigerated condensers. However, the rewriting of this section removes the need to clarify this issue in the CTSA. Also, the 50 ppm level was not found by EPA in the literature.

Comment #1-130: p. 1-11, first paragraph: A quick reference to release standards in the Clean Air Act would put the 10,000 PPM concentration in perspective. If occupational exposure standards under OSHA are in the 25-100 PPM level, what is the significance of this number?

Response: EPA interprets the comment as referring to the PCE drycleaning NESHAP requirement of 45F refrigerated condenser maximum temperature, resulting the a saturation concentration of PCE of about 8,500 ppm (e.g., less than 10,000 ppm). The drum concentrations of different emission control configurations have been compared in the CTSA. However, the drum concentrations have no known relationships to exposure standards.

Comment #1-131: p. 1-11, fourth paragraph: Fugitive PCE emissions occur (eliminate may, as the emissions are real) during transfer

Response: This change would have been made, but the section was rewritten and this point was restated.

Comment #1-132: p. 1-11: The discussion on the CARB data should include a discussion of the lower emissions data from dry-to-dry closed loop machines vs dry-to-dry vented machines with a control device.

The statement that carbon adsorbers obtain better control provided they don't have problems is specious. Carbon adsorbers used as a primary control device always have problems.

For years, there has been controversy about the solvation process and whether it actually achieves

any emission control. There are very few in use today and the bottom line is that if the solvation device is paired with carbon adsorber, it achieves the same emissions control as a carbon adsorber alone. If it is not paired with a carbon adsorber, it achieves virtually no control.

Response: Emissions data are not relevant to the equipment description but are discussed in the release section. The statement regarding carbon adsorbers has been deleted. The explanation of azeotropic control technology has been clarified and reduced in the CTSA.

Comment #1-133: p. 1-11, second paragraph: It would be very helpful to have a schematic of a hamper enclosure.

Response: Although it would be helpful to have schematics of much of the equipment covered in this CTSA, the number of schematics and development of them was prohibitive. However, the hamper enclosure description was improved.

Comment #1-134: p. 1-11: Shouldn't airing of cothes by the consumer be listed as a fugitive emission?

Response: The discussions of emissions are no longer covered in the rewritten and refocused process equipment sections. The emission discussion is covered in the release section. Although this emission occurs off-site, it is included as part of the total fugitive emission in estimating releases.

Comment #1-135: p. 1-12, third paragraph: "The EPA estimates that room enclosures are 95% effective at controlling fugitive emissions during article transfer." Room enclosures simply contain the emissions and exhaust them to the air stream, without control.

Response: The room enclosure mentioned here includes, as mentioned in the text, routing the air from the enclosure through a carbon adsorber. Where the PCE drycleaning NESHAP requires a room enclosure, the NESHAP also requires the air within that room be vented through a carbon adsorber or equivalent control device. The distinction between vapor barrier rooms and room enclosures are clarified in the CTSA.

Comment #1-136: p. 1-12, third paragraph: The reference to a carbon absorber is, again, referred to in my general comment B [Comment #G-74]. The air could also be routed to a secondary refrigeration vapor recovery unit.

Response: A refrigerated condenser is not capable of reducing the low concentration of PCE ($<<$ 2,000 ppm) expected in the room enclosure.

Comment #1-137: p. 1-12, third paragraph: The CTSA should recognize that placing more equipment inside the enclosure could also make the worker spend more time in it, and thus lead to higher levels of exposure and risk.

Response: This suggestion was incorporated in the new Chapter 9 discussion of this issue.

Comment #1-138: p. 1-12, first paragraph: I don't follow the note in parentheses. It seems to imply that some dry-to-dry machines are not operated as they are intended. The fourth paragraph appears to contradict this parenthetical statement in that it states dry-to-dry machines are a replacement alternative for the transfer units.

Response: The implication commented upon is correct. The apparent contradiction occurs if the dry-to-dry machine is not used as intended. However, since the section has been rewritten, this point is not necessary.

Comment #1-139: p. 1-12, third paragraph, fourth sentence: POSITIVE pressure should be NEGATIVE pressure.

Response: The Agency will review the description.

This error has been corrected.

Comment #1-140: p. 1-12, third paragraph: Give examples of designs that would reduce worker exposure (or put them in pollution prevention section and refer to them there).

Response: No change needed. It is not clear what, specifically, the commentator had in mind.

Comment #1-141: p. 1-12, second paragraph: PCE fumes is an incorrect term. Fumes are generally submicron particles dispersed in an aerosol, e.g., smoke from heated metals. (See Hawley's condensed Chemical Dictionary 12th edition Van Nostrand Reinhold) PCE <u>vapors</u> would be better here.

Response: This term was deleted.

Comment #1-142: p. 1-12: Filtration is not a means of recovering solvent. The solvent must be filtered for performance reasons. If it is not, a residue will be left on the clothing. The same holds true for distillation. At this stage, these methods are an integral part of the drycleaning process, not an add-on that achieves recovery.

Response: The issues of performance, as it pertains to this comment, and recycling are essentially the same in this instance. Filtration and distillation are not needed for performance if the solvent were only used in a "once-through" cycle after which solvent containing soils, detergent, etc, were disposed. But in order to restore solvent to usable quality, the solvent is filtered and recycled. The wording has been changed in the updated CTSA to show both issues.

Comment #1-143: p. 1-12: Again information on <u>control</u> technologies should be considered here or in Chapter 7, but not in both places.

Response: The process description headers and the title to Chapter 7 misrepresent the intent of the process description sections and the flow of the CTSA. The headers have been changed to

clarify that these sections cover process equipment. Chapter 7 has been retitled to indicate the contents are for environmental improvements. Control options are considered to be process equipment, thus requiring a place in the equipment characterization.

Comment #1-144: p. 1-12, Section on Filtration and Distillation Option: Filtration and distillation can hardly be described as optional. They are really the only two means of clarifying solvent. To say that they are optional almost implies that discarding the solvent after use is an option which, of course, it isn't. Again, this whole section of the document shows a serious lack of technical knowledge with respect to the drycleaning process.

Response: The section title contains a typographical error and was to read "Filtration and Distillation Options." The title has been revised in the revamping of this section, and the misinterpretation discussed in this comment has been removed.

Comment #1-145: p. 1-13, last paragraph: I would insert the word *odors* in the phrase in the first line, "solvent clean enough to avoid *odors* and darkening articles." In the sixth line describing the concentrated waste material, I would insert "still bottoms" or "muck" and add under the list of "contains" in addition to the dyes, dirt, and lint I would add *oils, soils, detergents*.

Response: This wording has been added.

Comment #1-146: p. 1-13, fourth paragraph: I take exception to the statement that "may eliminate the need for distillation." This is a very debatable point within the industry, but it is my understanding that the general consensus is that fats and oils dissolved during the cleaning process will eventually need to be removed by distillation. In the last statement in the paragraph regarding firms that treat the separator waste water, I believe a more appropriate statement would be "firms that treat the still bottoms and/or distillation muck."

Response: This debatable point was removed since it did not add value to the information in the CTSA. The description of treatment firms has been changed.

Comment #1-147: p. 1-13, first paragraph: The diatomaceous earth and carbon are added to the PCE. (You could also add to HC, PS, etc.) However, this is done as a coating step only. No cleaning is done during this coating step. After the coating is formed and cleaning begins. Rather than "after some amount of solvent passes through," the filter is spun after "some volume of cleaning has been done." The spinning time for the filter is not necessarily four minutes, and would vary depending upon the design and recommendations of the manufacturer of the filter.

Response: The filtration equipment description has been updated.

Comment #1-148: p. 1-13, third paragraph: I would delete the statement that says "they may be more effective because they can be made as fine as 8-20 microns." I believe in terms of filter effectiveness the most effective is a filter coated with a layer of diatomaceous earth and carbon. However, this practice is being reduced because the diatomaceous earth and carbon add to the solid waste that must be disposed of later in the process. The statements in paragraph 5 seem to

be more consistent with the industry position, and, again, are not unique to PCE machines, but can be installed on HC and PS machines as well.

Response: Such PCE filtration details as the commenter has discussed have been deleted.

Comment #1-149: p. 1-14, fourth paragraph: "As much as half of the still bottoms is composed of PCE." This can vary greatly between machines and operators. A properly operating modern distillation unit can reduce the amount of PCE in distillate residue to less than 1%. The new, PCE-M, Permac 4th Gen. Machine has a second cycle on the distillation process that reduces the volume 90% and the PCE content to less than 1%.

Response: The PCE content of still bottoms issue has been clarified and expounded in the CTSA.

Comment #1-150: p. 1-13, second paragraph: This is not unique to PCE and could also be used with HC and PS solvents.

Response: This filtration issue has been clarified in the hydrocarbon solvent equipment section.

Comment #1-151: p. 1-13, last paragraph: This paragraph is a bit confusing. It implies that cleaners continually reuse solvent, but it fails to note that some solvent is lost in the still much or otherwise released. This sets up a bit of a logical disconnect between releases and the technology.

Response: The paragraph has been clarified, and the word "continually" has been removed.

Comment #1-152: p. 1-14, fourth paragraph: "A significant number of drycleaners use a muck cooker..." This is not accurate. Most cleaners do not use a muck cooker as they do not have the room and the newer machines do not require a muck cooker. Muck cookers were supplied for the original "Auto-Flex: filters that produced a mixture of solvent impurities, DI and Carbon powder. This heavy mixture was called "Muck" and a Muck Cooker was used.

Response: The phrase "significant number of" has been removed in the CTSA.

Comment #1-153: p. 1-13: The CTSA states hat as much as half the still bottoms is composed of PERC> Some still bottoms can contain up to 90 percent PERC.

Response: The PCE content of still bottoms issue has been clarified and expounded in the CTSA.

Comment #1-154: p.1-13, first paragraph: "...filter media on outside of disks", unclear to me, ?on rim, ?on surface.

Response: The sentence has been clarified.

Comment #1-155: p. 1-13, first and second paragraphs: Spent filter media must be treated as hazardous waste and disposed of properly through a licensed Treatment, Storage, and Disposal Facility.

Response: This point has been made in this section.

Comment #1-156: p. 1-13, fifth paragraph: The sentence "Although disk filters..." implies that filters dominate the sales of drycleaning machines and could be read to contradict the sentence that follows it. I'd change these 2 sentences into one that reads "Although cartridge filters are currently the most common, disk filters are a relatively new innovation that are now more preferred for use in the new top-of-the-line PCE drycleaning machines."

Response: These sentences needed improvement. The rewriting of this section has effected this improvement.

Comment #1-157: p. 1-14, third paragraph, first sentence: How can non-volatiles boil-off? Non-volatiles are left behind in the still bottoms. Some more volatiles substances could end up in the distilled PCE.

Response: The issue of boil over of non-volatiles was rewritten.

Comment #1-158: p. 1-14, last sentence: Explain the importance of the lock-out feature clearly.

Response: This explanation was included.

Comment #1-159: p. 1-14, third paragraph: I believe this paragraph is totally inaccurate. In conventional distillation the NVR's are not boiled off. The term NVR means nonvolatile residue. Being nonvolatile, they are not boiled off. Where NVR causes an odor in clothing is when the solvent is not distilled. If clothes are cleaned in solvent containing a high level of NVR, during the drying of the clothes the PCE is evaporated, and the NVR remains behind on the clothing. This is, in fact, why it is necessary to distill the solvent. Again, this can happen with PCE, PS, HC or any solvent, just as in evaporating water in a washing process will leave behind any residues that were in the solution that do not volatilize with the water.

Response: The issue of boil over of non-volatiles was rewritten.

Comment #1-160: p. 1-14, fourth paragraph: This paragraph is outdated in that some of the newer machines have distillation units that can reach the efficiency of distillation in muck cookers in a single distillation unit.

Response: This issue has been addressed in the CTSA.

Comment #1-161: p. 1-14, fifth paragraph: I believe some of the discussion prior to this point has

been referring to secondary controls. I really begin to be confused when I reach this point in the chapter. Please refer to my suggestion in general comment B [Comment #G-74]. How often an absorber needs to be absorbed would depend upon the volume of solvent reaching the absorber. If a highly efficient primary condenser precedes the absorber this could be an infrequent occurrence.

Response: The descriptions of controls for solvent process machinery has been clarified in the CTSA.

Comment #1-162: p. 1-14, third paragraph: "In conventional distillation, non-volatile residues may be boiled off with the PCE and redeposited on clothes, causing an odor." Non-volatile means it will not volatize at the lower temperatures that PCE and water boil. Redeposition from distillation normally occurs when the separator malfunctions or when the distillation "Boils-over". There is concern that "Steam-Sweeping" is more trouble than it is worth. The addition of steam and water may help the distillation but may cause maintenance problems in the distillation unit and create additional separator water.

Response: The issues of boil over of non-volatiles, steam sweeping, and maintenance have been revised and clarified in the CTSA.

Comment #1-163: p. 1-14 and throughout: Write out secondary instead of using the abbreviation.

Response: This change has been made.

Comment #1-164: p. 1-14, first paragraph: Regarding line 3, all PCE stills use azeotropic distillation due to the water that must necessarily be present in the clothing. The last sentence should include *perchloroethylene/water* azeotropic distillation since other azeotropic combinations are possible.

Response: Conventional distillation has been described as a process in which no water is added. The azeotropic distillation has been described as a process in which additional water is intentionally added to the distillation to recover additional solvent.

Comment #1-165: p. 1-14, end of fifth paragraph: The Earnest, 1997 reference is not in the overall compilation of references for the reviewers, but it does appear on 1-25. This is a reference to overhead slides at a recent meeting, May 22, 1997.

Response: This may have been an administrative error. However, this reference has been replace in the CTSA by a published NIOSH document.

Comment #1-166: p. 1-14, second paragraph: The second sentence implies that the aezotropic device must discharge water to the sewer. It should be possible for the water to be collected and disposed of otherwise.

Response: The wording has been revised to prevent possible misconceptions.

Comment #1-167: p. 1-14, Other Control Devices: The term "secondary (2°) controls" could be confusing if applied to door fan controls, as this term is used in California by CARB and in New York to mainly refer to fourth generation machines with integral carbon adsorbers.

The Maine DEP, NYS DEC drycleaning regulations, and NEPA guidance, requires an inward air flow of 100 fpm to effectively control PCE emissions from machine door openings, to less than 50 PPM PCE fugitive emissions.

The Permac system is an example of a 4th generation, refrigerated condenser, integral carbon adsorber machine. This deserves at least a separate paragraph; this represents a leading drycleaning control strategy in the drycleaning industry; especially its ability to achieve 300 ppm PCE of lower concentrations in the machine drum. The Dow TVS system, is in very limited use, and is not being used on a commercial scale, as is the case of 4th generation drycleaning equipment, which should be duly noted.

There appears to be a typographical error in the last sentence on this page, "will not allow the door to be opened until the concentration of PCE reaches a specific maximum". Shouldn't it say minimum, e.g., 300 ppm PCE for 4th generation machines?

Response: These issues have been clarified in the resolution of Comment #G-74. The issue of inward air flow to control PCE emissions has been included in the CTSA. Although the CTSA language is technically correct, others, including the commenter have been confused by the maximum/minimum issue. This language has been clarified to minimize similar misunderstandings.

Comment #1-168: p. 1-14, last line: Need to revise for greater clarity: "...PCE is below a specified maximum level."

Response: Regarding the "maximum level" wording, although the CTSA language is technically correct, others, including the commentator have been confused by it. This language has been clarified to minimize similar misunderstandings.

Comment #1-169: p. 1-14, first paragraph: PCE azeotropic distillation occurs at 189.7 F (87.1 C).

Response: EPA agrees, however, this particular temperature is no longer included in the CTSA.

Comment #1-170: p. 1-14: It is not conventional to refer to secondary control as 2°. The discussion in the COSA about secondary control is very confusing. At the end of the dry cycle, in a dry-to-dry closed loop machine, the drum is opened and this is the source of emissions of PERC. The PERC concentration in the drum, at this stage, assuming a refrigerated condenser outlet temperature of 45 degrees F, is about 8,600 ppm. Fugitive controls are placed on a machine to prevent the operator from being exposed to high concentrations of PERC when the door to the machine is opened. An exhaust fan comes on when the door is opened and routes the PERC either to a small carbon adsorber or to the atmosphere. Secondary controls are different and their purpose is to reduce PERC emissions rather than to prevent worker exposure (although they do that too). With secondary control, a fan comes on before the door is opened. It routes the PERC in the

drum to a small carbon adsorber. The carbon adsorber is desorbed with a hot air at the beginning of the next drying cycle. The captured PERC is therefore never emitted. The PERC concentration can b reduced to 300 ppm in the drum with use of secondary controls.

It is not clear why "Earnest" is quoted. Secondary control systems are commonly designed to desorb at the beginning of the drying cycle. Otherwise they are ineffective. In contrast, since the purpose of the fugitive controls is to reduce worker exposure, many fugitive systems simply vent the PERC to the atmosphere.

I would suggest the authors have a discussion with an equipment manufacturer to make the discussion more accurate and less confused.

Virtually all secondary control devices desorb with hot air rather than steam to minimize the separator water problem.

Response: The descriptions of controls and other solvent process machinery have been clarified in the CTSA.

Comment #1-171: p. 1-14: A major advantage of azeotropic distillation is the energy savings from using a temperature of 190 instead of 250 degrees F. This should be stated. A disadvantage is that more separator water is generated with azeotropic distillation. There is no path to the sewer from the distillation unit. Most drycleaners (except those operating illegally) do not discharge still bottoms to the sewer. It is not common practice.

Response: Regarding the advantages and disadvantages of azeotropic distillation, although the commenter's statements are accurate, the advantages and disadvantages of azeotropic distillation are reflected in the release and costs sections of the updated CTSA. The erroneous statement regarding the waste water and sewer issue was corrected.

Comment #1-172: p. 1-14, second paragraph: I take great exception to the lead-off sentence, and do not believe it to be true in any sense. In azeotropic distillation, the dirts, soils, fatty acids and other insolubles are not discharged in the waste water to the sewer. They remain as still bottoms. When the temperature reaches 190°F it does not indicate that all of the PCE is distilled. It indicates that all of the azeotropic mixture is distilled, and this may be due to all of the PCE being distilled or all of the water being distilled. It is common practice at this point to allow the still to cool, add water and reheat to distill additional azeotrope.

Response: The errors in this comment have been corrected.

Comment #1-173: p. 1-14, second paragraph: In azeotropic distillation, dirt, soils and other insoluble are <u>not</u> discharged in the waste water to the sewer. These residues are the still bottom which waste management companies pick up. The temperature is monitored and when it <u>exceeds 189.7 F (87.1 C)</u>.....the distillation cycle is completed.

Response: The errors noted in this comment have been corrected. However, this particular temperature is no longer included in the CTSA.

Comment #1-174: p. 1-15, fourth paragraph: A unique double ventilated ceiling, positive air pressure, vapor barrier system is in use in Hamburg, Germany (as seen by this writer in 4/97). This vapor barrier for a mixed use building with residential apartments, also uses a plastic/metal foil tape on the walls of the drycleaning room as an additional, side vapor barrier. This unique vapor barrier control system, has been tested on several occasions by the German environmental authorities, and is satisfactorily controlling PCE emissions in adjacent residential apartments to the very stringent German indoor air standard of 100 μp/cm or 15 ppm PCE.

PCE cleaning – add that the EPA NESHAPS mainly specifies rerigerated condenser or 3rd generation type controls. California and New York State have recognized the need for further fugitive emission controls for 3rd generation refrigerated drycleaning machines and the specification of 4th generation controls as state-of-the-art PCE drycleaning control technology. Further local and general exhaust ventilation controls may be necessary for PCE cleaning systems.

Response: A reference to vapor barriers, which sounds very similar to the examples from New York State mentioned in the third paragraph of p. 1-15, has been added to the CTSA. However, specifics, such as materials of construction, are no longer intended to be covered in this section. This process description section and the regulatory section both refer directly to the PCE drycleaning NESHAP information to promote clarity in the updated CTSA. Regarding the states' requirements, B = Agree. These requirements are covered in the regulatory section of the updated CTSA. Regarding the further controls issue, C = No action required. The issue intended in this comment was not clear and could not be addressed.

Comment #1-175: p. 1-15, third paragraph: The typical example of a vapor barrier enclosure room used in N.Y. State is a 10 x 12 x 8, or a 960 cubic foot room. Even for an air change every 2 minutes, which is a conservative design, the exhaust requirement would be 480 CFM or about 500 CFM. The 2500 CEM shown as an example, would be excessive and result in discomfort and high heat losses in winter operation, for the typical sized vapor barrier room enclosure.

Response: Design specifics such as those discussed in the comment are no longer covered in the updated CTSA.

Comment #1-176: p. 1-15: Regarding petroleum solvent process, please refer to my general statement A [Comment #G-73] regarding the HC classification and the need to include synthetic hydrocarbons.

Response: See the response to comment #G-73.

Comment #1-177: p. 1-15: Spill containment is not a "control" that reduces PERC loss. It is a method of protection against a spill that could lead to site contamination.

Response: The headers to each section have been revised to prevent misinterpretation and to better represent the discussion. This issue is addressed by those revisions.

Comment #1-178: p. 1-15: The COSA states that PS (petroleum solvents) are not as effective as PERC in drycleaning. This is not necessarily true. PS, although they are a less aggressive solvent than PERC, are better for cleaning certain types of items like drapes, for example.

Response: Solvent performance is not appropriate to this section of the CTSA and has been removed.

Comment #1-179: p. 1-15: The EPA, 1982 and Turner and Lute, 1979 references are 15 years old! Is there not a more recent source of information on PS facilities? This reviewer is bothered by the use of recent personal communications in the PCE section and these old published references in the PS section. The authors should at least have up-to-date personal communication references with industry experts for both sections.

Response: Some more recent sources of data on petroleum solvent facilities were found and relevant information from those sources were incorporated into the CTSA. Unfortunately, little more recent information was available.

Comment #1-180: p. 1-15: NYS DEC and California officials require double carbon adsorber treatment of PCE separator waters before evaporation. Some drycleaners recycle their double activated carbon treated wastewater to their boilers.

Response: These state-specific issues are not intended to be covered in this section

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Comment #1-181: p. 1-15, third paragraph, lines 10-11: remove commas after aluminum.

Response: EPA has removed this sentence from the CTSA.

Comment #1-182: p. 1-15, first paragraph, last sentence: Vapor is vented from the vaporator to the INSIDE...This should not be recommended as it would cause worker exposure to go up if there are no controls in place. Also, local air regulations should be reviewed for applicable regulations.

Response: These concerns are addressed elsewhere in the CTSA.

Comment #1-183: p. 1-15, second paragraph: Spill containment is introduced without any feel for the level of soil contamination that has already occurred and its impact on real estate values. The DFE project presumably was started because of information held by the EPA on the potential risks associated with drycleaning. It might be useful to summarize the hazards either in the introduction or as each mitigation strategy is detailed. In the case of PS systems, the use of underground storage tanks should be discussed.

Response: This issue is not applicable to this equipment section. Mention of sites contaminated with PCE is included in the CTSA and underground storage requirements are discussed in the Selected Federal Regulations Chapter.

Comment #1-184: p. 1-16, Exhibit 1-4: Underground Solvent Storage Tanks are rapidly disappearing because of LUST regulations. The exhibit should probably reflect that above ground storage is now widely used as well.

Response: The exhibit was changed. However, specific issues such as this are not intended to be reflected in the exhibits, and the exhibit now does not address this issue at all.

Comment #1-185: p. 1-16, first paragraph: I do not believe the statement about PS being completely vented prior to drying is true in light of the possibility of using oxygen vacuuming, nitrogen blanketing, or steam injection.

Response: The content and wording of this paragraph was revised.

Comment #1-186: p. 1-16, second paragraph: This paragraph is very outdated as evidenced by the reference being in a 1979 publication. Exhibit 1-4 needs to be expanded to show the addition of a primary and secondary condensing unit on dryer. The exhibit represents the very worst of petroleum technology. The underground solvent storage tank, as pointed out later, creates a problem and are most likely being quickly phased out of use. I believe an exhibit showing a dry-to-dry PS system would be more appropriate.

Response: EPA has corrected some errors (including carbon adsorption) and has researched for new information on these technologies. However, little new information are available. The new information found has been included in the updated CTSA. The exhibits have been updated to include newer technologies. Discussion of underground storage tanks is not applicable to this equipment section, however, is discussed in the Selected Federal Regulations Chapter.

Comment #1-187: There is a contradiction between paragraph 1 on page 1-16 and paragraph 2 on page 1-18. On the first page, EPA notes that PS cannot be used with dry-to-dry because of flammability concerns, but then EPA mentions the use of dry-to-dry with controlled PS processes. The exceptions on use of dry-to-dry should be mentioned on page 1-15.

Response: EPA corrected this contradiction.

Comment #1-188: p. 1-16, third sentence: The very limited use of dry-to-dry machines for PS is due to their flammability. Stating that dry-to-dry machines are "therefore safer" when it comes to PS machines ignores the very real flammability risks. This paragraph needs to be rewritten. All of the sources of information for this section seem very old and outdated. Is there any more recent information available? Also, similar to the PCE control, the information for PS control should be included in the same section, not given its own section heading on page 1-18.

Response: The content and wording of this paragraph were clarified and revised. EPA has corrected some errors related to the hydrocarbon technologies (including carbon adsorption) and has researched for new information on these technologies. However, little new information are available. The new information found has been included in the updated CTSA.

Comment #1-189: p. 1-16: Exhibit 1-4 needs to be moved after its reference on page 1-8. The shading on the exhibit makes it difficult to read the words.

Response: This exhibit is not referenced on p. 1-8. The exhibit is first referenced on the same page on which it is shown. To the extent possible, the exhibits have been made more readable.

Comment #1-190: p. 1-16: The second paragraph refers to "under loading" of coin-operated drycleaning machines; perhaps this is meant to be "over loading," a more likely scenario.

Response: There is no such reference in this paragraph.

Comment #1-191: p. 1-16, third paragraph, line 5: change being to be

Response: EPA disagrees because this would be grammatically incorrect. However, this sentence was revised as part of a broader rewrite.

Comment #1-192: p. 1-16, first paragraph: "Due to the potential generation of an ignitible..." This is inaccurate. Modern DTD PS Machines do not have to vent.

Response: The content and wording of this paragraph has been revised.

Comment #1-193: p. 1-17, sixth paragraph: A little more information should be presented on the issue of filters. The 1982 statement on cartridge filters was probably true. However, subsequent land disposal regulations have caused these filters to be considered hazardous waste in many areas. As a result, most cartridge filters are now chopped up and burned. More importantly, nearly all imported machines come with older style drum or centrifugal filters that while not as efficient, don't have the same disposal problem. It also brings up the point that the impact on the drycleaning issue extends well beyond the individual drycleaner and into the equipment and supply industries that support them. The focus of the CTSA is on the "mom and pop" cleaner but should recognize up front that fabricare is really a collected set of interwoven industries (no pun intended). More emphasis should be put on the supply end of this business.

Response: The descriptions of filtration systems for PS systems have been updated. The CTSA mentions the relationship of the support industries, that other EPA efforts are exploring the relationships, and that the CTSA is not intended to deal with these relationships and the issues which surround them.

Comment #1-194: p. 1-17, second paragraph: I would delete the introductory prepositional phrase regarding transferring the articles to a dryer. Since there are dry-to-dry petroleum machines, the paragraph should begin with *solvent remaining in the articles. . .* The fourth line of the paragraph gives a drying temperature of 60-66°F. This would indicate an extremely volatile, very low flash point solvent. This would indicate the drying temperature is done at lower than room temperature. There must be an error.

Response: Temperatures were incorrectly shown as degrees Fahrenheit, while they should have

been in degrees Celsius. This correction would have been made, but the temperatures are no longer referred to in the text.

Comment #1-195: p. 1-17, first paragraph: Typical drying temperatures are from 125°F-150°F. Carbon adsorbers are not used.

Response: These temperatures were incorrectly shown as degrees Fahrenheit, while they should have been in degrees Celsius. This correction would have been made, but the temperatures are no longer referred to in the text. Regarding carbon adsorbers, EPA has corrected some errors regarding HC technologies, including carbon adsorption as an emission control.

Comment #1-196: p. 1-17, fifth paragraph: This paragraph describes only powder coated filters. Again, this is old technology, and the full range of filtration alternatives are available for HC and PS machines.

Response: The descriptions of filtration systems for PS systems have been updated.

Comment #1-197: p. 1-17, Section on PS Solvent Recovery Process, second paragraph: As I noted in the general comments, I think we might have a great deal of trouble finding one of these installations.

Response: EPA has corrected some errors regarding HC technologies, including carbon adsorption as an emission control.

Comment #1-198: p. 1-17, third paragraph: "Carbon Adsorption units such as those used in PCE facilities may also be applied to petroleum drycleaning facilities." I have visited many, many Petroleum plants and have never observed nor even heard mentioned the use of CA for primary vent control or fugitive control of PS vapor. If it were used, it would not be exposed to PS vapor at elevated temperatures since the carbon would not adsorb at these temperatures. When a CA is used in a PCE plant, it is not used during the heated dry cycle for the same reasons.

Response: EPA has corrected some errors regarding HC technologies, including carbon adsorption as an emission control.

Comment #1-199: p. 1-17, Section on PS Solvent Recovery, fifth paragraph: See previous comment on Exhibit 1-4 (Comment #1-290) regarding above ground tanks.

Response: No action required.

Comment #1-200: p. 1-18, last paragraph, fourth line: *To being* appears to be a typographical error.

Response: EPA has deleted this section in its rewrite.

Comment #1-201: p. 1-18, third paragraph, second sentence: Delete in combination with PS. The PS is already in the machine. Only the nitrogen gas is added.

Response: This accidental repetition would have been corrected, but the rewriting of this part excluded the need for correction.

Comment #1-202: p. 1-18 and 1-19, section on multiprocess wetcleaning: As noted above, I believe that this section should be lumped into wetcleaning.

Response: EPA has not included multiprocess wetcleaning as an alternative process in the revised CTSA.

Comment #1-203: p. 1-18, first paragraph: In line 9, the distillation overhead needs to be changed to read the distillation vapor. Regarding the last sentence, I wonder what statistics are available to indicate how much of the separator water is discharged to POTWs, how much is evaporated, and how much is processed.

Response: This incorrect wording regarding overhead vapor terminology would have been corrected, but the rewriting of this part excluded the need for correction. Information on waste water disposal practices from HC technologies could not be found. This section was rewritten, and this issue was not addressed.

Comment #1-204: p. 1-18 to 1-21: The use of only a not-widely available contract report to EPA, Abt 1994, as reference does not reassure this reviewer that a comprehensive review of the material has been accomplished.

Response: Other sources of information have been referenced, and this source is no longer cited in this section.

Comment #1-205: p. 1-18, fourth paragraph, third sentence: Delete *and relies on petroleum solvents to clean the garment.* This is obvious.

Response: This accidental repetition would have been corrected, but the rewriting of this part excluded the need for correction.

Comment #1-206: p. 1-18, second and fourth paragraphs: Last sentence of paragraph 2 says that the oxygen vacuum is usually used only during the drying cycle which contradicts paragraph 4 which states that the concentration of oxygen is reduced and pressure lowered, relying on PS to clean the garments which implies that this is during the cleaning cycle.

Response: This inconsistency has been corrected.

Comment #1-207: p. 1-18, fourth paragraph: The "oxygen vacuum" does not lower the flash point of the solvent. The flash point is an intrinsic property of the solvent. The vacuum lowers the oxygen concentration in the vapor phase within the machine. By lowering the concentration below 6%, the fuel (petroleum vapor) and a source of ignition (i.e., electrostatic spark or excessive heat for auto ignition) would not cause sustain or cause a fire or explosion.

Response: This error has been corrected, and the language has been clarified.

Comment #1-208: p. 1-18, third paragraph: Steam injection during the drying cycle is not as functional as the oxygen or nitrogen technology. Excessive moisture can lead to excessive shrinkage and defeat the purpose of drycleaning.

Response: The function of steam in dry-to-dry PS (HC) process could not be ascertained, and this issue was not addressed in the CTSA.

Comment #1-209: p. 1-18, third paragraph: "Alternatively, steam serves the same function as nitrogen." This is inaccurate and this inaccuracy has affected several of the key cost tables and assumptions in chapters 6 and 7. Steam injection on the PS Reclaimers and PS Dry-to-Dry machines is only a safety mechanism that is released when a fire or explosion takes place. Steam injection of any significant amount would damage most of the garments in every load.

Response: The function of steam in dry-to-dry PS (HC) process could not be ascertained, and this issue was not addressed in the CTSA.

Comment #1-210: p. 1-18, second paragraph: This section, discussing controlled PS machines, indicates that the process only works on dry-to-dry machines. Paragraph 1 on page 1-16 indicates that dry-to-dry PS machines are very limited. Some numbers in these sections might help. Also, a mention on page 1-18 that the controlled machines represent a different method might help.

Response: EPA has rewritten the section on HC (PS) technologies to correct, clarify, and update the issues to the extent possible. However, numbers requested by the commentator are not intended to be supplied in this section.

Comment #1-211: p. 1-18, Section on Oxygen Vacuum: The statement "and relies on petroleum solvents to clean the garment" is silly. What else would clean the garment?

Response: This accidental repetition would have been corrected, but the rewriting of this part excluded the need for correction.

Comment #1-212: p. 1-19, third paragraph: *According to one vendor, biodegradable natural soaps and detergents are used wherever possible* - This is true of the entire fabric cleaning industry. The author of this paragraph is implying more to the process than is really there. The last sentence is also in error. The oxalic acid and sodium perborate listed are not solvent based chemicals.

Response: The commenter's points would have been incorporated, but this section was removed entirely from the CTSA.

Comment #1-213: p. 1-19, section on machine wetcleaning: This section uses a lot of terminology with which the reader may not be familiar. For example, why should the reader care about an acceleration rate of 0.9g during spin drying? What is a polymer sleeve? Are micron-sized water and air bubbles the same as micron-sized air bubbles?

Response: This section has been reworded and clarified to remove overly specific information.

Comment #1-214: p. 1-19, last paragraph in Multi-process Wetcleaning Section: In the last sentence in this paragraph, only amyl acetate is normally described as a solvent. Oxalic acid and sodium perborate are definitely not solvents at all. I suppose hydrogen peroxide and ammonia could be described as water based solvents of sorts but this is not normally done.

Response: Multiprocess wetcleaning was not included in the document as a technology alternative.

Comment #1-215: p. 1-19, second paragraph: In wetcleaning, aqueous solvents, such as terpines can be used in place of chlorinated ones – as noted, biodegradable soaps and detergents are available. As such, the analysis of risk in wetcleaning should not be limited only to those chemicals that are currently most widely used, according to EPA. There is no indication of the amounts of detergents used in the machine wetcleaning process.

Response: EPA acknowledges that many chemicals may be used as solvents, however, EPA can not speculate on all the possibilities of future development in this industry. Thus, no analysis can be conducted. Amounts of detergents are discussed in parts of the CTSA.

Comment #1-216: p. 1-19, second paragraph: Oxalic acid used to be a popular rust remover in the textile care industry. Because of it high toxicity, it is no longer used. It surprises me that the "environmental safe" multiprocess wetcleaning section makes no reference to it. Both oxalic acid and sodium perborate are solid powders, not liquids.

Response: This section was removed entirely from the CTSA.

Comment #1-217: p. 1-19, fourth paragraph: Other wetcleaning machines, such as the Daiwoo, should be mentioned as they are relatively inexpensive.

Response: EPA disagrees because this process description section is not intended to fully list all possible machine types and designs unless processes vary significantly. Later sections in this chapter are for the purpose of informing on machine market availability and economics issues, and discuss many alternatives.

Comment #1-218: p. 1-19, third paragraph, first sentence: Difficult to understand. Try: Although multiprocess wetcleaning does not use a large volume of drycleaning solvent, small amounts of various other solvents, soaps, and detergents are used.

Response: The commenter's points would have been incorporated, but this section was removed entirely from the CTSA.

Comment #1-219: p. 1-19, fourth paragraph: In addition to the reduced agitation, there are generally more sophisticated controls for temperature, cycle variation, and water levels.

Response: These factors have been included in this discussion.

Comment #1-220: p. 1-20/1-21: There are many, many pages devoted to the description of PCE drycleaning which is what people are familiar with yet the new technologies, particularly wetcleaning, has a very basic description.

Response: The commenter has a valid point, and there is one main reason for more process description information on PCE relative to wetcleaning. The PCE process is more complicated (more equipment and more options) due to the need to control solvent loss.

Comment #1-221: p. 1-21, sixth paragraph: The removal of the inorganics is described as a research problem here but the solution (jet agitation) is described on page 1-23, paragraph 2. These two sections should be combined.

Response: The primary issue discussed on p. 1-21 is one of chemically aiding the removal of inorganics (e.g., solubilizing) from the fabric. The mechanical aspect is mentioned in the next paragraph, but it is not "the solution" that the commentator states it to be. These two issues are in the same section but different paragraphs. Although these issues are related, their placements in their section are proper.

Comment #1-222: p. 1-21, sixth paragraph: In the carbon dioxide section it should be noted that the new processes have received a tremendous amount of press attention and have received a number of technical awards at the prototype stage. The DryWash® process was named in the 1996 "Best of What's New," Popular Science's list of the year's 100 greatest achievements in science and technology. In a subsequent selection process it was selected as the Readers Choice Award as the top new technology for 1996. The DryWash® also received a 1997 R&D 100 Award. The developers of the MiCell system were honored as 1997 Presidential Green Chemistry Award winners.

Response: EPA does not find the discussion of technology awards appropriate for the CTSA.

Comment #1-223: p. 1-21: Supercritical carbon dioxide has the same problems in metal cleaning as it does in drycleaning. It is ineffective on particles and it is an extremely expensive technology. Very few applications where it is applicable or cost effective exist.

The whole discussion throughout the document on liquid carbon dioxide is completely speculative since no machine yet exists. To pass off vendor claims as fact is a mistake. The CTSA indicates that one developer states that the liquid carbon dioxide washing process will be similar to that currently used with PERC. How can we possibly know that if no machine has been produced. Furthermore, the machine with carbon dioxide will have to be pressurized; that is not similar to PERC drycleaning.

Response: EPA wholly acknowledges the uncertainties regarding this developing technology. Every attempt has been made to clearly identify vendor claims in order to avert misinterpretation. Similarities between PCE and liquid CO_2 cannot be known if a fully developed machine is not available, and such statements will be proven or not proven only in the future. This vendor claim has been clarified to reflect that it was related to equipment size. Also, the commentator point that PCE and carbon dioxide machines differ in terms of pressurization will be obvious to anyone who reads the process descriptions of each.

Comment #1-224: p. 1-21, Section on Carbon Dioxide Processes, first paragraph: The last sentence in this paragraph states that carbon dioxide is non-toxic. Like almost any other substance, this is only true if its use is properly controlled. Carbon dioxide is actually extremely hazardous in some circumstances.

Response: This incorrect wording regarding non-toxicity would have been corrected, but some rewriting eliminated this sentence and the need for this correction.

Comment #1-225: p. 1-21, last paragraph, third line (clays and rust): This should be replaced with sugars and perspiration. These are soils of greater concern. Last line you can add *in drycleaning with PCE, PS and HC.*

Response: The commenter's suggestions would have been incorporated. However, the rewriting of this paragraph eliminated the need to adopt these suggestions.

Comment #1-226: p. 1-21, second paragraph, line 11: The generic definition of distillation is "a process of vaporization and subsequent condensation, as for purification and concentration." This is what is done when contaminated carbon dioxide liquid is purified. It differs from conventional distillation of solvents only in that this phase transition occurs in a non-conventional high pressure environment.

Response: The carbon dioxide purification issue has been clarified.

Comment #1-227: p. 1-21, second paragraph, line 2: Carbon dioxide does <u>not</u> have the solvent power of trichloroethane under the conditions proposed for textile cleaning. This is wishful thinking intended to "snow" drycleaners.

Response: This performance issue is not relevant to this process description section and has been removed.

Comment #1-228: p. 1-21, Section on Carbon Dioxide Processes, second paragraph: The last sentence of this paragraph states that these processes "do not involve conventional distillation "then go on to describe a distillation process. In the last paragraph in this section on page 1-23 it is noted that "The stored cleaning fluid is distilled isobaricly." This is probably a better way of describing this process.

Response: The carbon dioxide purification issue has been clarified.

Comment #1-229: p. 1-21, first paragraph: The reference that carbon dioxide is "nontoxic" is false. As stated earlier, carbon dioxide can be toxic and fatal, as documented in the NIOSH health assessment report referenced earlier. The proposed process uses liquefied carbon dioxide at high pressures (800-1,000 psi). This poses a potential physical safety hazard. In addition, accidental leakage of carbon dioxide could occur and generate a lethal environment for workers. As recently as last year, a truck driver delivering carbon dioxide to a restaurant was asphyxiated. These issues must be addressed in a more responsible way.

Response: This incorrect wording regarding non-toxicity would have been corrected, but some rewriting eliminated this sentence and the need for this correction. Physical and asphyxiation hazards are not covered in the CTSA.

Comment #1-230: p. 1-21, fourth paragraph: I do not understand the statement that the CO_2 washing process will be similar to that used with PCE. Similar in what way? Cost, operation of the machine? The statement that CO_2 does not involve the conventional distillation is, perhaps, misleading in that CO_2 is converted in the process from liquid to gas and back to liquid by pressure change. This will accomplish the same function as distillation.

Response: The developer's claim of similarities of PCE and carbon dioxide processes has been clarified to reflect that it was related to equipment size. The carbon dioxide purification issue has been clarified.

Comment #1-231: p. 1-21, section on CO_2: Carbon dioxide is non-toxic at low concentrations, but it can be lethal at high ones for long enough exposures and it is the primary greenhouse gas. Why is the estimated KB only appearing here? It should be defined and summarized for all solvents in a table.

Response: This incorrect wording regarding non-toxicity would have been corrected, but some rewriting eliminated this sentence and the need for this correction. Regarding the KB value, EPA agrees that a change should be made regarding this issue. This performance issue is not relevant to this process description and has been removed.

Comment #1-232: Exhibit 1-22: Should go on page 1-21.

Response: There is no Exhibit 1-22.

Comment #1-233: p. 1-22: The diagram for wetcleaning process, in all fairness, should indicate that soils, detergents, lint, etc. are discharged with the water.

Response: This change was made for all diagrams which were insufficient in this way.

Comment #1-234: p. 1-22, Exhibit 1-6: Normally, water is not filtered when it is reused in wetcleaning processes. Under normal circumstances, final rinse water is reused in the next suds operation, etc.

Response: This exhibit has been updated.

Comment #1-235: p. 1-23, fourth paragraph: Under Ultrasonic Cleaning, I would delete ozone as an additive in this system unless you also wish to talk about ozone as an additive in all of the wetcleaning systems. In particular, I believe the Natural Clean process would be very compatible to the addition of ozone. I am not sure, however, if this would be desirable. End of line 4 appears to be a type. I think it should read *to be*.

Response: Ozone was mentioned in the ultrasonic process reference, but not in any machine wetcleaning reference. EPA has corrected typographical errors where applicable.

Comment #1-236: p. 1-23, first paragraph, third line: It is my impression that the fluoro surfactants are no longer used in the MiCELL system. However, you need to confirm this statement with representatives from MiCELL. In line 6, the regain moisture that occurs naturally in fabric is not 80% for wool. Twelve percent is a more reasonable figure, but you should confirm this number with a textile text.

Response: These facts would have deserved further investigation. However, all process descriptions were revised to remove overly-specific information which did not add value to the sections or which were too vendor-specific. The issues relevant to the comment were among those removed and need no further consideration.

Comment #1-237: p. 1-23 to 1-34: The references in addition to Abt, 1994 are mainly personal communications, conference presentations, and manufacturer's brochures. Are published sources not available?

Response: EPA relied on published sources where possible. Often, the most up to date information was available only through communications with industry and other experts.

Comment #1-238: p. 1-23, fourth paragraph, line 5: ...<u>be</u> feasible...

Response: This change would have been adopted, but rewriting of this issue makes this correction unnecessary.

Comment #1-239: p. 1-23, first paragraph, line 2: Surfactants needed will not be inorganic, but organic in nature. As of today, the surfactants developed show the colloid chemical prerequisites required for cleaning, but their detergency has yet to be proven.

Response: The error in the wording would have been adopted, but rewriting of this issue makes this correction unnecessary.

Comment #1-240: p. 1-23, first paragraph, line 5: The statement that regain moisture that occurs naturally in fabrics is sufficient to utilize the detergent for water soluble soil removal is incorrect. Adding no water to the system would require extensive and labor-intensive pre- or post-spotting to remove water soluble soils. The regain references to fibers (8% in cotton and 80% - much too high, should be 12-14% under standard conditions - in wool) are irrelevant. Moisture regain of textiles is governed by kinetic and thermodynamic principles and a function of the environmental conditions in air or in the liquid media to which the textile is exposed. There is obviously a need for fundamental research to establish these process parameters.

Response: These facts would have deserved further investigation. However, all process descriptions were revised to remove overly-specific information which did not add value to the sections or which were too vendor-specific. The issues relevant to the comment were among those removed and need no further consideration.

Comment #1-241: p. 1-23, middle of the page: Change "isobaricly" to "at constant pressure." The last paragraph on the page is confusing.

Response: The error in the wording would have been adopted, but rewriting of this issue makes this correction unnecessary. The language in the last paragraph has been clarified.

Comment #1-242: p. 1-23, second paragraph: isobarically is misspelled.

Response: The misspelling would have been corrected, but rewriting of this issue makes this correction unnecessary.

Comment #1-243: p. 1-23: Same comment on speculations offered by vendors.

Ultrasonic cleaning should not be presented as a separate technology. It is a mechanical method of wetcleaning. Again, as is true for the carbon dioxide process, nothing is known about what the ultimate process will be like.

Response: Both the ultrasonic and liquid CO_2 technologies have been moved to an Emerging Technologies chapter. Ultrasonics have been characterized as an aqueous-based technology.

Comment #1-244: p. 1-24, Section on Ultrasonic Cleaning, last paragraph on the page: The statement "Generating the ultrasonic aqueous solution" is confusing. I believe it should read something like "Generating the ultrasonic energy in the wash liquor" or a similar statement.

Response: This statement has been reworded.

Comment #1-245: p. 1-24, Section on Ultrasonic Cleaning, first bullet point: This is a fascinating statement but I'm not sure that it means anything at all.

Response: This statement has been clarified.

Comment #1-246: p. 1-24: It is not clear what "regular aqueous cleaning cycles" are. Ultrasonics are used by many firms in metal cleaning with water-based cleaning. It is a regular aqueous cleaning cycle.

Response: This phrase has been clarified.

Comment #1-247: p. 1-25, Section on Ultrasonic Cleaning, last paragraph in the section: All of this is fascinating but I'm not really sure that anyone has ever seen any of this work. It may just be a theoretical concept at this point. In any event, I think there needs to be some verification of how far this concept has progressed before this sort of detail is presented.

Response: The status of this technology has been stated more definitively.

Comment #1-248: p. 1-25: The CTSA indicates that one benefit of the ultrasonic cleaning system is that it includes in-line continuous processing. Regular wetcleaning without ultrasonics could be done with in-line continuous processing. It may or may not be more efficient than batch processing; it depends on the final system configuration.

Response: This efficiency issue is uncertain and has been removed from the CTSA.

Comment #1-249: p. 1-25, third paragraph, sixth line: It sounds like sales rhetoric. I do not understand how widespread use of microwave drying equipment would lead to modifications of fabrics used by clothes designers. If this statement remains, there needs to be some further explanation.

Response: The microwave technology is no longer included in the CTSA.

Comment #1-250: p. 1-25, third paragraph: Why is it that widespread use of microwave drying will be able to influence choices made by clothing designers more than other technologies? This seems somewhat presumptuous.

Response: The microwave technology is no longer included in the CTSA.

Comment #1-251: p. 1-25: Is there an estimated time frame for when ultrasonics will be available commercially?

Response: EPA has not speculated on the commercial availability of this technology.

Comment #1-252: p. 1-25, third paragraph: One limitation of the microwave drying technique is the presence of metal in the clothing, zippers, buttons, etc. Some damage to the clothing in the immediate vicinity of the metal may occur. I'm sure that the manufacturers have addressed this but without access to the literature I don't know what the solution is. The material should be reviewed to pull this material out.

Response: The microwave drying technology is not included in the CTSA.

Comment #1-253: p. 1-26/1-27, Exhibit 1-8/1-9: The total volume of articles cleaned in the two tables do not agree; 573,200,000 vs 446,492,000+97,200,000=543,692,000, a difference of 30,000,000 kg. The title for the last row in 1-9 should read "Average number of articles cleaned per year per facility"

Response: The estimate of the volume of articles cleaned has been updated.

Comment #1-254: p. 1-26, last paragraph: Change to "<u>the</u> commercial <u>dry-cleaning</u> facilities"

Response: Revisions of this section of the chapter no longer include this exact passage.

Comment #1-255: p. 1-26, last paragraph: I believe the distribution of solvents used between PCE, PS, and synthetic HC have rapidly changed, and these numbers are no longer accurate. In the second sentence, there really must be three categories of HC solvents, and the synthetic must be added. Please seek input from Jim Shriner of Exxon regarding the use of Exxon's DF-2000.

Response: This section of the document has been revised to incorporate the information provided by the commenter.

Comment #1-256: p. 1-26, last paragraph: "The two largest volume (add drycleaning) solvents in the US."

Response: Revisions of this section of the chapter no longer include this exact passage.

Comment #1-257: p. 1-26, end of first full paragraph and Exhibit 1-8: Are there really still 3000 coinops? The CTSA needs to be updated to reflect the market now, post NESHAP. The last paragraph on the page is redundant, the same thing was poorly written earlier on page 1-7.

Response: Revisions of this section of the chapter no longer include this information.

Comment #1-258: p. 1-26, Section 1.3, first paragraph at top of page: The statement "with two drycleaning machines, might have the volume to support a sophisticated wetcleaning machine" is a very anecdotal sort of observation. It sort of reminds me of a "two chair barber." I'm not sure it adds anything to the discussion.

Response: Revisions of this section of the chapter no longer include this information.

Comment #1-259: p. 1-26, third paragraph: This needs to be totally redone. At this point we throw in an unrelated technology of uniforms and linens for hospitals, restaurants, and hotels. The only items that should be of concern here would be those uniform items that would have drycleaning as a recommended care procedure. There is nothing in this CTSA that even begins to address the requirements for laundering of linens for hospitals, restaurants or hotels. Furthermore, these uniform and linen laundries represent a much larger industry than the 325 industrial drycleaners that are cited in line 3. Indeed, almost all uniforms and linens are laundered. Some of the industrial cleaning is done because of the fabric involved, but is done because of the soils involved. Soils that are primarily oils and greases can be removed in industrial drycleaning more effectively than in industrial laundering. However, I believe this segment of the industry is either beyond the scope of this CTSA, or the CTSA would need to be totally rewritten to include a number of other issues.

Response: Revisions of this section of the chapter no longer include this information.

Comment #1-260: p. 1-26, third paragraph: The fact that 92% by weight of industrial drycleaners now use water in place of solvent is important in that it demonstrates the potential for such a shift in the commercial cleaning industry. This should be duly noted.

Response: Revisions of this section of the chapter no longer include this information.

Comment #1-261: p. 1-26, second paragraph and Exhibit 1-8: On page 1-10 and Exhibit 1-3, it was indicated that coin-op and industrial processes were left out of the analysis, yet here they are described again and included in the table where coin-op data was excluded in exhibit 1-3. Again, consistency would help and if they are excluded, removing the description here would shorten the text.

Response: Revisions of this section of the chapter no longer include this information.

Comment #1-262: p. 1-26, second paragraph, last sentence: I would question the number 3,000. What is the date of this reference? It was my understanding that these units have all but disappeared.

Response: Revisions of this section of the chapter no longer include this information.

Comment #1-263: p. 1-27, third paragraph: The 42% PCE drycleaning use does not match with consumption figures on page 1-28 (55 million kg = 49%, 68 million kg = 60%) and both numbers

conflict with the previous sentence which says that use is going down from both environmental pressures and increased mileage.

Response: This information has been revised to reflect a more accurate estimate.

Comment #1-264: p. 1-27, Exhibit 1-9: The inclusion of wetcleaning in the table offers little since there is not data. Note that the number of commercial cleaner in Exhibit 1-9 does not agree with the number in Exhibit 1-8 despite coming from the same reference.

Response: The information contained in this table has been modified in light of updated estimates provided by stakeholders. The information pertaining to wetcleaning was included in this table in order to maintain the Agency's document format.

Comment #1-265: p. 1-27, Exhibit 1-9: The petroleum solvent consumption figure of 53,054,000 kg per year is based entirely on conventional technology. It certainly highlights the inefficiency of old petroleum methodologies. Unfortunately, the document does not really deal well with the immense increase in efficiency that "state of the art" petroleum technology offers. As per the discussion on petroleum in my general comments, I think the document does a very poor job with petroleum generally.

Response: The information contained in this exhibit has been updated based on estimates from stakeholders. Additional discussion of "state of the art" petroleum solvents (hydrocarbons) and technology has been included in the final draft of the document.

Comment #1-266: p. 1-27: There are a lot of problems with Exhibit 1-9. The CARP report indicates that the amount of clothing cleaned by surveyed drycleaners in California was about 100,000 pounds annually (page III-6 in CARB document). The survey population represents about half the drycleaners in the state. Thus the total amount of clothing cleaned in California might be 200,000 pounds or about 91,000 kg annually. Again if California represents 11 percent of the U.S. population, then about 825,000 kg of clothing should be cleaned in the U.S. Exhibit 1-9 indicates that about 446,000 kg of clothing was cleaned in the U.S. This is half of the value indicated above and is probably underestimated significantly. As discussed earlier, the number of drycleaning facilities used in the analysis is also underestimated.

The CARB document presents the pounds of clothes cleaned per gallon of PERC used on Page III-11 from the surveyed facilities. Depending on the type of equipment used, the mean value varies from 424 for a dry-to-dry closed loop machine to 174 for a transfer machine. The data in Exhibit 1-9 (arrived at by dividing the pounds of clothing cleaned by the solvent consumption and converting to the proper units) give a value of 89 pounds of clothing cleaned per gallon of PERC used. This number is not reasonable. The solvent consumption value in Exhibit 1-9 is a fairly good estimate and agrees with the data in the 1995 Chemical marketing Reporter Profile for PERC if it is assumed that about half the PERC is used in drycleaning. The number that is in error is the drycleaning volume which is obviously far too low.

The column in Exhibit 1-9 should read "Average Number of Articles Cleaned" and "(kg/year)" should not be included.

Response: Information and estimates contained in Exhibit 1-9 have been modified based on updated information provided to EPA by stakeholders. These modifications are reflected in the latest draft of the document.

Comment #1-267: p. 1-27, Section 1.3.1, third paragraph: I am not comfortable with the wording "Because of health" being included as a hazard.

Response: This passage of text has been modified in the latest draft version of the document.

Comment #1-268: p. 1-27, first full paragraph: The last sentence is inaccurate. The consumption of PCE for drycleaning has been declining since the mid 1970s (see Figure 4.2 in Thompson, 1997) and this is not due to reduced consumption of drycleaning services. What is particularly notable about this decline is that it has occurred while more clothes have been cleaned and other solvents have dropped in market share (PS and CFCs). In the next paragraph, I think it is more informative to give historical trends. Who cares where the PCE (and on page 1-30 the PS, and page 1-31,32 the wetcleaning) is produced? I would drop these, but if the CTSA lists them then it needs to also list where CO_2 is made.

Response: EPA has reviewed the comments provided above and has modified this section of the chapter to provide a more clear and accurate discussion. The discussion of PCE production remains in the text of the chapter. A discussion of CO_2 is now included in Chapter 11 (emerging technologies); however, the discussion does not address the manufacture of CO_2.

Comment #1-269: p. 1-27, Exhibit 1-9: Number of wetcleaning facilities inaccurate. Should be ~40 (contradicts Exhibit 1-11).

Response: The document has been revised to include a more accurate estimate.

Comment #1-270: p. 1-27, third paragraph, second sentence: Exhibit 1-9 depicts almost 85% of drycleaning facilities use PCE.

Response: The statement in the CTSA is accurate. Therefore, the text of this chapter was not changed with regard to the above suggestion.

Comment #1-271: p. 1-28, Exhibit 1-10: Footnote b states PCE use for drycleaning and fabric manufacturing. Is this a fair indication since fabric manufacturing is included? What percent is used for fabric manufacturing?

Response: EPA has reviewed this comment, but did not have data to make the distinction suggested by the commenter.

Comment #1-272: p. 1-28, first paragraph: I believe the PCE use has declined more than thirty percent; Michigan has seen an eighty percent decline since 1985.

Response: This estimate was updated to reflect information provided by stakeholders (72% decrease in PCE use from 1981 to 1996).

Comment #1-273: p. 1-28: The Chemical Marketing Report Chemical Profile for PERC for 1995 indicates that PERC production capacity is 211 million kilograms rather than 193.1 as specified in Exhibit 1-10. It also lists imports at about 25 million kilograms rather than 38.6; exports are also a different value. The Profile is enclosed here for your information.

The CTSA indicates that the mileage in 1989 was 35.2 kg of clothes cleaned per liter of PERC (294 pounds of clothes er gallon of PERC), up from 17.4 (145) in 1975. These data are in conflict with the data given in Exhibit 1-9 (see comment above) where the mileage was listed at 89 pounds of clothing per gallon of PERC used. The values of 294 in 1989 and 145 in 1975 agree better with the CARB values.

The CTSA states that PS solvent use declined partly because of the fire and explosion hazard. I would change "partly" to "primarily."

Response: The PCE production capacity and import estimates was revised based on the 1997 Mannsville PCE Product Synopsis and the Chemical Marketing Report Chemical Profile included by the commenter.

Text regarding solvent mileages is no longer included in this passage, but can be calculated based on the information found in Exhibit 3-3. Mileages are calculated for each machine configuration by dividing the total amount of clothes cleaned (53,330 lbs) by the total PCE loss per year (gallons; varies with each configuration). Solvent mileages for all PCE machine configurations range from 85 to 300 pounds of clothes per gallon of PCE. Based on information provided in Exhibit 2-6 and Appendix A-9, solvent mileage is calculated to be 220 pounds of clothes per gallon of PCE.

EPA has modified the text to use the word "primarily" versus "partly."

Comment #1-274: p. 1-29, first paragraph: As PS technology is likely to differ very little between Japan and the US, explosions in PS dryers should indicate that explosion is (not may be) a concern in the U.S. The rates should be considered similar unless proven otherwise.

Response: EPA has removed references to explosions in Japanese PS dryers from the CTSA. It is not clear how factors, such as zoning requirements, may affect rates, so that EPA believes that the comparison is not appropriate.

Comment #1-275: p. 1-29: The first word on the page is buildings. To multi-dwelling buildings, add "and shopping centers."

The document does not really discuss the new higher flashpoint petroleum solvents used in conjunction with the nitrogen inerted or vacuum units. These are actually being used in the field and cost data could be generated on them. Much more is known about this process than about ultrasonic systems or carbon dioxide cleaning. Why is it not presented?

The CTSA contains a discussion of the definition of a photochemically reactive solvent. It refers to the California Air Quality management Districts' definition. In fact, this point is totally irrelevant. Non-photochemically reactive substances are classified as VOCs unless they are specifically exempted by EPA, CARB and the local California air districts from VOC regulations. The fact that solvents have an aromatic content of less than one percent has no relevance as to how it is regulated.

Response: The paragraph containing the reference to "buildings" has been modified to no longer include this information. Additional information regarding nitrogen and vacuum units has been included in other sections of the CTSA. The discussion of PS photo-chemical reactivity and applicable regulations has been removed from this section of the chapter.

Comment #1-276: p. 1-29: The information on explosion risk in Japan for PS dryers seems useful, and the risk seems quite high, $2x10^{-4}$ for presumably life-threatening accident. The reference is old, EPA, 1982. Is not information of this type available for other countries, including the US? Was the fire insurance industry consulted?

Response: EPA was unable to locate information sources of explosion and fire risks. The information on Japanese PS dryers was removed from the CTSA because it is not clear how it relates to the potential for fire and explosion incidents in the United States.

Comment #1-277: p. 1-29, sixth paragraph: I believe the reason these numbers appear to be in conflict is related to the dates of 1991 vs. 1993 vs. 1997. Because of the industry's concern regarding the use of PCE, there has been an increase in the use of HC solvents.

Response: The paragraph which the commenter refers to has been removed from the text of this chapter.

Comment #1-278: p. 1-29, seventh paragraph: The description that 60% of industrial cleaners use PS seems inconsistent with page 1-26, paragraph 3 which indicates the dominant use of water. The earlier reference might be annotated.

Response: One statement regards the weight of clothes cleaned while the other refers to the percent of facilities.

Comment #1-279: p. 1-30: There should be a discussion of the new high flash petroleum solvent and the new nitrogen inerted and vacuum equipment. In many cases, these machines are being approved for use by fire departments in California in multi-occupied buildings.

Ozone Depleting Substances have not been banned. Their production has been banned. They can still be used.

Response: Additional discussion of higher flashpoint petroleum solvents has been included in the revised versions of this chapter. The text has been modified to use the term "production" versus an outright ban on use of ozone depleting substances.

Comment #1-280: p. 1-30, third paragraph: The manufacturer stating 20 fold increases in mileage should be identified. Also, the market does not equal the number of suppliers serving it. The market has supported an increase from 1 to 5 suppliers.

Response: The manufacturer stating a 20 fold increase was referenced in the document. EPA has changed the wording on the number of suppliers.

The market has supported an increase from 1 to 5 suppliers.

Comment #1-281: p. 1-30, fourth paragraph, first sentence: ...commonly used as a degreasers in manufacturing...

Response: The text has been modified to reflect the suggestions of the commenter.

Comment #1-282: p. 1-30, Section 1.3.2, third paragraph: The average mileage (pounds cleaned per gallon solvent used) for Stoddard solvent in Michigan in 1,200 (1996).

Response: This text was eliminated from this section of the chapter.

Comment #1-283: p. 1-31: Again, the description of controlled PS technology should go in the same section as the regular PS technology. Controlled PS technology and Wetcleaning are not comparable in terms of their hazards, whereas Controlled PS and PS are (since the Controlled variation is only an add on to the latter).

Response: The organization of the entire CTSA has been significantly modified, and, consequently, this discussion has been consolidated into the PS (hydrocarbon) section of the chapter.

Comment #1-284: p. 1-31: Section 1.3.4 could easily be eliminated. This is the third restatement that alternatives are available. The new information on manufacturers and chemicals should be moved to the first discussion in section 1.2.

Response: The organization of the entire CTSA has been significantly modified, and, consequently, this discussion has been consolidated into the PS (hydrocarbon) section of the chapter.

Comment #1-285: p. 1-31, fifth paragraph: Attach vendor list in appendix.

Response: A list of wetcleaning chemical and equipment manufacturers has been included in the text, but a vendor list has not been included in the appendix.

Comment #1-286: p. 1-31, third paragraph: I would delete the statement, *the first half of 1997*. We have already passed the first half of 1997.

Response: This passage of text has been modified and no longer appears in this format within the chapter.

Comment #1-287: p. 1-31, fourth paragraph: Attach vendor list in appendix.

Response: A list of wetcleaning chemical and equipment manufacturers has been included in the text, but a vendor list has not been included in the appendix.

Comment #1-288: p. 1-31: At the bottom of the page, there is a list of wetcleaning chemical manufacturers. In the Center for Neighborhood Technology (CNY study), an MSDS of the water-based cleaning formulation used by the cleaner in Chicago was provided. Why did the CTSA document not consider the components of this formulation in the evaluation of wetcleaning formulations?

Response: EPA considered a formulation provided by vendors and modified by EPA to ensure that it was a reasonable sample detergent. Individual components are expected to vary and it would not be possible to cover all detergents in the CTSA. EPA has identified general considerations related to detergent use, and does not believe that a different choice of detergent would significantly affect the results of the CTSA.

Comment #1-289: p. 1-31: The CTSA refers to an alcohol solvent that is predicted to pose no environmental hazards. Virtually all alcohols are VOCs so the alcohol will pose at least one environmental problem.

Part of the new interest in PS is because of the new nitrogen inerted and vacuum equipment that can get fire department approval.

The CTSA indicates that most facilities have a washer and dryer that are being used for wetcleaning. I would question that. Most facilities do not have washers and dryers.

Response: The discussion of alcohol solvents has been eliminated from this section of the CTSA. The revised text of this chapter reflects the fact that newer petroleum solvents and equipment provide significant reduction in fire hazards, therefore allowing greater approval by fire departments. EPA has included quotation marks around the word wetcleaning in reference to its traditional use in drycleaning facilities.

Comment #1-290: p. 1-31, third paragraph, third sentence: What is the status of Global Technologies beta machine that was slated to be out the first half of 1997? Is there an update that could be added (at least in a footnote)?

Response: Information on emerging technologies has been moved to Chapter 11 of the CTSA.

Comment #1-291: p. 1-31, second paragraph, first sentence: ...multiprocess wetcleaning is a potential wetcleaning substitute. Yet in p.1-8, paragraph 2, lines 10-11 it states that multiprocess wetcleaning is no longer used commercially.

Response: This passage of text has been eliminated from the chapter.

Comment #1-292: p. 1-31, first paragraph, line 7: ...warming, therefore would probably not be a suitable alternative for environmental improvements.

Response: This section of the document has been revised and does not include this textual paragraph altogether. The information, however, is reflected in other sections of this chapter and other chapters of the CTSA.

Comment #1-293: p. 1-31, first paragraph, line 5: As previously mentioned, new PS...

Response: The information on all PS technologies has been consolidated into the PS section of this chapter.

Comment #1-294: p. 1-31, Section 1.3.4, first paragraph: The last sentence in this section states "commercial prototypes will be introduced in 1997." I think it would be wise to confirm this before the document is published.

Response: The information has been moved to the emerging technologies chapter (chapter 11) of the CTSA and has been modified appropriately with information provided by manufacturers.

Comment #1-295: p. 1-31, Section 1.3.4, last paragraph on the page: R.R. Street & Co. of Naperville, Illinois also supplies wetcleaning chemicals and was heavily involved in the Canadian research project. I think they should be mentioned here.

Response: This section of the chapter has been modified to include R.R. Street & Co. in the manufacturer list. The Agency did not include information that this organization was involved in the Environment Canada study.

Comment #1-296: p. 1-31, Section 1.3.4, second paragraph: To describe water as the "primary" solvent in this process implies that there is also a secondary solvent. Water is the only solvent in this process.

Response: The structure and text of this section of the chapter has been significantly modified so that it no longer reflects this wording.

Comment #1-297: p. 1-32, first paragraph: It would be useful to examine here and throughout the document the amount of detergents needed in drycleaning vs. wetcleaning (realizing that the amounts used in drycleaning are low but greater than 0).

Response: The suggestion made by the commenter is outside the scope of the study of the CTSA.

Comment #1-298: p. 1-32, section 1.4: Why are international markets relevant?

Response: The international market section was removed from the revised CTSA.

Comment #1-299: Section 1.5: Not a market projection - re-name or modify.

Response: EPA has renamed the section to be called "Fabricare Industry Trends," however the information in this section has been revised based on a complete reorganization of the entire CTSA.

Comment #1-300: p. 1-33, fifth paragraph, line 1: Remove PCE - Increasingly, (PCE) drycleaners...

Response: The text of this sentence has been modified to use the term "fabricare professionals" versus "PCE drycleaners," based on the suggestion of the commenter.

Comment #1-301: p. 1-33, fourth paragraph: There was no PS in use 5 years ago yet earlier in the document it was stated that PS was used exclusively in the 1950's. What changed the shifts?

Response: Section 2.5.3 (HC solvent market share and volume) has been modified to discuss the reasons for the shift in HC from the 1950s to the 1990s. However, this information is not necessarily repeated in section 2.5.5 (fabricare industry trends).

Comment #1-302: p. 1-33, fourth paragraph, tenth line: I would add in the list of differences for direct comparison *lifestyle*.

Response: The text has been modified based on the suggestion of the commenter.

Comment #1-303: p. 1-33, Section 1.4.3: Since I am quoted here, I would like to clarify a point, I purportedly made the statement that "In general, Canada is behind the U.S. in the adoption of drycleaning alternatives." To clarify this, in terms of the thought process of change, I think Canada is well ahead of the U.S. Ironically, I think it is somewhat behind in actual capitalization. As I recall, this is what I said at the time. If it isn't, it is certainly what I meant.

Response: This passage of text has been eliminated from this chapter of the CTSA.

Comment #1-304: p. 1-34: It is clear that the fabricare industry is trying to encourage the use of fabrics requiring professional fabricare techniques. All fabrics currently are and will be compatible with professional fabricare techniques.

Response: EPA did not modify the CTSA to include this comment. Part of the professional cleaners' approach has been to broaden the public's view of professional clothes cleaning to include pressing and finishing. This will potentially increase the quantity of clothes customers have professionally cleaned.

Comment #1-305: p. 1-34: I believe the increase in percent washed is due more to changes in lifestyle (casual Friday, etc.) and not cleaners washing in water items that are labeled "dry clean." The liability of doing this has not yet been addressed.

Response: EPA did not modify the statement in the CTSA because it had referenced sources citing both reasons for the increase in the quantity of clothes washed at professional cleaners.

Comment #1-306: p. 1-35: I believe the drycleaning training manuals used by IFI, NCA, SDA, etc. should have been reviewed and should be among this list of references.

Response: EPA attempted to review these documents, however, was either unable to obtain copies from the named organizations or, in the case of the NCA-I document, the quantitative information necessary was not found in the document.

Chapter 2

Comment #2-1: Q-3: The chemical properties and information tables are "fillers". Summary tables should be prepared separately for chemicals in each technology application. The most important properties could be listed and marked according to their most important properties in the context of their application.

Response : This change has been made.

Comment #2-2: References: There is no cited reference for any of the information related to hazards and/or toxicity associated with microwave drying. Some summary references are:

Adair ER (1986): Thermoregulation in the presence of microwave fields. In Polk C, Postow E (Eds): "Handbook of Biological Effects of Electromagnetic Fields." Boca Raton, FL, CRC Press.

Baranski S (1972): Histological and histochemical effects of microwave irradiation on the central nervous system of rabbits and guinea pigs. Am J Phys Med 51:182-191.

Polk C, Postow E (1985): Handbook of Biological Effects of Electromagnetic Fields. CRC Press, Boca Raton, FL.

Response: Microwave drying is no longer being considered in this CTSA.

Comment #2-3: This information seems to be a compilation of standard data on the chemicals. The sources of these data should be given. The discussion of health effects of PCE is particularly troubling, because this discussion differs in some specifics with the material in Appendix A, and no references whatsoever are given as to the source of the information. This reviewer finds the discussion of health effects of PCE in Appendix A to be more carefully and accurately written, as well as much more comprehensive, than the discussion in chapter 2.

Response: The current draft of the CTSA has been changed to add some references to Chapter 3 (old Ch. 2) and make sure that the text in Chapter 3 reflects the information presented in Appendix C (old App. A). However, most details on a given study are in the Appendix while an overview is presented in the body of the document.

Comment #2-4: As I understand it, this chapter is meant to convey the nature of the concerns associated with certain chemicals. Apart from section 2.1, which does not fit this framework (see below), there also seems to be a certain amount of interpretive material interpolated into the text, e.g., assessing whether a result (never referenced) is reliable or based on a study with "weaknesses." It is not clear to me why such judgments should be in this chapter.

Response: The old Section 2.1 has been taken out of the Chapter and relegated to an Appendix (now Appendix A). As noted above, (see response to Comment #2-3), some references have been brought into the text of Chapter 3.

Comment #2-5: The text is, for the most part, clearly written. Exceptions are noted, below.

Response: No response required.

Comment #2-6: Tables are fine. Of marginal utility to me, however.

Response: No response required.

Comment #2-7: Tables and text appear to be consistent (and redundant).

Response: No response required.

Comment #2-8: There is no specific referencing at all in my copy.

Response: See response to Comment #2-3.

Comment #2-9: Q-2: A glossary of terms and their usefulness for decision making within the objectives of DfE would be desirable. For example, defining hazard and risk generically and how both terms relate to each other should precede the health hazard information. Definitions and of the terms risk assessment, risk management and risk communication should be explained and discussed in the context of the various fabricare technologies. Diagnostic questions about characteristics of hazards as recommended by the National Research Council would help the reader better understand this document (Understanding Risk, National Academic Press, 1996 p. 144).

There is too much emphasis on hazard and no reference to safety issues. All drycleaners should have material safety data sheets (MSDA's) which contain many useful safety information on the chemicals they use. They may not read them, so EPA's DfE program and this document could be used to remind them about their existence. What is often not mentioned or not recognized by laypeople is the fact that a hazardous substance does not pose a risk if the necessary safety precautions prevent its exposure to people or the environment. Following existing industrial health and occupational safety practices (i.e., OSHA standards and regulations) can go a long way to protect workers and the environment.

Response: Partially agree. Risk assessment terminology (hazard, exposure, dose-response, risk characterization) is defined in the risk assessment chapter (now Ch. 5). Sprinkled throughout the document are listings of the objectives of the CTSA related to risk: executive summary, Risk Chapter (5), and the Trade-Off Chapter (10).

The issue of safety has been dealt with in the hazard chapter in terms of toxicity, and, to a certain extent, in terms of flammability for the hydrocarbon solvents. The suggestion that the CTSA remind drycleaners of the existence, purpose and use of MSDS's is a good one. However, because it is a risk communication issue, it may not belong in the hazard chapter.

Comment #2-10: Q-1: Just like the previous chapter, Chapter 2 is too long. The content is too diverse and confuses the reader. The chemical information should be in the appendix and only a brief summary relevant to their application should be presented in the text section of this document. It would be useful to list the chemicals according to their technology application so that

the reader can easily see which chemical is used for each cleaning technology. Each section (2.1-2.4) should be a separate chapter to make it reader friendly.

Response: Agree. The chemical information has been relegated to an Appendix (now App. A), and the information has been organized by technology headings.

Comment #2-11: The chemical analysis and safety analysis both leave out CO_2. The chemical properties of CO_2 are readily available and are needed for comparison to other solvents. The primary safety issues with CO_2 are suffocation and dealing with gases under pressure. There are additional concerns with CO_2 as a greenhouse gas but the release from drycleaning operations is likely to be negligible and the CO_2 is generally produced from industrial sources to begin with. However, in the interest of completeness, the data is available. Similarly, ultrasonic technology presents many of the same risks as microwave exposure, particularly with regard to thermal heating. It is worth noting that there is not estimate of the cost of regulatory paperwork for the small operator. This may be factored into labor rates but the workload will differ with alternative technologies. This is a major concern in the business and should be a factor when comparing alternatives.

Response: Details on the hazards of liquid CO_2 and ultrasonic technologies are not extensively covered because these technologies are currently under development. The microwave technology has not been included in the CTSA. The CTSA has included the costs of paperwork associated with hazardous waste in its cost estimates, however, may not have accounted for costs associated with all other regulatory requirements. The CTSA does suggest that users consider the effects of regulations on their choice of technology.

Comment #2-12: The purpose of this chapter is unclear. The reader is not sure of what purpose this chapter serves and what the data collection will be used for in the rest of the document. For example, the regulatory summary is not used again. It appears to be placed there because there was no where else for it to go.

Response: The reformatting of the chapter (moving the chemical information to an appendix and moving the regulatory summary out to form its own, new chapter) has narrowed the focus of the chapter to its title: Hazard.

Comment #2-13: The text could be presented more clearly through the use of summary paragraphs, placing information on the same chemical in the same section, and better use of tables.

Response: EPA believes the reformatting mentioned above (many responses) accomplishes the goal of clarity.

Comment #2-14: In general, this chapter is too complex for even the most technically advanced drycleaners. The chapter needs simplification in information.

Response: Agree. See response to Comment #2-13.

Comment #2-15: Relevant references/citations are not adequately provided in the text.

Response: Agree. See response to Comment #2-3.

Comment #2-16: There is a lot of overlap between this chapter, chapter 3, and chapter 4 that can be eliminated. While. There is no need to repeat the same information.

Response: The CTSA has been extensively reformatted to deal with redundancies.

Comment #2-17: There is no need in a hazard identification section to include all of the physical properties of each chemical. These can be relegated to an appendix.

Response: The information on physical properties has been moved to an appendix.

Comment #2-18: Finally, there is no mention of well documented effects on the immune system, specifically the appearance of serious autoimmune disease (scleroderma). Such cases have been reported in the literature for forty years and the association of PCE with scleroderma or scleroderma-like disease is in many textbooks of occupational dermatology. This is a serious omission.

Response: These are <u>not</u> well documented, if they are not specifically and uniquely associated with exposure in, for instance, *Immunotoxicology and Immunopharmacology* (eds. JH Dean, M Luster, A Munson, I Kimber. 1994, Raven Press). EPA has also received a TSCA 8(e) submission (8EHQ-96-13799) which acknowledges that study is needed if an association is to be established.

Comment #2-19: This discussion of toxicities needs references. Much of the rest of the text was excellently referenced but it was strangely absent here.

Response: Agree, see response to Comment #2-3.

Comment #2-20: 2. I am not aware of additional information that should be included.

Response: No action is necessary.

Comment #2-21: The information for PCE is reasonably comprehensive, although the current presentation does not fully convey the important uncertainties as described in the previous paragraph or emphasize population risk.

Response: The CTSA has been revised to highlight discussion of uncertainties in the risk chapter (Chapter 5). Population risk is one of a number of societal issues mentioned in the current Chapter 10.

Comment #2-22: Q-6: Adding the above references strengthens chapter 2.

[NIOSH document PB 266 597 Criteria for a Recommended Standard, Occupational Exposure to Carbon Dioxide, August 1976.]
[Hohenstein's report FKZ 01 ZH 90A31, August 1994.]

Response: The NIOSH document has been reviewed and added to the document.

Comment #2-23: Q-5: Hazard information on carbon dioxide can be found in the NIOSH document PB 266 597 Criteria for a Recommended Standard, Occupational Exposure to Carbon Dioxide, August 1976. There are several references in the document which state that there are no hazard, exposure and regulatory information available on carbon dioxide. This is incorrect and needs to be revised. New petroleum solvent specifications can be obtained from Exxon or can be found in Hohenstein's report FKZ 01 ZH 90A31, August 1994. EPA DfE should have both information.

The section on federal regulations needs to be updated. For example, as of March 8, 1996, PCE is excluded from the VOC list (61 FR 4588). There is also no explanation of the Safe Drinking Water Act (SDWA) which impacts PCE users as it relates to separator water discharge into sewers, ground and well water contamination and clean-up standards. Also, a new care labeling rule (2.4.6) is now in force and should be explained in the context of its impact on care technologies.

Response: As stated above (response to Comment #2-22), the NIOSH document has been included.
The regulatory summary has been moved out of the hazard chapter and is currently its own chapter (8).

Comment #2-24: Q-4: Information about the chemical properties and the hazards of new petroleum solvents and carbon dioxide are missing. They should be included here. Environmental hazard rankings for the two petroleum solvents (Stoddard and 140 F) are listed as high (Exhibit 2-5). In Chapter 8, p. 8-2, the environmental risk is stated to be low for conventional PS processes. This is confusing to readers and needs to be explained. Defining the difference between hazard and risk as it relates to conventional petroleum solvents may help.

Response: Regarding the hazard and risk discussion of the petroleum (hydrocarbon) solvents, EPA believes the CTSA addresses this apparent discrepancy. Although the hazard ranking for hydrocarbon solvents is high (Exhibit 3-3), the expected releases to the aquatic environment found in Chapter 4 are low. Consequently, the potential risk to aquatic organisms is projected to be low.

Comment #2-25: p. 2-1: The last sentence on the page doesn't make scientific sense. Molecular weight and structure can certainly by "measured" (experimentally determined). I am not sure why these distinctions are being made and what purpose they serve.

Response: Molecular weights can be measured but are usually calculated. Structures can not be measured directly. EPA has revised the document to clarify.

Comment #2-26: p. 2-1, Section 2.1: This chapter is meant to present the *concerns* associated with certain chemicals. There it is not clear to me why Section 2.1 is in this chapter at all. It

seems to me it could be relegated to an Appendix, as it presents information on physical and chemical properties.

Response: This change was made.

Comment #2-27: second paragraph: Does not describe data collection.

Response: No action is necessary.

Comment #2-28: p. 2-1, second paragraph: The second sentence should be changed to read "Section 2.2 presents *summaries* of known...", and refer the reader to the Technical Appendix A for more detail.

Response: This change was made.

Comment #2-29: p. 2-1, section 2.1.1: It is not clear in this section how chemicals were identified for examination in this chapter. Please make this more explicit (see also Exhibit 2-2)

Response: The chemicals considered in the hazard chapter were identified by product vendors.

Comment #2-30: p. 2-1, second paragraph, Section 2.1.1: This paragraph is not clear (why this determination is being made), unnecessary and should be deleted.

Response: This change was made.

Comment #2-31: Section 2.1: Text under 2.1 and 2.1.1 is a bit cumbersome.

Response: EPA has revised the CTSA to enhance readability.

Comment #2-32: p. 2-1: The transition in the beginning of this chapter is very abrupt. It is not clear why the particular set of chemicals was selected for analysis. There is no MSDS fr a cleaner and no way of knowing why the particular chemicals are the subject of focus. There should be a summary of water-based cleaners, the substances they contain and why those substances are there. In the CNT study, a particular formulation was used. It contained a glycol ether that is included on the hazardous Air Pollutant list in the Clean Air Act Amendments. This was a widely distributed report and it seems as if that formulation should be included here for analysis.

Response: The CTSA has been revised; the current Chapter 2 provides a list of the chemicals that are considered throughout the CTSA. This reorganization includes considering the chemicals by technology. Also, propylene glycol ethers have been included in the CTSA.

Comment #2-33: p. 2-1, *Chemical Information:* General comment - Organizing this section by

cleaning type (i.e., PCE, PS, wetcleaning chemicals) seems to be more logical than alphabetical (in both tables and narratives).

Response: This change was made (see response to Comment #2-32).

Comment #2-34: Section 2.1.1: Much of the chemical properties information contributes little or nothing to the overall purpose of the document. Might be OK as appendix material.

Response: This change was made.

Comment #2-35: p.2-1, 2.1: Between sentence 1 and sentence 2 add: PCE and PS is used at 100% concentrations in drycleaning. However, in wetcleaning, the detergents and soaps are chemical mixtures, typically containing up to 3-13 different chemicals and water. Most of the formulations are a trade secret and therefore the individual chemical concentrations are unknown. Nor is it known how representative the formulations considered in this report will be of the potential universe of formulations in existence for these developing processes. The following discussion provides descriptions of some of the various types of chemical that are commonly found in wetcleaning formulations but it is important to remember that the constituents and concentrations may vary significantly.

Response: Due to the reorganization of the hazard chapter, the introduction has changed dramatically. The intent of the suggested wording, however, was deemed useful and was inserted elsewhere in the current draft (at the beginning of the wetcleaning section).

Comment #2-36: p. 2-2, exhibit 2-1: the definition of the term Bioconcentration Factor is followed by ($Log_{10}K_{ow}$), but this should be (LogBCF).

Response: Agree, this change has been made.

Comment #2-37: p. 2-2: In Exhibit 2-1, why aren't LEL and UEL considered?

Response: These were included as properties for Stoddard Solvent but were not defined in the exhibit.

Comment #2-38: p. 2-2: Definition of Flash Point, 2nd line: should read "for an ignitible mixture with ~~an~~ air near the surface"

Response: This change was made.

Comment #2-39: p. 2-2: well balanced description of biologic effects

Response: No response necessary.

Comment #2-40: p. 2-2: Under flash point in Exhibit 2-1, it should read "an ignitible mixture with air."

Response: This change was made.

Comment #2-41: p. 2-2, Exhibit 2-1, Octanol Water Partition: Give an indication of direction (i.e., The higher(lower) and number the greater(less) the...

Response: This exhibit has been removed and the text has been changed.

Comment #2-42: p. 2-2: I hope this is a typographical error under the Octanol-Water Partition. I hope it is supposed to read "organics" rather than "organs."

Response: The statement has been corrected.

Comment #2-43: p. 2-2: The reproductive effects summary leaves a lot unstated, and a better statement would be, similar to our HESIS fact sheet: "Like other organic solvents, perchloroethylene can harm a developing fetus if the mother is frequently overexposed. Perchloroethylene inhaled by a pregnant woman can reach a developing fetus. Perchloroethylene can also contaminate breast milk. Therefore, pregnant or nursing women should avoid overexposure, just as they should avoid exposure to alcohol, tobacco, and other drugs."

Response: The commenter is comparing PCE with alcohol, tobacco, and drugs with respect to effects on pregnant women/fetuses; there are no data to support that.

Comment #2-44: p. 2-3, first paragraph: Can't some of the proprietary information on the chemicals (e.g., testing on the mixture) be obtained from MSDS sheets and TSCA s.5 Pre-Manufacture Notifications?

Response: Proprietary information was not available on MSDS's or Pre-manufacturer. Notifications and Pre-manufacture Notification information is generally kept confidential and would not be available for presentation in the CTSA.

Comment #2-45: p. 2-4, Exhibit 2-2: The footnotes explaining notations a, b, c, d and n/a don't seem to refer to anything in the exhibit.

Response: This change was made in the Appendix where this table has been moved.

Comment #2-46: p. 2-4: Chemical Synonyms for Perchloroethylene: should include "tetrachloroethene" the currently accepted IUPAC name (standard chemical nomenclature)

Response: Agree, see response to Comment #2-45.

Comment #2-47: p. 2-4: The chemicals in Exhibit 2-2 are listed with no explanation of why they are there. Again, a discussion with MSDSs is needed.

Response: See response to Comment #2-32.

Comment #2-48: p. 2-5 - 2-15: Please indicate how and where the chemical is used (e.g., wetcleaning, drycleaning, as part of a detergent or softener). Again, this information can be placed in an appendix.

Response: See response to Comment #2-32.

Comment #2-49: p. 2-9: Vapor pressure for Perchloroethylene is not listed. It is 18.47 mm Hg @ 25°C. Also useful would be the conversion factor: 1ppm = 6.78 mg/m^3 @ 25°C.

Response: The vapor pressure is listed as 18.5 mmHg @ 25°C. This is not significantly different than 18.47. The conversion factor was not deemed necessary.

Comment #2-50: p. 2-9: In the summary of chemical properties for PCE, there is no LogBCF given. This is an oversight, the value is 38.9.

Response: This change was made.

Comment #2-51: p.2-9: Under PCE synonyms, mark those that are a trade name.

Response: EPA has removed trade-names from the chemical descriptions except in the case of DF-2000.

Comment #2-52: p. 2-9: In the chemical properties of Perchloroethylene nothing is said about flash point. I believe it should be listed here that it is not flammable. However, if you turn ahead to page 2-53 a flash point is listed which I believe is in error.

Response: This change was made.

Comment #2-53: p. 2-9: Odor Threshold; Michigan's students found 50 parts per million (ppm) to be more fair and realistic for the industry to detect by smell.

Response: This change was made.

Comment #2-54: p. 2-13, and p.2-4: Synonym for Stoddard solvent - Mineral spirits (?)

Response: Mineral spirits has been included as a synonym for Stoddard solvent.

Comment #2-55: p. 2-13 and 2-15: Under molecular weight, the entries for Stoddard solvent and 140 degree solvent are identical. Yet the solvents have different properties. This is not possible. If they are composed of exactly the same chemicals, they must have the same properties.

Response: The presentation of the molecular weights has been modified. They represent typical low molecular weights and not the average molecular weights of the solvent mixtures.

Comment #2-56: p. 2-16 ***Safety Hazard Factors:*** Move this section to immediately following page 2-13, prior to the individual chemical property tables for clarity.

Response: Reformatting/reorganization has resulted in this information's being presented elsewhere (beginning of the Chapter).

Comment #2-57: p. 2-17, Section 2.2: A short summary of the health hazard of each chemical at the beginning of its description would be helpful. Also, PCE and PS should be first in the hazard analysis as they are first in the exposure assessment and risk assessment and are the chemicals for which substitutes/cleaner technologies are being sought.

Response: These changes were made.

Comment #2-58: p. 2-17, paragraphs on ignitability and corrosivity: This is not carried through consistently in the chemical exhibits. In fact, corrosivity doesn't seem to be indicated for any of the substances dealt with.

Response: These paragraphs have been removed.

Comment #2-59: p. 2-17, Section 2.2: I think it would be helpful to the reader to include one sentence at the outset of each chemical's health hazard summary to indicate the use of the chemical in the drycleaning process.

Response: Partially agree. We believe the reformatting/reorganization of the CTSA will clarify these types of issues throughout the document.

EPA has included mentions of chemical function and use in the cleaning process.

Comment #2-60: p. 2-18, last paragraph: Information on exposure, metabolism, etc. should be included in the exposure chapter.

Response: Although this portion of the document has changed, exposure is described in terms of route of exposure. Route of exposure, along with metabolism, is one of many critical elements of a hazard analysis.

Comment #2-61: p. 2-19: This table is often difficult to read, given its many abbreviations. Why is no LD50 provided for PCE. In the PCE section what do you mean when you say "unit risk 4.7x106 ug/m^3 below 2.1x103 ug/m^3. Under Stoddard solvent, what does levels based on human mean? This table should be all on one page.

Response: This table has been considerably reformatted and placed on a single page. The original was structured so that no LD50 or LC50 was supplied for any compound for which a LOAEL has been determined; the idea was that this is more nearly the range in which the reader is interested in knowing effects. "Unit risk 4.7 x 10^{-6} ug/m^3 below 2.1 x 10^{-3} ug/m^3" indicated that the unit risk should not be used at higher exposures. Multiplication of a unit risk by an exposure does not apply at higher exposures where the curve is expected not to be linear; historically this approximation has been assumed not to hold above 1% excess response. Under Stoddard solvent, the word "studies" mistakenly was omitted. These data are summarized now later in the final Chapter 3 and are cited in Appendix C.

Comment #2-62: p. 2-19, Exhibit 2-3: Exhibit 2-3 lists the adverse toxicological effects reported in the literature for PCE, yet it does not list oral exposure under the heading for Exposure Route. This is inconsistent with Chapter 4, Appendix A, and Appendix C, where information on the oral toxicity of PCE is presented.

In addition, the listed toxicity endpoints for PCE do not include liver and kidney toxicity, which are discussed in Appendix A and C. For example, the Exhibit does not contain the LOEL used to derive a RfC for PCE (Appendix C), which is used to assess non-cancer risks in Chapter 4. This inconsistency should be corrected.

Response: This table has been considerably reformatted and placed on a single page. The headings have been changed so these are routes of expected exposure, not of study exposure. The table (then Exhibit 2-3) was not intended to be exhaustive; the NOAEL and LOAEL shown, however, were the observed levels from the Stewart study used to corroborate the calculated levels in what was Appendix C. The Franchini levels utilized as a starting point in the final Appendix D are derived, not directly observed.

Comment #2-63: p. 2-19: Exhibit 2-3 is very difficult to comprehend because the information in many of the boxes has been truncated to fit the table on one page. I would suggest a two page table.

Response: This table has been considerably reformatted; the single page should now be clearer.

Comment #2-64: In Exhibit 2-3, under SLS synonyms, there is a ? in the table.

Response: The ? has been removed.

Comment #2-65: p. 2-19, Exhibit 2-3: Add a note for the abbreviation NOAEL and LOAEL. Also, rather than put all notes at the end of the table that is continued on p. 2-20, split the table earlier and put the notes that correspond to that page.

Response: This table has been considerably reformatted and placed on a single page.

Comment #2-66: p. 2-20, Section 2.2.1: EPA should be more explicit about the amounts of chemical constituents of the detergent mixtures that people will be exposed to. The amounts may be so minimal that providing hazard information on the individual components is misleading. For example, an individual cleaner may see that the detergent contains 10 different chemicals and think that exposure to those 10 is worse then exposure to just one, PCE. What is to say that the mixtures will act like the some of their components? Shouldn't EPA use information on the mixture as a whole? This is a difficult question, but EPA should be more explicit about these assumptions.

Response: The discussion on mixtures and formulation ingredients has been expanded in the final hazard chapter (Chapter 3) and simplified in the final risk chapter (Chapter 5). While the best information on a mixture comes from the mixture itself in the exposure circumstance of interest, risk assessment of mixtures is a complex endeavor, as the commenter noted. It is hoped the added discussions will assist the reader.

Comment #2-67: p. 2-20, second paragraph: A discussion of the respiratory hazards of acetic acid would be useful here: Glacial acetic acid is a known cause of the Reactive Airways Dysfunction Syndrome (RADS). See Kern DG. Outbreak of the reactive airways dysfunction syndrome after a spill of glacial acetic acid. Am Rev Resp Dis 1991:144:1058-1064. It can also cause late asthmatic responses (Kivity S., Fireman E., Lerman Y. Late asthmatic response to inhaled glacial acetic acid. Thorax 1994;49:727-728). Further discussion could go into the Technical Appendix A.

Response: EPA briefly reviewed these papers and it was decided that their inclusion was not important for this level of review.

Comment #2-68: p. 2-20, Section 2.2.1: Although this section is quite correct from a technical standpoint, I think it is overly dramatic. It should be mentioned that in its dilute form, we call acetic acid vinegar. This is done later in the document but I think it would be appropriate here as well.

Response: This change was made.

Comment #2-69: p. 2-20: All of the health hazard summaries are problematic. These summaries are very difficult to write especially for a general situation (as opposed to a specific exposure scenario). I found many of the statements to be quite misleading about health effects. They all should be rewritten. Perhaps the problem is the intended audience, but more specificity about the basis for attributing some health hazard would be more helpful even for those not trained in environmental health, etc.

Response: EPA reorganized, reformatted, and in many cases rewrote many sections of this chapter to make a better work product that is technically correct and easier to read.

Comment #2-70: p. 2-21: The phrase "...does not interact with genetic material in the test tube." is quite awkward. If the term *in vitro* is considered too technical perhaps a phrase like "...does not

interact with genetic material in tests with cells or cellular components." could be used. This phrase is used on several other pages in this section.

Response: Changes were made throughout the document where this phrase originally occurred.

Comment #2-71: p. 2-22: CAPB has been shown to be a contact allergen. This should probably be referenced. (DeGroot AC, van der Walle HB, Weyland JW. Contact allergy to cocamidopropyl betaine. Contact Dermatitis 1995,33:419-422).

Response: EPA disagrees. Angelini et al (1995) and Pigatto et al. (1995) have both confirmed that the major allergen is the impurity dimethylaminopropylamine used in the synthesis of CAPB. This new information has been added to the current draft of the CTSA.

Comment #2-72: p. 2-22: Bottom of page. Why provide detail on the hair dye study with CAPB when it appears to be negative?

Response: This change was made.

Comment #2-73: p. 2-23, fourth paragraph: Under what conditions is Ethoxylated Sorbitan Monodecanoate shown to enhance the activity of known cancer causing substances.

Response: This chapter summarizes information found in the Appendix. Appendix C contains a more detailed description of the tumor enhancing studies (MNNG administered to test animals with or without ethyoxylated sorbitan monodecanoate; slight tumor enhancement observed), and the tumor inhibition studies (in vitro studies with a mouse-derived tumor cell line).

Comment #2-74: p. 2-24, fifth paragraph, last line: To say it is not known if PCE can produce CNS effects through skin absorption, shouldn't this mean, "by skin absorption *alone*.?"

Response: No action is necessary.

Comment #2-75: p. 2-24: The Health Hazard Summary for PCE needs to be updated to reflect recent articles on the effects of PCE in human populations. These articles include studies on CNS effects (Altmann et al., 1990, 1992; 1995; Cavalleri et al., 1994; Ferroni et al., 1992), kidney effects (Mutti et al., 1992), and liver effects (Gennari et al., 1992; Brodkin et al., 1995). We have provided copies of each of these studies and the Preprint Draft of New York State Tetrachloroethylene Ambient Air Criteria Document (February 1997) for your information. The NYSDOH Criteria Document contains summaries of relevant tetrachloroethylene literature, including those articles mentioned above.

[Altmann, L., H. Florian Neuhann, Ursula Kramer, Jutta Witten, and Erich Jermann. 1995. Neurobehavioral and neurophysiological outcome of chronic low-level tetrachloroethene exposure measured in neighborhoods of dry cleaning shops. Environmental Research: 69: 83-89.

Altmann, L., H. Wiegand, A. Bottger, F. Elstemeier and G. Winneke. 1992. Neurobehavioral and neurophysiological outcomes of acute repeated Perchloroethylene exposure. Appl. Psych. 41: 269-279.

Altmann, L., A. Bottger and H. Wiegand. 1990. Neurophysiological and psychophysical measurements reveal effects of acute low-level organic solvent exposure in humans. Int. Arch Occup. Environ. Health. 3: 493-499.

Brodkin, C.A., W. Daniell, H. Checkoway, D. Echeverria, J. Johnson, K. Wang, R. Sohaey, D. Green, C.Redlich, D. Gretch and L. Rosenstock. 1995. Hepatic ultrasonic changes in workers exposed to Perchloroethylene. Occup. Environ. Med. 52: 679-685.

Cavalleri, A., F. Gobba, M. Paltrinieri, G. Fantuzzi, E. Righi and G. Aggazzotti. 1994. Perchloroethylene exposure can induce colour vision loss. Neurosci. Lett. 179: 162-166.

Ferroni, C., L. Selis, A. Mutti, D. Folli, E. Bergamaschi and I. Franchini. 1992. Neurobehavioral and neuroendocrine effects of occupational exposure to Perchloroethylene. Neurotoxicology. 13: 243-248.

Gennari, P., M. Naldi and R. Motta. 1992. Gamma-glutamyltransferase isoenzyme pattern in workers exposed to tetrachloroethylene. Am. J. Ind. Med. 21: 661-671.

Mutti, A., R. Alinovi, E. Bergamaschi, C. Biagini, S. Cavazzini, I. Franchini, R.R. Lauwerys, A. M. Bernard, H. Roels, E. Gelpi, J. Rosello, I. Ramis, R. G. Price, S. A. Taylor, M. DeBroe, G. D. Nuyts, H. Stolte, L. M. Fels and C. Herbort. 1992. Nephropathies and exposure to Perchloroethylene in dry-cleaners. Lancet 340: 189-193.

NYSDOH (New York State Department of Health) 1997. Preprint Draft. Tetrachloroethene Ambient Air Criteria Document. February 1997. Bureau of Toxic Substance Assessment. Albany, N.Y.]

Response: The CTSA is not a *de novo* assessment of risk, nor an exhaustive discussion of the literature. A number of these studies had been reviewed prior to the peer-reviewed draft, and we looked at this entire list prior to making our revisions and for this response to comments. Some changes have been made to augment the discussion of these endpoints.

Comment #2-76: p. 2-24: The discussion indicates that kidney, but not liver toxicity, has been observed in humans from long-term exposure to lower levels of PCE (first two sentences in third paragraph of section 2.2.7). On page 4-5, the discussion (first two sentences of second paragraph of section 4.2.1) indicates that dysfunction of the central nervous system, kidneys, and liver can occur in humans after long-term exposures to low levels of PCE. The inconsistency should be resolved. There is evidence of liver effects in humans from long-term exposure (Brodkin et al., 1995; Gennari et al., 1992).

[Brodkin, C.A., W. Daniell, H. Checkoway, D. Echeverria, J. Johnson, K. Wang, R. Sohaey, D. Green, C.Redlich, D. Gretch and L. Rosenstock. 1995. Hepatic ultrasonic changes in workers exposed to Perchloroethylene. Occup. Environ. Med. 52: 679-685.

Gennari, P., M. Naldi and R. Motta. 1992. Gamma-glutamyltransferase isoenzyme pattern in workers exposed to tetrachloroethylene. Am. J. Ind. Med. 21: 661-671.]

Response: These changes were made. The Brodkin and Gennari papers were reviewed and included in Appendix C.

Comment #2-77: p. 2-24, fifth paragraph, second last line: It would be clearer and more accurate to say that drycleaning personnel "did not perform as well on tasks that measure function of specific portions of the nervous system" rather than the existing text.

Response: The text was changed to read " did not perform well on neurobehavioral tests".

Comment #2-78: p. 2-24, fifth paragraph: Why do you say "suggestive of depressed brain activity. There is no question that PCE is a CNS depressant, on the one hand, while on the other, people may experience effects that *to them* seem at first like a stimulating effect (euphoria, release of inhibitions).

Response: While it may be true that PCE is not only a depressant, more details on the CNS effects of
PCE are provided in Appendix C.

Comment #2-79: p. 2-24, Section 2.2.7: PCE: General comment - After I received the CTSA draft, I received a "clarification" of EPA's evaluation of PCE's carcinogenicity (enclosed with your letter of August 6, 1997). The cover letter suggested that this applied specifically to certain sections, but did not reference section 2.2.7, where it is quite pertinent. In particular, sentences that question the relevance of the animal studies to humans in this section (2.2.7 paragraph 4) and the oblique reference to the weaknesses in the finding of increased rates of esophageal cancer confuse the issue addressed by the "clarification" (which is not itself very "clear"). Moreover, it does not mention that the esophageal cancer results were found specifically in drycleaning workers, making them particularly relevant. Also, there is no mention of results from 1993 of leukemia and bladder cancer in a PCE-only exposed population (Aschengrau et al., 1993).

[Aschengrau, A., D. Ozonoff, C. Paulu, P. Coogan, R. Vezina, T. Heeren, Y. Zhang. 1993 Cancer risk and tetrachloroethylene-contaminated drinking water in Massachusetts. Arch. Environ. Health 48: 284-292.]

Response: The Aschengrau et al. (1993) study had been used in preparing the hazard summary for PCE, as is made clear in final Appendix C, where citations are included. While the language of this paragraph is not much changed in final Chapter 3, the overall discussion explicitly identifies the conclusion of IARC that PCE is probably carcinogenic to humans.

Comment #2-80: p. 2-24 (PCE Health Hazard Summary) and p. 2-33 (Environmental Hazard Summary for PCE): Information should be added to the Human Health Hazard Summary indicating that values are available for acute and chronic inhalation Minimal Risk Levels (MRLs) from the Agency for Toxic Substances and Disease Registry (ATSDR). For PCE, the acute inhalation MRL for exposures of 24 hours or less is 0.2 parts per million (ppm) (1,360 micrograms per cubic meter) and the chronic inhalation MRL for exposures of 1 year or more is 0.04 ppm (270 micrograms per cubic meter). There is no intermediate inhalation MRL.

In addition, the EPA Maximum Contaminant Level (MCL) for PCE in drinking water is 5 micrograms per liter. This information is very useful to allow the reader to put into context the levels of PCE in air and water referred to later in the CTSA. These guidance values and standards should be added to this section. The Environmental Hazard Summary already contains estimated acute and chronic toxicity values for fish, daphnid and algae. By adding information to the Human Health Hazard Summary, the two sections would be more uniform in approach.

Response: References are made to the MCL in Chapter 5, where discussion of comparison values is appropriate. The study (Ferroni et al., 1992) used by the ATSDR to derive its chronic (>1 year) MRL was reviewed; the MRL was derived from effects observed at a level higher than those in the study (Franchini et al., 1983) used for our provisional RfC.

Comment #2-81: p. 2-24: The nervous system effects should be characterized as central or peripheral or both. Further, the central effects may be permanent if the dose is high enough and prolonged, e.g., an individual in coma after an exposure.

Response: The data reviewed and presented in the CTSA suggest that perchloroethylene affects primarily the central nervous system.

Comment #2-82: p. 2-24, seventh paragraph, first sentence: Should read, "probably carcinogenic *to humans.*"

Response: This change was made.

Comment #2-83: p. 2-24: Symptoms should probably be more clearly stated: the literature suggests that dizziness on rapidly arising is a prominently-reported system, followed by fatigue, eye irritation, headache and nervousness (Echeverria D, White RF, Sampaio C. A neurobehavioral evaluation of PCE exposure in patients and drycleaners I: A possible relationship between clinical and pre-clinical effects. Proc. of 9th Int. Symposium on Epi. In Occ Hlth. Sept. 23-5, 1992, Cincinnati, OH, ICOH. NIOSH Pub. 94-112, pp. 376-383.)

Response: This chapter summarizes more detailed information that may be found in Appendix C, where more complete information on symptoms observed in humans is presented.

Comment #2-84: p. 2-24: Discussion of 'low' and 'high' exposure levels for Perchloroethylene would benefit from definitions of these terms: does low mean <PEL (100 ppm), or <ACGIH (50 ppm), or <OSHA proposed 1989 PEL (25 ppm), or some other value? Further examples of acute toxicity to humans should also be discussed in the summary. Perchloroethylene is an eye, skin, and respiratory irritant. Cardiac sensitization and arrythmias have been reported following acute exposure to high concentrations of Perchloroethylene (Reprotext System. Dabney BJ, Ed. Micromedex, Inc. Denver Co. 1993). Persons with high blood pressure may be at increased risk of exhibiting elevated blood pressure following exposure to Perchloroethylene. Interactions between Perchloroethylene and ethyl alcohol ingestion have been reported, resulting in potentiation of toxicity (Reprotext, 1993).

Response: This change was made.

Comment #2-85: p. 2-24: The four sections (sections 2.27, 4.2, Appendix A, and Appendix C) discussing the health effects of PCE are inconsistent and should be revised to provide a more uniform approach.

Response: EPA believes that the extensive reorganization/reformatting has taken care of these inconsistencies.

Comment #2-86: p. 2-24: Section 2.2.7: The type of nervous system tests used on drycleaning operators should be described (neurobehavioral, etc.).

Response: This change was made.

Comment #2-87: p. 2-24, Section 2.2.7: It is unclear why reviewers were not instructed to insert the EPA clarification here. PCE is a known nervous system depressant, the fact of which is downplayed in the 2nd paragraph. In Paragraph 4, EPA notes that "it is not clear if the tumors developed in these animals are relevant to humans." Unless proven otherwise, it is generally accepted that tumors in laboratory animals are indicative of potential for tumors in humans. The next sentence noting "the significance of this finding is limited due to weaknesses in the study" is disingenuous in that all epidemiologic studies are limited - this statement tends to downplay uncertain health risks (which almost always occurs.) Given the large amounts of PCE used in the industry, this section needs to consider interactions of PCE with other chemicals both in the workplace (air) and in groundwater.

Response: No action is necessary.

Comment #2-88: p. 2-24, second paragraph in Section 2.2.7, third sentence: I would insert "short term" before "effects on the nervous system." The more subtle neurotoxicity that has been by Echeveria et al (1995) (see ref. 69 in Appendix A) appear to be long term and may be an indicator of other essentially irreversible neurotoxicity.

Response: This change was made.

Comment #2-89: p. 2-24, first paragraph in Section 2.2.7: The good absorption of PCE by ingestion is generally irrelevant to the modes of exposure that result from drycleaning. More objectionable is the repeated statement here and elsewhere (see, for example, p. 4-5, 1st paragraph under Section 4.2.1) that PCE is "more slowly" or "poorly" absorbed via the skin. What quantitatively is meant by "more slowly" or "poorly" or the other vague quantifiers that are used? Also, there is no reference to the skin absorption data here or, as far as I can tell, elsewhere. The specific references providing the basis for this conclusion should be cited.

Response: Changes have been made by retrieving, reviewing and including studies by McDougal et al. (1990) and Riihimaki and Pfaffli (1978) in Appendix C. A summary of this information is also in the current hazard chapter (3).

Comment #2-90: Sec. 2.2.7, fourth paragraph: Critical summary of human health effects, but is too vague, overly-simplified.

Response: The chapter is intended as a summary. More detailed reviews appear in (final) Appendix C.

Comment #2-91: p. 2-24: in the first paragraph of section 2.2.7, there is a statement that "Most of the PCE that is absorbed into the body..." I think this statement should read, "Most of the PCE that is inhaled into the body rapidly leaves, unchanged, in the exhaled air."

Response: This suggestion is reasonable, but not necessary. The statement is in the middle of the

paragraph describing inhalation exposures.

Comment #2-92: p. 2-25: This summary should at least mention the issue of take-home exposure to family members, and this route of exposure is not addressed anywhere in the document. (Aggazzotti G, et al. Occupational and Environmental Exposure to Perchloroethylene in Drycleaners and their Family Members. Arch Env Health 1994; 49:487-493, and Aggazzotti G, et al. Indoor Exposure to Perchloroethylene in Individuals Living with Dry-Cleaning Workers. Science of Total Environment 1994;156:133-137). Discussion of exposure and risk should be added to the respective chapters for this important subgroup of family members of drycleaning workers.

Response: The exposure chapter (4) addresses take-home potential.

Comment #2-93: p. 2-25, second paragraph: There is abundant laboratory evidence for the effects of the metabolic products of PCE (TCA and DCA) having an effect on reproduction, and some epidemiological evidence as well. To say that some existing epidemiological studies have "limitations" is to say nothing. That is the nature of *every* epidemiological study. This is just a disingenuous way to avoid confronting some uncomfortable data.

Response: No action is necessary.

Comment #2-94: p. 2-25: The cancer discussion should probably mention other cancers, including Non-Hodgkin's Lymphoma which have been found to be elevated with Perchloroethylene exposure. (Weisenburger DD. Epidemic of Non-Hodgkin's Lymphoma: Recent findings regarding an emerging epidemic. Annals of Oncology 1994:5:S19-S24).

Response: The Weisenburger study was retrieved and reviewed. It appears to give no specific evidence of NHL associated with PCE exposure. Its citations will likely be examined for the Agency reassessment to be undertaken soon.

Comment #2-95: p. 2-25: "However, it is not clear if the tumors developed in these animals are relevant to humans." What does this mean? Only one study of PCE workers is indicated. A more comprehensive assessment of the human studies should be included.

Response: A comprehensive assessment was beyond the scope of the CTSA. We hope the revised language regarding the conclusion by IARC and others will be helpful.

Comment #2-96: p. 2-25, top of page: I believe there have been esophageal cancer excesses found in the Blair study, as well as Ruder, 1994. The authors should refer to the recent reviews by the New York Department of Health and Weiss (1995) on this point.

Response: Additional interpretations of studies we included can be helpful. We did not include Weiss (1995), however, because we already had the conclusions of IARC available to include in our discussion.

Comment #2-97: p. 2-26, Section 2.2.9, SLS, second paragraph, third line: There are some words missing here ("no to severe skin irritation") that obscures the meaning.

Response: No action is necessary.

Comment #2-98: p. 2-26, Section 2.2.1.1 Stoddard (Petroleum) Solvent Health Hazard Summary: This section should contain a discussion of the aspiration potential of Stoddard solvent. One citation to support the aspiration potential of PS is a paper by Dr. Horace Gerarde published in 1963, entitled Toxicological Studies on Hydrocarbons IX. The Aspiration Hazard and Toxicity of Hydrocarbons and Hydrocarbon Mixtures (copy enclosed).

[Copies of web pages at: http//www.cdc.gov/niosh/127184.html -- http//www.cdc.gov/niosh/8052413.html]
[Thompson, K.M., and J. S. Evans, 1997. The value of improved National Exposure information for Perchloroethylene (PCE): A case study for drycleaners. Risk Analysis. 17:253-271.]
[Gerade, H.W. 1963. Toxicological Studies on Hydrocarbons IX. The Aspiration Hazard and Toxicity of Hydrocarbons and Hydrocarbon Mixtures. Archives of Environ. Health. 6:329-341.]

Response: EPA disagrees. After reviewing the Gerade paper, it appears that any discussion of aspiration potential is speculative; no direct evidence for aspiration toxicity of Stoddard Solvent was mentioned in Gerarde.

Comment #2-99: p. 2-27: The CTSA indicates that it is not known if petroleum solvent can produce cancer. Virtually all petroleum solvents contain some aromatic fractions including benzene. Benzene is an established human carcinogen. It would seem that it could be assumed that petroleum solvent is a potential carcinogen.

Response: EPA agrees.

Comment #2-100: p. 2-27: I believe this is based on the Dr. Mergler's Canadian group and should be listed as "decreased color discrimination" not full "color blindness."

Response: This change was made.

Comment #2-101: p. 2-27, section 2.2.12, second paragraph: confusing -- lens defects vs. cataracts

Response: Microwave drying is no longer being considered in this CTSA.

Comment #2-102: p. 2-27: Prior history of Stoddard Solvent exposure has been shown in one study to correlate with adverse neurological ratings among drycleaners (Tuttle TC, et al. A behavioral and neurological evaluation of drycleaners exposed to Perchloroethylene. DBBS, NIOSH, Pub. No. 77-214, 88 pages). Also, animal studies have demonstrated carcinogenic activity of Stoddard Solvent for skin, liver and kidney. Studies also suggest variable excesses in respiratory, bladder, and kidney cancers in humans exposed to Stoddard Solvent. Cigarette smoking may be confounder in some of these studies, however. (Rothman N, Emmett EA. The carcinogenic potential of selected petroleum-based products. Occupational Medicine: State of the Art Reviews 1988;475-

494).

Response: Thank you for bringing this information to our attention.

Comment #2-103: p. 2-27, fifth paragraph, section 2.2.12, Microwaves: Recent information from Australia on pulsed digital microwaves suggests tumor promotion. What kind of microwaves are used here?

Response: Consideration of microwave drying has been deleted from the CTSA.

Comment #2-104: p. 2-28, General comment on Section 2.2: It is interesting to note in Section 2.2.13 that many substances have been left out of the discussion. Although it is not mentioned in this section, carbon dioxide is not dealt with either. By any standards, carbon dioxide can be very hazardous. It is not appropriate to leave it out of this discussion.

Response: Because of the emergent status of this technology, it is not clear how relevant CO_2 hazards are to the liquid CO_2 process. Therefore, CO_2 hazards have not been included.

Comment #2-105: p. 2-28, Section 2.3: Much of this section has nothing to do with the hazard evaluation of the different alternatives and should be relegated to an appendix (it is methodology). This comment applies to the majority of places where methodology is described in the text.

Response: EPA has revised the document to enhance readability.

Comment #2-106: p. 2-28, Section 2.2.13: EPA notes that no health information was located for sodium carbonate - this was included in s. 2.2.8.

Response: This change was made.

Comment #2-107: Section 2.3 of Chapter 2 is very difficult to understand. There is too much information provided which makes it hard to glean what is important and clouds the issue. This reviewer feels that the point could be better made if most of this section was in the Appendix and summarized here. Exhibit 2-4 itself provides a clear picture of the aquatic toxicity impact but when reading through this section, it all becomes muddied in technical terms that may be an informative read for a toxicologist but not others. This reviewer believes this section should be limited to a general overview to lessen confusion.

Possible modifications (marked on document copy):
Section 2.3.1, Env. Hazard Assessment Methodology
Par 1: OK
Par 2: (including bullets): OK
Par 3-Par 7: appendix
Determination of Concern Concentrations
Par 1: OK (include S1 of P2)
Par2-Par 3: appendix

Hazard Ranking: OK

Section 2.3.2, Results

Par 1: OK

Par 2: repeat of above Hazard Ranking - remove

Par 3: OK

Section 2.3.3: appendix - table says it more clearly

Section 2.3.4: appendix - "(except for paragraph 3, last sentence, which should be moved to *Determination of Concern Conc.*, par 1 - "If the discharge of a chemical to the aquatic env. results in a concentration...to aquatic organisms.")

Exhibits 2-6, 2-7: appendix

Response: Much of this information is now Appendix B.

Comment #2-108: p. 2-28, seventh paragraph: six effective concentration, three chronic and three acute,...

Response: This change was made.

Comment #2-109: p. 2-28. Under section 2.2.13, the CTSA indicates that no health data were located for sodium carbonate. This material was already discussed on page 2-25.

Response: This change was made.

Comment #2-110: p. 2-29, last paragraph: Again, I must keep reminding that synthetic hydrocarbons are noticeably absent from this CTSA. In this last paragraph they would not fit in that I believe they are most likely single component materials and not mixtures.

Response: EPA has included information on the synthetic hydrocarbons (DF-2000) where possible.

Comment #2-111: p. 2-29, last paragraph: Detergents, softeners, and surfactants are also mixtures that do not lend themselves readily to hazard assessment using SARs.

Response: The language has been changed to reflect his.

Comment #2-112: p. 2-30, second paragraph: Given the complexity of ecological systems, there is no reasonable basis to use smaller assessment factors when more information is available (this does not necessarily mean more certainty, given that the uncertainty is in the model not in parameters). The determination of safety factor information should be relegated to an appendix.

Response: This change has been made.

Comment #2-113: p. 2-30: Determination of Concern Concentration. This section is very confusing. The definition of concern concentration should be contained in a box.

Response: Most of this information has been moved to an appendix and the discussion has been revised to make it clearer.

Comment #2-114: p. 2-31, line 1 (Hazard Ranking): Chemicals can then be...

Response: This text was revised.

Comment #2-115: Section 2.3.1, p. 2-31: First sentence under "Hazard Ranking" missing "be".

Response: This text was revised.

Comment #2-116: p. 2-31, Section on Hazard Ranking: The word "be" is left out of the phrase "Chemicals can then be ranked."

Response: This text was revised.

Comment #2-117: p. 2-32: The use of SAR in this context is appropriate and useful.

Response: No response necessary.

Comment #2-118: p. 2-32, Exhibit 2-4: Note on concern concentration has typographical error in 0.001. Also, the lowest chronic values are supposed to be in bold but not depicted that way. Note on concern concentration states that the lowest is divided by 10 but there is an entire description in the narrative of how this is calculated. Which is correct?

Response: These changes have been made. The discussion on concern concentration has been made clear.

Comment #2-119: p. 2-32, Exhibit 2-4: Place high, medium or low concern determination in the table. Need to indicate which assessment factors are applied here.

Response: Exhibits 2-4 and 2-5 were combined.

Comment #2-120: p. 2-33, first paragraph: "The results of this listing (not ranking) are summarized..." Exhibit 2-5 can be combined with Exhibit 2-4 here. If not, Exhibit 2-5 should be on this page.

Response: EPA has clarified the language.

Comment #2-121: p. 2-33, Section 2.3.3: It is unclear how the chronic toxicity ranking was conducted for PCE (or for the other chemicals). Please be more explicit.

Response: This language was revised.

Comment #2-122: p. 2-33, Section 2.3.4, third paragraph: The last sentence of this paragraph is repetitive and can be deleted.

Response: This language was revised.

Comment #2-123: p. 2-33, line 1, second sentence: The chemicals are not ranked by hazard potential, they are in alphabetical order in Exhibit 2-5.

Response: The language has been made clear.

Comment #2-124: p. 2-34, Exhibit 2-5: This is a listing and not a ranking. It is unclear why EPA chose the concentration of concern for some chemicals (such as citric acid and acetic acid) and the lowest chronic value for others. If the lowest chronic value is used consistently, acetic acid would receive a hazard rank or low and citric acid of medium.

Response: The ranking for acetic acid is low and for citric acid is medium. Explanation has been included.

Comment #2-125: p. 2-35, Section 2.3.5: What about environmental fate of PCE in mixtures. When found in groundwater this is frequently the case (for any chlorinated solvent). It would be useful to put the environmental hazard and fate sections for each chemical together to increase readability.

Response: The information on fate has been included with the chemical-physical properties. Environmental fate of PCE in mixtures was not addressed, in part, because of the complexity of anticipating what mixtures may be present.

Comment #2-126: p. 2-35: Move Exhibit 2-7 to right after Exhibit 2-6.

Response: The format of the CTSA has been revised to make the presentation better.

Comment #2-127: p. 2-35, Exhibit 2-7: Move up to be directly below Exhibit 2-6.

Response: The format of the CTSA has bee revised to make the presentation better.

Comment #2-128: p. 2-36, third paragraph: Two typographical errors on line 8 - *"the"* and *"thought."*

Response: These have been corrected.

Comment #2-129: Sec. 2.3.6, second paragraph: Describes action, not fate.

Response:

Comment #2-130: p. 2-36: There is no disagreement as to whether PCE is an ozone depleter; it is not.

There are two typographical errors in the first small print paragraph about halfway down. It should read "The source of the chlorine atoms in the smog chamber is thought...."

The exemption of PCE from VOC regulations was finalized long ago. PCE/s toxicity has nothing to do with whether it is a VOC or not.

Response: This material was removed from the CTSA.

Comment #2-131: p. 2-36 (quotation): "The (not Th) source of the chlorine atom...

Response: This change was made.

Comment #2-132: p. 2-37, Section 2.4: FEDERAL REGULATORY SUMMARY of Chapter 2 does not fit into the overall purpose of Chapter 2. It seems to be more suited to the background information of Chapter 1. In addition, the Clean Air Act NESHAP is a major burden on drycleaners and would seem to have a significant impact on a cleaners decision to consider alternative technologies. Yet the impact of the regulation on a drycleaner is not apparent from this brief summary. This reviewer believes that more attention should be given to this area.

Response: In light of this and similar comments, EPA has moved the *Federal Regulatory Summary* into a separate chapter. EPA has also expanded the current discussion on the impact of the NESHAP on clothes cleaners.

Comment #2-133: p. 2-37:. Stoddard solvent is not a "potential" VOC, it is a VOC because it has not been specifically exempted from VOC regulations. This should be changed in two places on this page.

Response: This change was made.

Comment #2-134: p. 2-37, Section 2.4: I am not sure why this section is in this chapter as it has nothing to do with hazard (once again, EPA is mixing its idea of a risk assessment with an alternatives assessment). Throughout the document, it is often unclear as to what the exact purpose of the document is. Is it a technology options assessment, a risk assessment, a regulatory summary, a financial analysis, etc. Given the current structure of the document, this section should go in an appendix or in the trade-off or costs sections. The rationale for this is that current and future regulatory requirements/actions will have an important influence in the choice of technologies for a specific drycleaner. Alternatively, some of this information could go in the first chapter.

Response: The *Federal Regulatory Summary* has been moved to a separate section of the document.

Comment #2-135: p. 2-37, Section 2.4: While there is a wealth of information in this section the whole thing should be summarized in a single table: chemical substance vs. regulatory compliance requirement - is the substance covered, what section of the regulation applies and what are the release limits. A major problem is that this section is presented as having an impact on decision making concerning alternatives to current processes. Yet virtually all of the data presented is on the current methods. The lack of any data concerning alternatives significantly decreases the utility of the data other than to repeat baseline information.

Response: EPA has included a summary table at the beginning of the chapter which lists the technologies and their applicable regulations. Information on potential regulation of alternative processes is speculative. Therefore, EPA can only present information on those technologies that are currently regulated. These necessarily correspond to the established technologies. EPA does not believe that this diminishes the utility of the CTSA, but merely illustrates the current trade-offs associated with choosing one technology over another.

Comment #2-136: p. 2-37: 2.3.7 contains a description of adsorption and biodegradation. This should have been described earlier in the document where it is first mentioned for PCE/PS.

Response: EPA believes that these terms will be familiar to the reader and that they are adequately described.

Comment #2-137: p. 2-38, Exhibit 2-8: Does the % removal of 0 for sodium carbonate mean that there is 0% removal or it is unspecified?

Response: 0% means that there is no removal expected in a POTW.

Comment #2-138: p. 2-38: Exhibit 2-8 does not include PCE, Stoddard solvent, and other petroleum solvents. It does include sodium alkylbenzene sulfonate, not previously seen in CTSA tables.

Response: The environmental fate of perc and stoddard solvent (now called hydrocarbon) are discussed in previous paragraphs. The exhibit has been retitled to make it clear that the table refers to machine wetcleaning chemicals. Sodium alkylbenzene sulfonate has been removed from the exhibit.

Comment #2-139: p. 2-39: Under the discussion of section 112 of the Clean Air Act, the CTSA states that "these standards require emitters to establish and maintain records, make reports" and so on. They also require emitters to install controls.

Title VI of the Clean Air Act has been superseded by regulations enacted later. The production ban date for the CFCs and 1,1,1-trichloroethane was moved from 2000 and 2002 respectively to January 1, 1996. The dates in the Clean Air Act are no longer relevant.

Response: EPA has modified the text to indicate the most accurate language found in Section 112 CAA. In addition, EPA has clarified the discussion regarding Title VI and edited the text with regard to the phase out dates for CFCs and 1,1,1-TCA.

Comment #2-140: p. 2-40: photo-chemical needs to be changed to photochemical.

Response: This change was made.

Comment #2-141: p. 2-40: I'd mention the Small Business Assistance Programs, set up by Section 507 of the Clean Air Act Amendments, under Chapter 2 (2-40) are available to help fabricare operators determine whether or not they are "major sources" under Title V. The 507 SBAPs, located in each state across the country, have done extensive work with drycleaners. The program contacts for each state could be listed in the appendix section. For a list of contacts, call Deb Elmore, EPA Federal SBAP Coordinator at 919-541-5437.

Response: EPA has included information about the SBAP programs in the text.

Comment #2-142: p. 2-40. EPA has apparently made a decision that all sources subject to a NESHAP--even area source NESHAPs (like drycleaners)--will have to eventually obtain a Title V permit.

Under the discussion of wetcleaning, the CTSA indicates that there is no information regarding regulation of wetcleaning under the CAA. The formulation used by the facility in the CNT study contained an ethylene glycol monobutyl ether which is a listed HAP under Title III and is a VOC.

Response: EPA has reviewed this section and determined that the sentence mentioned by the reviewer specifically points to "major sources", rather than stating that all sources must obtain a Title V permit.

EPA has acknowledged that some detergents used in machine wetcleaning processes may be subject to some of the requirements of the Clean Air Act, that, however, the constituents of the sample detergent selected for illustration in the CTSA, are not. However, EPA has included text specifically stating that other wetcleaning chemicals my apply to this and other regulations.

Comment #2-143: p. 2-42, third paragraph, line 1: remove commas: direct, or point source

Response: The text was edited.

Comment #2-144: p. 2-43, PCE cleaning: Not all carbon adsorbers will generate 1500 gallons of wastewater per year. This value is for a full sized carbon adsorber containing several hundred pounds of carbon, usually used for second generation equipment. Smaller door fan carbon adsorbers could be expected to generate 1/5-1/3 the wastewater of larger carbon adsorbers.

Response: The difference between the two carbon adsorbers was researched and it was determined that the text was accurate in its present form.

Comment #2-145: p. 2-43. Under waste water discharges, the CTSA indicates that commercial and industrial customers "may be" required to comply with regional and local discharge requirements. This should be changed to "are."

Under PCE Cleaning, the CTSA indicates that waste water typically is distilled. Waste water is never distilled. Refer to the description in the enclosed document.

[Water Environment Federation. 1995. Controlling Dry Cleaner Discharges in Wastewater: How to Develop and Administer a Source Control Program.]

Response: The text was edited where appropriate. The Agency has reviewed the referenced article and modified the text in a manner that makes the statement accurate.

Comment #2-146: p. 2-43, Section on Waste Water Discharges to POTW, last paragraph: Picrin is a trademark of R.R. Street & Co. for its volatile dry spotter. There are a number of commercially available volatile dry spotters, most if not all of which would be very similar to Picrin.

Response: EPA is aware that other spotting agents are available on the market. Picrin is used as an example because it was in the CNT study referenced in this paragraph.

Comment #2-147: p. 2-43, second paragraph, bullet #3: 33 lbs/month discharge of haz. waste...Where does this come from? Contradicts page 2-44, paragraph 1 which states 15 kg/mo.

Response: 33 lbs and 15 Kg are roughly equivalent values if the standard conversion of 1 kg = 2.205 lbs is used in the calculation. EPA has edited the document to include both units.

Comment #2-148: p. 2-43, Section on PCE Cleaning, first paragraph: Except in the event of a major malfunction with a distillation unit, it is most unlikely that boiler blowdown water would contain any PCE. On very rare occasions, a leaking steam chest in a still can cause still bottoms and hence PCE to be drawn back into a boiler after it is shut down. This is such a rare occurrence that it is hardly worth mentioning. Also, I have never encountered a plant that distilled waste water. Gravity separation is universal but to the best of my knowledge, distillation of waste water never occurs.

Response: EPA has conferred with an industry expert and determined that PCE contamination of boiler blow down water is an unlikely event. The text has been edited in an appropriate manner to develop a more accurate statement.

Comment #2-149: p. 2-44, Section on Petroleum Solvent Cleaning: This statement is most inconsistent with the earlier expression of concern about the aquatic toxicity of petroleum solvents.

Response: The text was edited to develop a more accurate statement regarding petroleum solvent toxicity.

Comment #2-150: p. 2-44. Under Petroleum Solvent Cleaning, the CTSA should indicate that some

POTWs have limits on flammable material discharge.

Response: The text was modified to include this information.

Comment #2-151: p. 2-44, paragraph 4, Petroleum Solvent Cleaning: Need an explanation of the waste water streams in the event of local discharges, similar to page 2-44, paragraph 5, line 5 on wetcleaning. POTWs may prohibit the discharge of PS or PS contaminated waste water. Limits may be exceeding, especially by an accidental spill or leak. PS would also be prohibited in a septic system.

Response: EPA has determined that there are not available waste water stream analyses for petroleum solvents, similar to the wetcleaning waste water discharge profile found in this section. EPA has also modified the text to reflect the most accurate information regarding discharge limits for hydrocarbon clothes cleaning processes.

Comment #2-152: p. 2-44 to 2-50: New York and California require double carbon wastewater treatment of PCE separator waster, whether or not it is discharged to a POTW.

Also add that if there are malfunctions of the still, such as still boilovers, PCE emulsions, and/or filter adsorbents, containing concentrated PCE, can carry over to the wastewater, greatly increasing the PCE concentration above its water solubility value of 150 ppm, perhaps by an order of magnitude or more.

Response: State and local regulations are not considered, as they pertain to Federal regulations, for this analysis. EPA has reviewed the text and determined that a discussion of the impact of still malfunctions on the concentration of PCE in wastewater is not necessary in this section.

Comment #2-153: p. 2-45, Paragraph 6: This paragraph is consistent with County and State regulations in NE States, which require DEPES permits or prohibit discharge of water from a cleaner into a septic system. This fact is not mentioned anywhere else in this document. Why?

Response: EPA has included additional information about discharge of waste water into septic systems under the Safe Drinking Water Act - Underground Injection Control regulations.

Comment #2-154: p. 2-46, *Classification of Haz. Waste*: Paragraph 1 poorly written. Remove sentence 2. Replace with: A waste can be classified as hazardous if it is either 1) listed or 2) characteristic. Add to sentence 3: Listed wastes are specifically named <u>in the regulations</u>(...) <u>as noted below</u>.

Response: EPA has edited this sentence in order to reflect the most accurate statement about Listed Wastes.

Comment #2-155: p. 2-47, last paragraph on the page: There are no conditions under which wetcleaning chemicals would be stored in UST's.

Response: This text was edited in order to clarify the statement.

Comment #2-156: p. 2-47: Suggested additions to generator requirements:

- Use only licensed Treatment, Storage and Disposal Facilities
- Comply with employee training requirements
- Conduct weekly inspection of haz. waste storage area
- Properly label containers
- Notify authorities of any spill exceeding the reportable quantity

Response: The text was modified at the suggestion of the reviewer, to include this information.

Comment #2-157: p. 2-48, second paragraph, sentence 4: exempts PCE waste water as a listed haz. waste but it could still be a hazardous waste if characteristic (TCLP).

Response: EPA has verified this information and modified the text.

Comment #2-158: p. 2-48, second paragraph: It does not refer to the possible use of evaporators to handle the waste water generated. Should it be included in this paragraph? Is it allowed? It is discussed earlier in the CTSA.

Response: The text was modified to include information regarding evaporators and waste water.

Comment #2-159: p. 2-48: The CTSA indicates that typical separator water contains 150 ppm of PCE and is considered hazardous waste because it exceeds the TC level. Actually the TC level is much lower but the separator water is hazardous waste no matter what level of PCE it contains because of the "derived from" rule.

Response: EPA has reviewed the "derived from" rule under RCRA and modified the text to portray the most accurate information regarding this topic.

Comment #2-160: p. 2-48, Section on PCE Cleaning: The first sentence in this section should read "Drycleaners using PCE commonly produce up to four types of listed hazardous wastes." Very few drycleaners produce all four types of waste. Also, the second sentence might better read: "Amounts of these wastes produced depend on the cleaning capacity of the facility and the type of equipment used."

Response: EPA has reviewed the suggested changes and modified the text accordingly.

Comment #2-161: p. 2-48, Exhibit 2-10: It has been my experience that modern Drycleaners in the NE (Primarily PCE-K, L & M's) generate approximately 30-40 Total Lbs. of waste/1000 Lbs. of Clothes cleaned.

Response: Exhibit 2-10 contains estimates of waste produced by the average drycleaner in the U.S. This information has been reviewed by EPA and was not modified in the text.

Comment #2-162: p. 2-48: Drycleaners using PCE or PS or HC would not generate both spent filter cartridges and cooked powder residue. Cooked powder residue would imply the use of diatomaceous earth which is not used with cartridges. This carries over to Exhibit 2-10.

Response: EPA has modified the text to reflect more accurate information regarding filter cartridges and cooked powder residues.

Comment #2-163: p. 2-48, first paragraph: Generator status may vary from month to month. This is not correct (or maybe misleading). If a generator is a SQG and one month out of the year goes over the SQG limit, he is a LQG for the entire year and similarly for CESQG becoming a SQG for the year.

Response: EPA has included a section on *episodic generator* status under RCRA which explains the issue of changing generator status, alluded to by the reviewer.

Comment #2-164: p. 2-49, first paragraph: PS could be regulated as a characteristic haz. waste if the flash point is less than 140 degrees (ignitable).

Response: EPA has verified this information and modified the text to reflect the commenter's suggestion.

Comment #2-165: p. 2-49: Spent petroleum solvent with a flash point less than 140 degrees F would be classified as a hazardous waste under RCRA.

Spent material from the wetcleaning process could be considered hazardous waste under RCRA if spotting chemicals contained within it were listed hazardous wastes (like PCE or trichloroethylene).

Response: EPA has verified this information and modified the text to reflect the above suggestion. EPA is not considering spotting chemicals as a part of this analysis.

Comment #2-166: p. 2-50: About halfway down "adsorbers" should read "adsorbers.

Response: The text was modified appropriately.

Comment #2-167: Sec. 2.4.4, p. 2-50, third paragraph: Under "PCE Cleaning": 1.9 pounds seems quite small. Is number correct (CTSA Review/Comments, page 8).

Response: EPA has verified this information in the cited text.

Comment #2-168: p. 2-50, second paragraph: should be jointly.

Response: EPA did not modify the text based on this comment.

Comment #2-169: p. 2-50, Section on Petroleum Solvent Cleaning: I find it difficult to believe that nothing can be found on this subject in CERCLA.

Response: EPA has provided additional text regarding CERCLA regulations and hydrocarbon solvent cleaning processes.

Comment #2-170: p. 2-50, fourth paragraph: PS can result in the contamination of soil and groundwater so care should be taken in selecting waste disposal sites.

Response: EPA has provided additional text regarding CERCLA regulations and hydrocarbon solvent cleaning processes.

Comment #2-171: p. 2-51: The OSHA regulation lowering the PCE PEL to 25 ppm was not a proposed rule but a final rule. It was remanded later by the circuit court.

Response: EPA has modified the explanation of the OSHA PEL for PCE in order to be more accurate.

Comment #2-172: p. 2-51, second paragraph: should be OSHA.

Response: The text was modified.

Comment #2-173: p. 2-51, third paragraph: Under the OSHA General Duty Clause, OSHA can enforce the 100 ppm standard for PCE as low as it needs to adequately protect worker health. This General Duty Clause power has been confirmed by the courts.

Response: The CTSA does indicate that the General Duty Clause can be used when the "unofficial" PELs are exceeded.

Comment #2-174: p. 2-51, third paragraph: The OSHA limits for PCE and PS are in different units. Please add a quick comparison to aid the reader.

Response: EPA has researched this suggestion and determined that the OSHA General Duty Clause does not apply to PCE given that there is an established PEL. The OSHA General Duty Clause applies to health and safety hazards which are not currently regulated by OSHA, but are a recognized threat to worker health and safety.

Comment #2-175: p. 2-51: The New York State DEC requires that all fugitive PCE drycleaning machine emissions be limited to 50ppm. The Bay area Air Quality Management District in California has a 25 ppm fugitive PCE limit. These PCE limits are to prevent significant PCE contamination of mixed use buildings and to protect the public health of nearby residents.

Response: EPA has limited this regulatory analysis to include only Federal laws which pertain to the

clothes cleaning technologies examined in the CTSA.

Comment #2-176: p. 2-51: The interpretation of the OSHA short-term exposure limits in Chapter 2 is incorrect. Rather than 200 ppm for 15 minutes and 300 ppm for 5 minutes, the exposure limits are 200 ppm for 5 minutes in any 3 hours and 300 ppm maximum which is never to be exceeded.

Response: EPA has modified the text to include both ppm and mg/m^3 in the paragraph.

Comment #2-177: p. 2-52: OSHA limits on CO_2 exposure as a suffocation hazard should be included. Regulations concerning control of compressed gases should also be cited.

Response: Because CO_2 is an emerging technology, information on the regulatory requirements covering it are not included in the CTSA.

Comment #2-178: p. 2-52: The first paragraph states "However, a dilute mixture ..." The however should be removed.

Response: The text was modified at the suggestion of the reviewer.

Comment #2-179: p. 2-52, fourth paragraph: Clothing manufacturers also label clothes with the dryclean only label to avoid liability.

Response: EPA has modified the text in this section to reflect a more detailed discussion of the Care Labeling Rule.

Comment #2-180: p. 2-52, Section on Wet Cleaning: Acetic acid is normally used as a spotting agent in drycleaning and wetcleaning. It is not normally added to the wash liquor.

Response: EPA realizes that there may be varying formulations for detergents and spotting agents. The Agency has consulted internally and has decided not to modify the text in the manner the reviewer has suggested, based on the example detergent formulations presented in the CTSA and EPA's decision not to cover spotting agents in this CTSA.

Comment #2-181: p. 2-52: Please refer to my general comment F [Comment #G-78] regarding the provisions of the care labeling rule.

Response: EPA has supplemented the text regarding care labeling using the suggestions of the reviewer.

Comment #2-182: p. 2-53: NPFA-32, "Type I - systems employing solvents with a flash point less than 100 F (37.8 C), such as PCE": My understanding was that PCE was not flammable so why does it have a flash point? If PCE does have a flash point, then why is it not listed on page 2-9?

Response: EPA inappropriately indicated that PCE is a Type I solvent under the National Fire Protection Association's (NFPA) standard NFPA-32. As noted by the commenter, PCE is not ranked as flammable under NFPA's flammability scale. EPA has re-evaluated the NFPA regulations and modified the text to use a more appropriate example.

Comment #2-183: p. 2-53, Section 2.4.7: Type I is not PCE solvent, it is a petroleum solvent.

Response: EPA has re-evaluated the NFPA regulations and modified the text to use a more appropriate example.

Comment #2-184: p. 2-53: NFPA-32 reference, bullet point 1, Type 1 - system employing solvents with a flash point less than 100 F (37.8 C), such as PCE. Reference to PCE is incorrect. PCE has no flash point and is listed in NFPA-32 as Class IV Solvents: Liquids classified as nonflammable.

Response: EPA has re-evaluated the NFPA regulations and modified the text to use a more appropriate example.

Comment #2-185: p. 2-53: Type 1 lists PCE as a type 1 solvent. This is certainly not correct. I believe the proper classification of PCE is either Type 4 or 5. Again, I must keep repeating my concern regarding the lack of information on synthetic hydrocarbons such as Exxon DF-2000.

Response: EPA has re-evaluated the NFPA regulations and modified the text to use a more appropriate example.

Comment #2-186: p. 2-53, Section 2.4.7, first bullet: This is incorrect. PCE is not flammable.

Response: EPA has corrected this language.

Comment #2-187: p. 2-53: Type I systems are described in the CTSA. PCE does not have a flash point at all; it certainly does not have one that is less than 100 degrees F.

Response: EPA has re-evaluated the NFPA regulations and modified the text to use a more appropriate example.

Comment #2-188: p. 2-53: all degree signs missing.

Response: EPA modified the text and put in degree signs.

Chapter 3

Comment #3-1: To my knowledge, the release estimates are reasonably accurate.

Response: No response required.

Comment #3-2: The release estimates appear to be adequate for the purpose intended.

Response: No response required.

Comment #3-3: I am not aware that any important equipment or operational factors have been omitted.

Response: No response required.

Comment #3-4: The assumptions are reasonable.

Response: No response required.

Comment #3-5: The estimates appear reasonable.

Response: No response required.

Comment #3-6: I don't know how representative the data sets are that were used in the report.

Response: No response required.

Comment #3-7: I am unable to judge the representativeness of the data sets are that were used for estimating inhalation exposure and dose rates.

Response: No action required.

Comment #3-8: The measures and descriptions of PCE exposures seemed adequate to me.

Response: No response required.

Comment #3-9: The assumptions are reasonable, in my opinion.

Response: No response required.

Comment #3-10: The exposure characterizations in Chapters 3 and 4 are consistent with one another.

Response: No response required.

Comment #3-11: The information on general population exposure is presented clearly.

Response: No response required.

Comment #3-12: The exposure scenarios appear realistic to me.

Response: No response required.

Comment #3-13: The exposed populations have been characterized adequately, in my opinion.

Response: No response required.

Comment #3-14: In the discussion of PCE, the dose-response modeling is sufficiently straightforward.

Response: No response required.

Comment #3-15: I know of no relevant information on human health effects that should be added to the summaries.

Response: No response required.

Comment #3-16: The exposure data, as appropriately noted in various places in the text, may not be representative, as they either represent relatively old measures (e.g., NIOSH, in which case they may over-estimate more recent levels as improvements to processes are implemented) or derive from complaint investigations (e.g., OSHA, in which exposure levels also would be over-estimated). It seems critical to be able to validly represent current conditions in any comparative assessment. More progressively, a comparison of conditions likely to be present five or ten years into the future (or whenever alternative technologies are likely to be commercially viable) would be interesting and possibly more relevant for realistic business planning purposes.

Response: Additional data sets on occupational exposure have been added to give more perspective on representativeness. Regarding future occupational exposure projections, EPA has made no projections for occupational exposure; there is no known method for making such predictions. Properly representing current data is itself extremely difficult.

This type of comparison would be useful. The problem is that we would have to make assumptions about future conditions in the face of limited knowledge. This means that any estimates we would make probably contain so much uncertainty that an accurate estimate of

future exposures would be difficult to calculate.

Comment #3-17: 2. Disparate setting by varied protocol. The summaries do convey the variety of protocols that have been used to collect the different data sets (sample size, sampling design, purpose of study) and that this needs to be considered in the exposure and risk assessment.

Response: This consideration has been made.

Comment #3-18: Are you aware of human health effects information... Article with references included in attachments.

[Center for Neighborhood Technology, The Greener Cleaner Water/Wastewater Study, Wet Cleaning Project, Chicago, IL, August 1996]

Response: EPA has provided a summary of health effects information in Chapter 3 and Appendix C of the revised CTSA.

Comment #3-19: Are the assumptions reasonable?

The OSHA PEL is established as a threshold over which workers should not be exposed. How can it be reasonable to assume that this is a base line of exposure as was done in Chapter 3 (3.3.1)?

What other data exists? Have we looked? For example, there are only a small number of companies that provide monitoring badges for PCE worker monitoring. These companies do the processing of the badge and send the results to the customer. Data on the badge provides information regarding job description, season, time of exposure, geographical location, etc. Why couldn't these results be viewed and used. The customers using these badges are not expert technicians on measuring data, but this fact was not considered in accepting the data provided from NYDOH, et al. Good or bad, at least this data was generated with clean hands, not because of a complaint. As much as the data was statistically treated, the majority of this very small sample was generated by, or related to, plants that may have had flawed equipment or operational techniques. We are using this small sample to make predictions of exposure on a large base.

Response: The discussion of the use of PELs in exposure assessments has been deleted from the CTSA since such use does not occur in the CTSA. For the peer review draft of the CTSA, a standard OPPT procedure was followed for gathering publicly or readily available data on occupational exposures. The peer review identified several additional data sets, several of which have been incorporated into the updated CTSA.

It is correct that there are difficulties inherent in making estimates of exposure based on small samples. However, a variety of studies have been done, which include census-based surveys, data gathered for specific machine types, and also data based on complaints. Even though one would expect the measurements based on complaints to be much higher than other results, this effect is not seen. The small sample sizes make it difficult to draw a general conclusion regarding the influence of complaints on measured PCE concentrations in co-located apartments.

Comment #3-20: The PCE exposure information derived from various settings seems reasonable, especially the environmental information. One apparent anomaly should be mentioned: in Exhibit 3-19, is it accurate that "aired-out" clothing contributes the highest LADC?

Response: The exposure chapter has been extensively rewritten and this scenario is no longer present. For details, see chapter 4 of the revised CTSA.

Comment #3-21: PCE exposures, occupational and residential, have been measured in a number of disparate settings by varied protocols...Do the summarization measures and descriptions adequately convey... Yes it does.

Response: No response necessary.

Comment #3-22: Are the data sets used for estimations reasonably representative of the industry as a whole?

I am not a mathematician; however, the use of a plant cleaning 39+k Lbs/Year was used throughout the paper as the model. All other data was extrapolated from this plant. A 40k plant is very small and is susceptible to "Mom & Pop" syndrome where many costs and events are buried in the family and are not available for data screening. Few, if any, cleaners can achieve financial success at this level. Although it was on a par with the "Showcase" Machine Wet Cleaning plants, it was a poor model for both PS and PCE plants.

Response: Exposure data (and resultant risk estimates) were completely independent of the model facilities. Release and cost estimates were dependent upon the model facilities. The model facilities' "size" (clothing throughput) was increased to be more representative of a "typical" facility. Releases and costs have been revised based on the new throughput in the revised CTSA.

Comment #3-23: Are the estimates reasonable... There were some areas that I thought needed improvement. Included in comments.

Response: No response necessary.

Comment #3-24: Are the assumptions reasonable? There were some areas that I thought needed improvement. Included in comments.

Response: No response necessary.

Comment #3-25: In my opinion, several important exposure populations have not been adequately characterized as described above. In particular, the focus on individual risk has apparently led to conclusion of the insignificance of consumers' exposures to residuals of PCE and PS left on clothes and to consumers' workplace exposures during drop-off and pick-up of clothes. In addition, the para-occupational exposure pathway of workers exposing their families via their exhaled breaths is not included (even though this is generally of more significance than the pathway of infant's exposure via breast milk which is included). The occupational data sets are not representative of

all of the data available or for the industry nor it is disaggregated as is required to support decision making. Discussions of these issues and relevant citations are included in the specific comments below in order to help those revising the draft put them in where they belong.

Response: Several new occupational data sets have been identified and included. These sets may address some of the commentator's concerns.

Additionally, the pathway of workers exposing their families has been included in the CTSA.

Comment #3-26: The exposure assumptions and scenarios are generally reasonable, although many of the scenarios considered will apply in only a small number of cases. I believe that the general population exposure information is not presented as well as it could be, and more importantly that the focus on individual risk for the general population exposure is somewhat misleading. Also, due to PCE's long lifetime in the troposphere PCE emissions from drycleaners cause global exposures. I believe that the methodology given in Thompson and Evans (1997) will be helpful in at least discussing this issue in the CTSA.

[Copies of web pages at: http//www.cdc.gov/niosh/127184.html -- http//www.cdc.gov/niosh/8052413.html

Thompson, K.M., and J. S. Evans, 1997. The value of improved National Exposure information for perchloroethylene (Perc): A case study for drycleaners. Risk Analysis. 17:253-271.

Gerade, H.W. 1963. Toxicological Studies on Hydrocarbons IX. The Aspiration Hazard and Toxicity of Hydrocarbons and Hydrocarbon Mixtures. archives of Environ. Health. 6:329-341.]

Response: The trade-off chapter identifies factors that are important considerations for the cleaner selecting among processes. The CTSA appropriately identifies some of these considerations as externalities, however does not, as the commenter alludes, value these externalities. EPA acknowledges that valuation of social costs requires additional work, however, it is not in the scope of the CTSA.

Although no specific changes have been made in this paragraph, the exposure and risk chapters have been revised to discuss implications for special populations. It is true the CTSA opens by describing that DfE projects include "encouraging business to ... incorporate environmental concerns into decision-making processes" and closes by trying to convey the concepts of a social cost/benefit analysis. The evaluation, however, is acknowledged to be difficult and focuses on private (rather than external) costs, evaluated qualitatively. These costs are ones that each business owner or manager can visualize, being at micro level.

To appropriately estimate population risk, accurate, detailed, and site-specific information is required for all of the release sites. This information is used in the environmental modeling. Uncertainties in locations, releases, and the conditions of releases (including stack heights and duration of release) create uncertainties in the modeled concentrations. These uncertainties can lead to significant inaccuracies in the results.

It is possible to model population risk as Thompson and Evans (1997) have done. However, as stated above, numerous assumptions are required to perform this modeling. There are so many uncertainties involved when estimates or default values are used for missing data that people could be unnecessarily alarmed (or reassured) if estimates of population risk were provided.

The National Research Council book Science and Judgment in Risk Assessment quotes the Risk

Assessment Council's 1991 Guidance: "Information about individual exposure and risk is important to communicating the results of a risk assessment...Population risk refers to an assessment of the extent of harm for the population as a whole. In theory, it can be calculated by summing the individuals for all individuals within the subject population. This task, of course, requires a great deal more information than is often available." (pp. 368-371).

Additionally, because the information in the CTSA is intended for the individual business decision maker, it is not clear that a quantitative presentation of population risk, including appropriate caveats of the uncertainties will be clear and more useful than the discussion of the social costs associated with risks, as currently discussed in the CTSA.

Comment #3-27: I believe that the exposure characterizations in Chapters 3 and 4 are reasonably consistent, and that with the reorganization suggested above it would be easier to make the connection between them (i.e., organizing by solvent instead of by exposure, risk, etc.).

Response: EPA has reorganized the CTSA to provide information by technology.

Comment #3-28: The draft does a good job of conveying the different sources and types of information, but it needs to do a much better job of synthesizing these in a meaningful way for the reader. I believe that part of the problem arises because the draft does not deal with uncertainty and variability well or explicitly. Instead, by relying on presenting point estimates of exposure and risk, the draft leaves one wondering "What is the right number?" This is particularly true for the occupational data. What is a drycleaner supposed to infer from this presentation of three apparently disparate data sets? More discussion of the occupational data sets is given in the specific comments below, along with citations to missing references.

Response: The discussion of uncertainty and variability has been improved. The discussion of the variables affecting exposure have been improved. However, there is no "right number." The general-population and co-located exposure sections have been revised to better present the data.

Comment #3-29: 3. Are the assumptions reasonable? The assumptions used in some of the exposure assessments may need to have either additional qualifiers added or be modified. These include:
a) assumption that dermal absorption is not important when using contaminated groundwater, as discussed for Page 3-45 Para 4/Page 4-5 [Comment #3-298].
b) the number of samples that are available for co-located residences and drycleaners is limited and only some of the factors that affect the concentration of PCE or petroleum solvent emission to these residences have been determined. Thus the data cannot be extended to a large population nor can their representativeness be determined. Since this is the high end non-occupational exposure, it is important to provide some more qualifies on the discussion of what the exposure distribution is for these residences and what percentage of the population may be exposed in this manner. A related issue to this, as discussed for Page 3-43 [Comment #3-287], is that the exposure assessment and risk assessment for nursing infants only includes the ingestion dose obtained from breast milk and not the inhalation exposure to the infant in the co-located apartment.
c) the ambient air concentration model assumes uniform concentration across the cities modeled (see comment on Page 3-39 [Comment #3-271]). This is an oversimplification which is not correct for residences within one to two blocks of drycleaning facilities.

d) assumptions about exposure to the portion of the populations that uses PCE drycleaned clothing needs clarification (see comments on Page 3-44/45 [Comment #3-294]). No estimate was made about the potential indoor air exposures to petroleum solvents since data on off gassing of garments does not exist. A caveat could be inserted at the beginning of the section saying that it can be assumed that indoor exposure associated with drycleaning with petroleum solvents is expected to be greater than that for outdoor sources to the general population based on observations with PCE drycleaning.

Response: The exposure chapter has been rewritten and should now do a better job of addressing these issues. Specifically:

a) this assumption has been changed, based on a review by Leonard Keifer, USEPA of dermal absorption studies
b) the description of the co-located exposure scenarios has been rewritten. A discussion of infant inhalation exposure is included.
c) the ambient air modeling has been deleted. Results from the TEAM study are used in discussing ambient exposures
d) the discussion of exposure from wearing drycleaned clothes has been redone. The revised scenario presents the results from the Consumers Union study, which included a report from the International Fabricare Institute on the frequency with which individuals wore drycleaned clothes.

Comment #3-30: Have any important equipment or operational factors been omitted? No attempt was made to predict releases from the next several generations of equipment. If a PCE machine required no replacement solvent after 12 months of operation, wouldn't that solve all the problems? If you track the rate of improvement in this technology in the last 10-12 years, 0 solvent loss is very close.

Response: EPA has taken no action. There is no known method for making predictions about future environmental releases. Properly representing current data is itself extremely difficult.

Comment #3-31: Are these release estimates adequate... The estimates involving the newest PCE and PS equipment were not up to date. Some revised data is included in comments.

[Memo to J. Higgins, dated 6-22-96, Submittal of Technical Comments Proposed New 6 NYCRR Part 232 "Perchloroethylene Dry Cleaning Facilities."

Memo to J. Higgins, dated 7-15-96, Supplemental Comments to 6-22-96 memo.]

Response: No action required.

Comment #3-32: Are the release estimates reasonably accurate... The estimates were not global. Most estimates were calculated from data that was obtained from situations resulting from malfunctioning equipment, or, data from equipment that was used in the past. No attempt was made to estimate releases based on geographical data from state DEP's, DOH's, etc., etc. Suppliers of PCE and PS can tell you exactly where all the solvent is delivered. That would be better than calculated estimates.

Response: There is no known support for the commenter's contention that data used for release

estimates "was obtained from situations resulting from malfunctioning equipment". There are no data from equipment which is no longer used. Regarding geographical release data, such regional information is not normally considered readily available for EPA's national risk screening purposes, and may sometimes be biased based on regional regulations and issues (and therefore not representative of national trends). Geographical data were not intended to be used, but rather "model" facilities' estimates, for comparing releases from various technologies. The purpose for obtaining data on where PCE and PS (hydrocarbon) solvent has not been made clear by the commenter.

Comment #3-33: Health and Environmental Hazards. I have already responded to these issues before in the general concerns section. EPA's position on PCE appears to be based on interpreting the existing research and literature from a lowest risk perspective which may be overly cautious. I expect that industry scientists and decision makers will question EPA's position on PCE and will interpret the same data base differently by stressing the uncertainties involved in the scientific methodologies and assumptions. This dialogue is likely to overshadow the sincere desire of all parties concerned to lower PCE consumption and exposure to workers, people and the environment.

As referenced earlier, human health effects information on carbon dioxide are available and should be summarized in this document.

Response: The commenter is speculating on the interpretation of the material in the CTSA. Some material on carbon dioxide hazard has been included in the chapter on emerging technologies.

Comment #3-34: Carbon Dioxide Exposure Estimates. As stated repeatedly before, exposure scenarios referenced in this document are not good predictors of what will happen under practical and commercial conditions. Drawing inferences from anecdotal CFC-113 exposure statements for carbon dioxide is stretching it too far. Exposure from accidental or normal equipment fugitive emission of carbon dioxide can be potentially hazardous to workers and can not be ruled out, especially if a machine is operated in a small room typically occupied by drycleaners.

If carbon dioxide is to replace other non-aqueous solvents as major cleaning, every effort must be made to objective address the various potential exposure pathways of workers and people in the near environment. Unless this is done, the future of this technology is clouded.

Response: EPA has removed estimates for exposure to liquid CO_2 because the process is not yet commercial and estimates are too speculative.

Comment #3-35: Wetcleaning Exposure Estimates. Exposure through inhalation is not a thread since most products are solids or water based liquids. Other routes of exposure can be adequately managed through educational and safety programs. Therefore, wetcleaning is an attractive textile care method for washable textiles.

Response: No action required.

Comment #3-36: Petroleum Solvent Exposure Estimates. The data from the conventional

technology are limited but appear realistic. No data from the "controlled" PS technology as well as the lower solvent vapor pressure of the new solvents, significant lower exposure scenarios are anticipated. This should be experimentally confirmed under practical field conditions.

Response: Experimental confirmation of exposures are not within the scope of this CTSA.

Comment #3-37: PCE-Exposure Estimates. The worker exposure data given in the various tables appear realistic. However, the data in Exhibit 3.9 for the manager exposure appears to be too high in comparison to other workers. No explanation is provided, but the data in Exhibition 3-22 do not verify this exposure. Exposure can be drastically reduced with 5. generation machines, and this should be the recommended technology for PCE. Regular monitoring through passive devices can provide guidance for responsible industrial hygiene practices.

Since the major exposure route is through inhalation, it should be mentioned that most of the inhaled vapor is exhaled unaltered (over 90%) and is not metabolized in the body.

Response: The "appearance" of manager exposure being "too high" has been discussed briefly in the CTSA. However, the HC data in exhibit 3-22 are not intended or expected to verify PCE data in exhibit 3-9. Rather, the "high" manager data indicates that there are instances in which managers have high PCE exposure levels. The NIOSH data indicate reduced exposures from fifth generation machines relative to several other machine types studied, and this data and discussion have been included in the CTSA.

Comment #3-38: Exposure Estimates. Fugitive emission governs solvent vapor exposure of drycleaning workers as well as that of people in the near environment of a plant. The report lists quantitative vapor exposure scenarios for several PCE technologies as well as the potential for other modes of exposure. What is also recognized is the fact that preventive equipment maintenance plays an important part in minimizing exposure.

These two variable illustrate the variability of exposure and document that engineering and human factors must be considered for any meaningful corrective program. Selective human failure to implement effective and preventive maintenance programs should not condemn a certain process technology nor blame the whole industry for it. Regulatory requirements and controls, coupled with mandatory educational programs with renewable certification go a long way in protecting workers, people and the environment.

Response: No action required.

Comment #3-39: Wetcleaning Release Estimates and Assessments. Not reviewed in detail because of time constraints. The chemicals used are related to household products, so a lot of information about their impact on the environment should be available.

Response: No action required.

Comment #3-40: Environmental Release Estimates and Assessment. The methodology for estimating environmental releases uses the assumption that the total amount of a chemical is

released to the environment. If one accepts this assumption, environmental releases can be estimated from aggregate sales figures of a particular chemical or from statistically reliable mass balance studies in cleaning plants. Both approaches should theoretically lead to the same numbers.

The assumption that all chemicals used by the fabricare industry are released to the environment is questionable. On the surface, this assumption may be correct for chemicals which are not recycled off-premise, such as wetcleaning chemicals or hazardous wastes which is not picked up by a licensed hazardous waste management company.

For example, PCE recovered from waste on the premises of a waste management company is generally not returned to drycleaners. In the overall mass balance of PCE, this amount should not be counted as emission from a drycleaning plant. Since hazardous waste is manifested, this information should be readily available. Also, with NESHAP's requirement to record PCE consumption, mass balances about the use and fate of PCE in drycleaning plants can be more accurately tracked.

The overall impression I get from looking at the release estimates in this document is that too many data are derived from old and outdated solvent cleaning technologies. This projects a "hidden bias" against the proven non-aqueous solvents such as PCE and petroleum solvents.

Response: EPA has not assumed, nor suggested that PCE recovered off-site be included as an emission. The data kept by drycleaners is not readily available and therefore, could not be included in the CTSA. To reduce potential for confusion, some estimates for less-frequently-used (older) technologies have been removed from the CTSA. However, some older data were the only data found for estimating releases, and some of those older data may also be valid. There is no "hidden bias." The best available information found has been used.

Comment #3-41: The characterizations appear consistent, and may be reasonable. However, as discussed above, the level of detail and the dependence on extensive modeling may unnecessarily obscure understanding. Ultimately, it is difficult to under how quantitative risks can be attributed (especially for cancers) to various exposures when it is not understood whether PCE is carcinogenic to humans. This seems to be a most speculative step, and may be misleading to a lay reader (such as a drycleaner). While this may serve as a great motivator for drycleaners to clean up their operations (or consider alternatives), it may also generate more ill health (in the form of fear and anxiety) than the cancers it purportedly would prevent. For a project which attempts to be holistic, this aspect has been overlooked.

Response: No specific suggestions for changes are made, and how modeling obscures understanding could not be determined.

Comment #3-42: <u>4. Consistency of exposure characterization between chapters 3 & 4.</u> The exposure characterizations between chapters 3 and 4 are consistent. While they help evaluate risk, the exposure presented may not be all inclusive for either the nursing infant or for the general population as outlined in comments on Page 3-43 [Comment #3-287] and Pages 3-44/45 [Comment #3-294]. For the general population the total risk is still small, but due to the low Margin of Exposure for nursing infants a true total exposure calculation is necessary for a complete risk assessment. The footnote in Exhibit 4-8 should indicate the duration (number of years) used for calculating the LADD for the nursing infant, which presumably is not for 70 years or a 70 kg

individual.

Response: A discussion of infant inhalation exposure has been added to the CTSA.

Comment #3-43: 1. Are data set representative of the industry as a whole? Overall the data appears to be representative of the median that might be expected from the drycleaning industry, particularly for PCE since it is based on a large NIOSH data set, collected for PCE. A reference to an additional large data set is provided below (comments on Page 3-28 [Comment #3-220]). However, these data sets may not provide adequate exposure estimates for high exposures that might occur in small shops that may not be well maintained and may be less likely to be included in a NIOSH effort. These shops may represent the 90th or 95th percentile exposures. Some data from non-US drycleaning facilities show higher levels, as do older data in the US, which may provide a better estimate of the high end occupational exposures, emissions to the environment and to co-located residences. Some additional considerations should be used to evaluate the upper end of the distribution. There may be a need to collect additional data that focus on small drycleaners using a probability-based sampling design, unless this was part of the NIOSH sampling design. As pointed out in the document, data for petroleum solvent and water-based systems are incomplete and therefore it is unknown how representative they are.

Response: Some data from the Thompson and Evans reference cited by the commenter are included in the occupational exposure section. However, available data are insufficient to different exposures in "small" and "not small" shops. Separating shops into these two categories presents another difficulty. Also, as the commentator noted, some of these "small shop" exposures may be similar to the "high end" exposures from the other studies. These high end exposure data are included in the CTSA. Thus, the exposures of concern to the commenter are covered in the exposure and risk assessments. Finally, experimental confirmation of exposures are not within the scope of this CTSA.

Comment #3-44: The general population information is well presented.

Response: No response required.

Comment #3-45: With the exceptions noted above, the exposure scenarios are fair.

Response: No response required.

Comment #3-46: The exposed populations have been reasonably characterized according to numbers, levels, etc., but minimally characterized demographically. Regarding occupationally-exposed groups, what is their socio-economic condition? Do they work in the industry by choice, or because it is a family business? Are there employment options? Are the owner/operators in a position (educationally or financially) to implement changes or consider alternative technologies? Similarly, are co-located residents (is there no better term?) Co-located by choice? What are their residential options?

Response: EPA did not include demographic information because it was not reported in the studies used and because no demographic information was found in the publicly available literature.

Comment #3-47: Environmental Release Estimates: These seem reasonable as far as I can tell.

Response: No action required.

Comment #3-48: Exposure Estimates: My main comment here is that comparisons among technology options would be greatly facilitated if the authors were to calculate population aggregate exposures (see above). It would also be of interest to know something about the population distribution of exposures (e.g., how many workers, consumers, etc. are likely to be exposed to how much PCE?). Also as mentioned previously, arithmetic means should be provided for all exposure modes. Geometric means combined with geometric standard deviations are also helpful as a basis for subsequent distributional analyses. Finally some sense of confidence limits (uncertainty distributions) for population mean estimates would also facilitate possible policy analyses with respect to specific control actions.

Response: Arithmetic means are provided in every case in which data are available. Geometric standard deviations (GSDs) have been provided in every case in which data or GSDs could be calculated or were given.

Geometric means have been replaced by arithmetic means in the discussions of general-population exposures.

The trade-off chapter identifies factors that are important considerations for the cleaner selecting among processes. The CTSA appropriately identifies some of these considerations as externalities, however does not, as the commenter alludes, value these externalities. EPA acknowledges that valuation of social costs requires additional work, however, it is not in the scope of the CTSA.

Although no specific changes have been made in this paragraph, the exposure and risk chapters have been revised to discuss implications for special populations. It is true the CTSA opens by describing that DfE projects include "encouraging business to ... incorporate environmental concerns into decision-making processes" and closes by trying to convey the concepts of a social cost/benefit analysis. The evaluation, however, is acknowledged to be difficult and focuses on private (rather than external) costs, evaluated qualitatively. These costs are ones that each business owner or manager can visualize, being at micro level.

To appropriately estimate population risk, accurate, detailed, and site-specific information is required for all of the release sites. This information is used in the environmental modeling. Uncertainties in locations, releases, and the conditions of releases (including stack heights and duration of release) create uncertainties in the modeled concentrations. These uncertainties can lead to significant inaccuracies in the results.

It is possible to model population risk as Thompson and Evans (1997) have done. However, as stated above, numerous assumptions are required to perform this modeling. There are so many uncertainties involved when estimates or default values are used for missing data that people could be unnecessarily alarmed (or reassured) if estimates of population risk were provided.

The National Research Council book Science and Judgment in Risk Assessment quotes the Risk Assessment Council's 1991 Guidance: "Information about individual exposure and risk is important

to communicating the results of a risk assessment...Population risk refers to an assessment of the extent of harm for the population as a whole. In theory, it can be calculated by summing the individuals for all individuals within the subject population. This task, of course, requires a great deal more information than is often available." (pp. 368-371).

Additionally, because the information in the CTSA is intended for the individual business decision maker, it is not clear that a quantitative presentation of population risk, including appropriate caveats of the uncertainties will be clear and more useful than the discussion of the social costs associated with risks, as currently discussed in the CTSA.

Comment #3-49: Q-1: For easier reading, I recommend splitting chapter 3 into two chapters. One chapter should cover environmental release estimates of chemicals from commercial fabricare sites using different technologies. The other chapter should focus on exposure.

Response: EPA has maintained its presentation, combining releases and exposures into a single chapter.

Comment #3-50: Q-2: Readers would have it easier to follow if there would be a general overview describing the sources (i.e., vapor, liquid, solid waste) and significance of releases to the environment (near environment, air, ground or soil, water) before discussing various technology releases. A similar reorganization of the exposure sections would be desirable. There is too much emphasis on release from outdated petroleum technology and virtually no discussion of the new ("controlled") PS technology.

Response: The discussions of sources and significance of releases and exposures has been expanded. EPA has searched for new information on PS (hydrocarbon) technologies and included the small amount of additional information available from the literature and other sources.

Comment #3-51: Q-3: Flow charts describing release and exposure pathways would make it easier for readers to conceptualize and integrate the objectives of this chapter. Their graphic design could be similar to the flow charts in chapter 1.

Response: A graphic describing exposure pathways has been added to the chapter.

Comment #3-52: Q-4: This chapter needs major revisions. Release data are inconsistent throughout this chapter, probably because the PCE consumption base is not consistent. Why was the "per site" release chosen as quantifier? Normalizing release per weight of garments cleaned is common in our industry. Since sites vary considerably in size, using a site as reference base is highly questionable.

There are technical inaccuracies in this chapter which need to be corrected. Also, there is too much emphasis on outdated and infrequently applied technology (azeotropic PCE recovery). The emerging technology carbon dioxide suddenly appears with quantitative release estimates which are based on anecdotal reports rather than on field data. This type of documentation and reference raises legitimate questions about the objectivity and credibility of the document.

Response: Some inconsistencies between nationwide and configurational estimates were expected and were noted in the CTSA. However, nationwide estimates have been removed from the CTSA. Per-site normalization was used because that is the standard used in OPPT risk screening and assessment. It was also necessary for the cost estimations. Although the intent was not to emphasize infrequently used technologies, a significant number of reviewers interpreted it this way. However, when information on a technology was available, it was presented. So-called outdated and infrequently applied technologies are still in use, but have been removed from quantitative analysis in the CTSA to prevent the misconception of "emphasis".

Comment #3-53: Q-5: The new PS technology has been studied and documented extensively in Germany. There needs to be more coverage about it in this document since many American drycleaners see it as a viable alternative to PCE cleaning.

Response: EPA searched for new information on new PS (hydrocarbon) technologies and found very little. To the extent available, new information is presented in the updated CTSA.

Comment #3-54: Q-6: An informative new PS reference is the Hohenstein Report FKZ-01 ZH 90A31 (August 1994). Several newer studies have been referenced in German trade journals. Hohenstein should be able to give us more updated information about this now well established technology in Germany.

Response: An English translation of the reference indicates that this study on replacing CFC-113 with hydrocarbons relates primarily to performance issues and appears to have little or no information on releases and worker exposures.

Comment #3-55: 7. Are the exposed populations adequately characterized The distribution of number of hours and days that workers are exposed in drycleaning shop should be documented, though the worse case is sometimes calculated. The distribution of the frequency of visiting and wearing of drycleaned clothing in the general public should be better established to characterize the population, particularly the 90th percentile exposed groups. More information on the distribution and length of time individuals live in apartments in the same building as drycleaners is needed.

Response: Regarding the occupational exposure issues in the document, data could not be found, nor did the commenter provide references that could provide such data.

Information on the frequency of wearing drycleaned clothing was reported by Consumers Union and this is included in the CTSA. Accurate information for residence time in apartments above drycleaners in New York City is not available, although Consumers Union did report some limited data showing that some individuals live in the same apartment for 20 years or more. For the purposes of the general-population exposure calculations, the residence data reported in the Exposure Factors Handbook has been used (see USEPA, 1997).

Comment #3-56: Environmental Release Estimates: 1. On the basis of the data available, the assumptions underlying the release estimates seem reasonable and the estimates acceptable

Response: No response required.

Comment #3-57: Environmental Release Estimates: 2. The release estimates are adequate to distinguish the differences between the various technologies for each solvent.

Response: No response required.

Comment #3-58: Environmental Release Estimates: 3. I have no knowledge of equipment or operational factors.

Response: No response required.

Comment #3-59: Environmental Release Estimates: 4. I regard the assumptions to be reasonable.

Response: No response required.

Comment #3-60: Environmental Release Assessments: 1. The estimates appear reasonable to me.

Response: No response required.

Comment #3-61: Environmental Release Assessments: 2. From the perspective of someone unfamiliar with the drycleaning industry, the data sets appear to be representative.

Response: No response required.

Comment #3-62: Exposure Estimates: 1. The data sets used to estimate inhalation exposure concentrations or potential dose rates appear to be representative of the industry.

Response: No response required.

Comment #3-63: Exposure Estimates: 2. The variety and uncertainties associated with the data regarding occupational and residential exposure to PCE are explained and incorporated in the risk evaluations.

Response: No response required.

Comment #3-64: Exposure Estimates: 3. The assumptions used are reasonable.

Response: No response required.

Comment #3-65: Exposure Estimates: 4. I regard the exposure characterizations in Chapters 3 and 4 to be consistent and helpful to the reader.

Response: No response required.

Comment #3-66: Exposure Estimates: 5. The general exposure information is presented clearly.

Response: No response required.

Comment #3-67: Exposure Estimates: 6. Considering the assumptions and the data upon which they are made, the exposure scenarios are realistic.

Response: No response required.

Comment #3-68: Exposure Estimates: 7. The exposed populations are adequately characterized.

Response: No response required.

Comment #3-69: 5. Is information on the general population exposure clearly presented Some suggestions for the general population exposure are presented on section on Pages 3-44/45 [Comment #3-294].

Response: No action required. Comment addressed elsewhere in response.

Comment #3-70: 6. Are the exposure scenarios realistic Exposure scenarios for workers for each of the cleaning agents seem appropriate, the co-location is fine for PCE, should be included for petroleum solvents, the exposure for the general population is discussed in comments on Pages 3-44/45 [Comment #3-294].

Response: An estimate of co-located exposure to PS has not been calculated. Such estimates would be speculative, being based on assumptions rather than measured data. Measured concentrations of PCE in apartments above drycleaners vary widely depending on factors such as machine condition.

Comment #3-71: The PCE "equipment configurations", on which release estimates are based, should include drop off stores because many co-located drycleaners in New York City (and other cities) will consider this option as they begin to comply with the New York State regulations on drycleaning. I believe there is a Japanese Study that evaluates PCE exposure among workers and residents of apartments co-located with drop off stores (a colleague described this study -- I will located it and forward it as soon as possible). Also, perhaps release estimates could be approximated from the data on PCE releases from drycleaned clothing.

Response: Estimation of releases from drop-off stores was not within the scope of this CTSA. No references are readily available, and studies from other countries, such as the Japanese study mentioned by the commenter are included only by exception. These workers would be expected to have exposures at or below those of non-operators in the facilities that clean the garments.

Comment #3-72: There is evidence that the PCE concentration in homes of drycleaning workers is significantly higher than the concentration of PCE in control homes (study attached). Family members other than breast feeding infants may be exposed to PCE and this should be considered in the exposure scenario section. The attached study reports a median concentration of 0.344 mg/m^3 in homes of drycleaning workers. There may be limitations to this particular study but many workers consider their families health before their own health and, therefore, information on this particular exposure scenario may be important when a drycleaner evaluates whether it makes sense to use PCE based processes.

Response: This study is described in the CTSA.

Comment #3-73: The chapter introduction is clear in terms of purpose, but some of the elements of the chapter (e.g., assumptions) are not well elaborated later on.

Response: EPA has revised the chapter to improve presentation.

Comment #3-74: Citations need to be added to the text in many places.

Response: Additional citations have been included.

Comment #3-75: There is no consideration of peak concentrations in the exposure assessment. Also, there is no consideration of exposure during handling, spilling of solvents.

Response: Some peak exposure data from a new NIOSH reference have been included. Exposure events such as exposure during handling and spilling of solvents would be included in 8-hour time-weighted average measurements. Higher exposures could occur during handling and spillage events, but exposure data from accidents could not be found to confirm this.

While peak exposures may be a hazard to humans, we do not have a way to integrate their magnitude with our current form of dose-response relationship, which relies on a lifetime animal study from which only average exposure (or, rather, a function of cumulative exposure) and end-of-life tumor-bearing status are incorporated into a model. Even the pharmacokinetic considerations and studies so far examined by the Agency have not informed a model utilizing occupational peak exposures.

Comment #3-76: Although we have more information on PCE exposures than for many other environmental pollutants, these data are still relatively sparse especially given the complexity of potential exposure scenarios (e.g., apartments above drycleaners). As indicated in my other comments, the presentation of the exposure data is fine. However, when these data are used in risk assessments or evaluations, this sparseness is not acknowledged; extrapolations are often made from very few data points. I believe that it would be better to present a range of exposure and extrapolated risks rather than implying more confidence than is warranted.

Response: Both the description and the presentation of the co-located data have been revised. Fewer co-located exposure scenarios are presented than previously. Longer descriptions of

uncertainty have been written.

Comment #3-77: This chapter needs. It is confusing going back and forth between releases, ecological exposure, PCE, PS, alternative technologies. The methodology should generally be relegated to the appendix. A general format for this chapter could be: releases, types of exposure, exposure estimates, for each technology.

Response: EPA has revised the format of the chapter to improve presentation.

Comment #3-78: Just because there are uncertainties in exposure estimates does not mean that there is no exposure, as the document suggests.

Response: That is correct. The language has been revised.

Comment #3-79: Why are no cumulative exposure or additive exposure scenarios considered? It is clear that some people may be exposed to PCE at both work and home. Also, people are exposed to more solvents than just PCE.

Response: Cumulative exposure is discussed in the risk chapter. The scope of the CTSA is limited to exposures resulting from the fabricare industry.

Comment #3-80: P. 3-1: The CTSA indicates that it is not known how representative the wetcleaning formulations analyzed here are. The authors should also include the formulation used in the CNT study, the most thorough study of wetcleaning to date.

Response: Releases of and exposure to total formulations of wetcleaning detergents have been included in the CTSA. Three studies were found on machine wetcleaning, and of those, the CNT study was the only one without enough information to generate release estimates. Chemical constituents in machine wetcleaning detergent's constituents were not available. Therefore health or exposure impacts of these formulations could not be assessed.

Comment #3-81: P. 3-1, first paragraph: Why is ingestion not considered, given that drycleaners may change a filter or move wet clothes and then eat.

Response: This issue has been discussed in the updated CTSA in the worker exposure assessment methodology (Appendix E, Exhibit E-9). There are no data to present on occupational ingestion exposure. Also, occupational exposure screening assessments used by EPA's OPPT normally assume this ingestion pathway to result in smaller exposures relative to inhalation. No method is known for estimating the levels of exposure resulting from this pathway. For these reasons, exposures from this pathway are not estimated.

Comment #3-82: P. 3-1, fourth paragraph, first bullet: Why is this point here. It has nothing to do with release an exposure.

Response: This uncertainty was associated with an approach which was not included in the CTSA, but the uncertainty was not removed from the text. This uncertainty has been removed from the updated CTSA.

Comment #3-83: P. 3-1, first bullet, second sentence: "This uncertainty makes ... uncertain.": I suggest deleting the second word of the sentence, "uncertainty."

Response: This sentence has been revised.

Comment #3-84: P. 3-2: In section 3.1.1, the discussion of the factors affecting the variability of releases does not include practices such as shortening the drying cycle or overloading the machine, both of which can increase the amount of perc left in the drum after drying and, thus, the amount released when the door is opened.

Response: Although a comprehensive list of all possible factors affecting releases was not intended to be generated in this section, this general category of improper procedures has been added to make a more comprehensive list of categories.

Comment #3-85: P. 3-2, Section 3.1.1: This is a current process, not an alternative one as mentioned in the introduction to the chapter. First sentence "Drycleaners release PCE... (they do release PCE, not can release)". This sort of conditional statement downplay the actual hazard. PCE is also released as unused solvent. While EPA mentions all of the variability in releases, it does not mention this variation in its risk assessment, pollution prevention, or trade-off sections. With so many drycleaners, an accurate assessment of conditions is impossible. Risk could be much worse than that calculated.

Response: EPA has maintained the language because some drycleaning facilities have no vented emissions (rather, these have only fugitives), and some do not release PCE to water. This sort of conditional statement properly accents the variability within the population of facilities; hazard is not relevant to determination and estimation of releases. The variability discussed in the release section is in regard to estimating quantitative values, which is not relevant to the P2 section. Uncertainties have been discussed in the risk chapter.

Comment #3-86: P. 3-2, PCE Release Assessment: The distinction between vented and fugitive emissions needs clarification. Emissions "when a vented machine's door is open during transfer of articles to and from the machine" would appear more appropriately fugitive than vented. Low volume process exhaust may be feasibly c with vapor capture devices (and captured solvent recycled) while local and general exhaust ventilation with higher volume can't be.

Response: These emissions issues have been included in the CTSA.

Comment #3-87: P. 3-2, PCE Release Assessment: It would also be helpful to focus more on sources of release and control of solvent which passes through workroom air on the way to the community environment.

Response: Although the primary purpose of the release estimations are to aid in the comparison of risks (cancer, non-cancer, and environmental) and economics (e.g., use = on-site release + off-site disposal), discussion of sources of release have been improved in this section. Chapter 7 includes more coverage on the issue of control noted in this comment.

Comment #3-88: P. 3-2, section 3.1: When considering environmental release estimates, it seems important to estimate these at the level of the facility for comparable facilities as the CTSA cost estimates do. It would be more valuable for a facility owner if the draft explained the idea of a mass-balance approach. In particular, we know that the PCE that any cleaner consumes during a year is used to replace PCE that is lost. Where the PCE is lost depends on the types of equipment used in the facility, but it will include losses to the air via emissions, losses to clothes (which then diffuse to the air), losses to wastes (some of which may be reclaimed), and losses to water sent down the sewer (if this applies). Using percents for this type of analysis is problematic when overall emissions change. In particular, with the addition of emissions control, the percent of releases to air go down and consequently the percent of releases to other media must group, even if the amounts have not changed. The section then needs to give some motivation for why one cares about these release estimates, particularly since they are not used later in the CTSA as a basis for estimating risks. There are a lot errors introduced by using the uncertain total estimates and dividing these by the numbers of sources, and generally with using a mass-balance approach and these should be noted. Finally, this section must be consistent in its assumption of days of operation with other sections (i.e., 250 d/yr or 312 d/yr). In addition, why report losses per day (kg/site/day) instead of per year. The loss per day is too variable and there is no need to use these small numbers. Estimates of emissions from different machine types as a function of the cleaning output are given in the NESAP background documents. This entire section would be much more helpful if it compared facilities of the same cleaning capacities (as did Blackler et al., Ref. 134).

Response: Comparable ("model") facilities have been assessed to allow for even comparisons. The motivation of economics of releases (needing to replace chemical losses) has been included. The problems of uncertain total estimates, daily releases, which were averages, and inconsistent numbers of days were all removed when all nationwide estimates were removed from the CTSA.

Comment #3-89: P. 3-2: PCE Release Assessment. PCE releases to water, in addition to separator water, include spills of PCE which reach groundwater or surface water in the vicinity of drycleaning facilities. The New York State Department of Health has evaluated impacts of drycleaning facilities on groundwater and found that drycleaning facilities have contaminated groundwater in at least 30 sites in New York State. All 30 of these sites are listed on the Inactive Hazardous Waste Disposal Sites in New York State. Information on these sites was contained in a letter to Mr. Bruce Jordan of the EPA from Dr. William Stasiuk of NYS DOH dated 11/18/93 (attached), in response to EPA's request for information on groundwater contamination related to the EPA NESHAPs.

We were surprised not to see a section explicitly dealing with spills of PCE and their effect on groundwater, soil and buildings. Many drycleaning facilities in New York State and elsewhere have faced financial hardships due to costs of cleaning up groundwater, soil and buildings. This should be addressed to the CTSA so that cleaners are aware of their potential liability resulting from PCE spills.

Response: Literature was not found to support development of a section on spills. Also, OPPT

generally does not estimate spillage amounts in release screening assessments for risk screening. Routine releases are normally the only releases estimated. Also, where releases are estimated based on use rates, losses from spills would be a portion of the average release totals.

A discussion on measured PCE concentrations in groundwater has been included and discusses the New York findings as well as data collected in California. Additionally, the results of a search of several databases for information on PCE concentrations in groundwater has been included in Appendix E.

Comment #3-90: P. 3-2, next to last paragraph, next to last line: Include in the list of difference "level of soil in items being cleaned."

Response: Although this list is not intended to be comprehensive, this item was included.

Comment #3-91: P. 3-2: Releases are also expected to vary by machine type (dry-to-dry closed loop, dry-to-dry vented and transfer).

Again, there is no aeration step in a dry-to-dry closed loop system.

Response: Although a comprehensive list of all possible factors affecting releases was not intended to be generated in this section, this factor has been included.

Comment #3-92: P. 3-3, third paragraph: I suggest adding that the dryclean cleaning residues from stills, i.e., distillation muck, can contain up to 50% PCE according to the California Air Resources Board Technical Support Document for the Proposed Airborne Toxic Control Measure for Drycleaning Operations 8/27/93. Appendix C, Development of the Perc Waste Factor, page C-4, lists the average volume fraction of Perc contained in the still bottoms as 0.50, and the volume of still bottoms disposed per 100 pounds of clothes cleaned being 0.22 gallons.

Response: The PCE residual in still waste has been more thoroughly covered. However, release factors were not generated. Releases from "model facilities" of given clothing throughput have been presented.

Comment #3-93: P. 3-3, second paragraph: Waste water is <u>not</u> released into sewers anymore but either evaporated (EPA approved) or picked up by hazardous waste management company.

Response: No data were found to support this contention. However, the different disposal methods have been mentioned.

A survey of drycleaners by the International Fabricare Institute (Focus on Drycleaning, March 1989) indicated that 52% discharged to the sewer.

Comment #3-94: P. 3-3, second paragraph: PCE containing waste water comes from "four" main sources. In addition to the three listed in this paragraph, the fourth source (which is described earlier in the CTSA) is the moisture that comes into the machine from the fabrics and is dependent

upon humidity, temperature and fiber content.

Response: The discussion of this issue has been changed to focus on the equipment sources.

Comment #3-95: P. 3-3, first paragraph: The release estimate of 87,000,000 kg/yr. should be discussed in terms of 1994 and 1995 dry-cleaning consumption values of 55 and 68 m kg, respectively cited on pg 1-28. This figure suggests that over half of all annual production of PCE is released.

Response: Although such a discussion would have been beneficial, this total PCE release from the PCE drycleaning NESHAP background document and all nationwide release estimates have been removed from the CTSA.

Comment #3-96: P. 3-3: There seems to be some misunderstanding by the authors about separator water. They appear to believe it is plumbed to the sewer. It is collected by most drycleaners in coffee cans and subsequently poured into the sewer, into drums or into evaporators. It does not really constitute an "effluent" in the normal sense.

Response: The discussion of collection and release of separator water has been improved.

A survey of drycleaners by the International Fabricare Institute (Focus on Drycleaning, March 1989) indicated that 52% discharged to the sewer. For the purposes of our assessment, it matters only that the separator water goes into the sewer, not whether the separator water is plumbed to the sewer or poured from a coffee can into the sewer.

Comment #3-97: P. 3-3, line 4: hyphen missing after 1,1,1.

Response: This chemical is no longer mentioned in this section.

Comment #3-98: P. 3-4, Exhibit 3-1: This Table relies on Tables 3-3 and 6-1 from USEPA 1991. I strongly suggest that these tables be reprinted or otherwise made available in the CTSA document. The calculations in this table and others depend on raw data, equations and assumptions. We are given the equations and the assumptions, but not the raw data. Modelers need to have this information to "play" with, i.e., change assumptions, propagate errors with assumed variances, etc. Having it in one document would be more convenient for the reader. In addition, the reader needs some sense of the accuracy and precision of the original data used for these calculations.

Response: This inclusion would have been a helpful reference. However, the Nationwide release estimates and the need to include these tables have been removed from the CTSA.

Comment #3-99: P. 3-4, Exhibit 3-1: Please refer to my general comment B [Comment #G-74] regarding condensers. I believe we are talking about secondary controls in this table. The released from machines would be a function of not only the nature of the secondary control but also the primary condenser. I am beginning to have some real problems at this point following the numbers and being comfortable with whether or not they are accurate.

Response: The descriptions of controls for solvent process machinery has been clarified and updated in the CTSA.

Comment #3-100: P. 3-4, Calculation: Why is EPA noting 10 loads per day when before it was saying these machines do 4 loads per machine? This is not clear.

Response: The issue of inconsistencies of various parameters, including loads/day, was not clearly discussed. However, the Nationwide release estimates and corresponding parameters' inconsistencies have been removed from the CTSA.

Comment #3-101: P. 3-4,5: The lack of any monitoring data for releases of PCE to air and to water strikes this reviewer as astonishing! Should not EPA and state and local agencies be collecting such data? California is an example of a state with a relatively rigorous compliance program for drycleaners. Data should be available to verify that the formulas on p. 3-4,5 do, or do not, provide reasonable estimates of releases and consequent environmental concentrations near the sources. If such data do not exist, then EPA should enlist its TEAM staff to obtain such data, and this should be a recommendation of the CTSA report.

Response: Release monitoring field work is not within the scope of the CTSA. Data to verify formulas on p. 3-4 and 5 have not been found in public, readily available sources. Also, the air release sample calculation, which was used only in the Nationwide release estimate section, has been removed as has that entire nationwide release section. The CTSA is not intended to make recommendations to the TEAM staff.

Comment #3-102: P. 3-4, second paragraph: Based on my observations, a PCE-L or M can achieve 900 Lbs/Gal, therefore, the 0.27 kg PCE loss/kg clothes should be more like 0.014 kg PCE loss/kg clothes

Response: This issue would have been discussed. However, the Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-103: P. 3-4, Exhibit 3-1: This exhibit is using 1991 data that is obviously out of date. It also does not state which Refrigerated condenser is being used to model the PCE losses. If "Refrigerated Condenser" was a PCE-M, and "No-Control" was 6.3, the Refrigerated Condenser would be 0.2 kg PCE/machine/day and the Carbon Adsorber would be 3.1.

Response: The Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-104: P. 3-4: I am beginning to have some problems following the modeling. Ten loads per day from a machine seems an unrealistically high number. Five would be more realistic. However, even with this in mind, there is all of the discussion that follows based upon a process doing 113 kg of clothes cleaning per day. This statistic seems to be absent in most of the tables that follow in this chapter. Are all the tables based on 113 kg?

Response: The 113 kg was used only to estimate PCE releases to air for nationwide risk screening.

However, the Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-105: P. 3-4, first equation: Are the 10 loads/day/site and the 0.027 kg PCE loss/kg clothes values from USEPA 1991 or are they assumptions? If this whole section uses data from USEPA 1991, then state it at the beginning of the section instead of next to the 11.3 kg clothes/load value only.)

Response: The Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-106: P. 3-4, *Air Releases*: Example calculation - what is the factor that is variable resulting in the range of values in Exhibit 3-1. What assumptions were made?

Response: The Nationwide release estimates and issues have been removed from the CTSA

Comment #3-107: P. 3-4, first paragraph: Air releases - The estimate that results from this equation does not jive with earlier estimates (i.e., 87,000,000 kg). If you multiply 52 weeks X 5 workdays X 3.1 kg/site/day X 29,495 sites (Exhibit 1-9) you get a release of 23,772,970 kg/hr. The water release figures add only 1,150 kg to this estimate so the water contribution to the total release is negligible. Given the caveats, Exhibit 3-1 has little scientific merit.

Response: The commenter uses an invalid equation by assuming all machines nationwide are refrigerated condenser machines and emit at the low end of the range. However, the Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-108: P. 3-4: The equation uses a figure of 0.027 kg PCE loss/kg clothes. Where did this come from?

The figures in Exhibit 3-1 for releases are far too high for dry-to-dry closed loop machines. A typical figure for a dry-to-dry closed loop machine would be about 2 kg per day. I do not agree with the footnote about the CARB report. The CARB figures are lower than the figures in the Exhibit.

Response: The Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-109: P. 3-5. Again, the authors seem to assume that the separator water is somehow continuously plumbed to the sewer.

The solubility of PERC in water is 150 ppm, not 200 ppm.

Response: The discussion of collection and release of separator water has been improved. The solubility of PCE shown in the CTSA has been revised. However, the Nationwide release estimates and issues have been removed from the CTSA.

The reviewer is correct regarding the water solubility. This has been corrected in the CTSA.

Regarding the discharge of separator water, see the response to comment 3-96.

Comment #3-110: P. 3-5, Exhibit 3-2: 200 ppm is used for the solubility of PCE in water. On page 2-48, 3rd paragraph, the solubility of PCE in water was 150 ppm.

Response: Although page 2-48 gives no solubility figure as stated in the comment, the solubility of PCE shown elsewhere in the CTSA has been revised. However, the Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-111: P. 3-5, Exhibit 3-2: Again, I take exception and feel like the categories of machine control are misleading.

Response: The descriptions of controls for solvent process machinery have been clarified and updated in the CTSA.

Comment #3-112: P. 3-5: In the event that separator water is not released to the sewer but is evaporated, these figures would be totally different.

Response: The commenter's point is stated in the sentence which immediately precedes Exhibit 3-2. However, the Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-113: P. 3-5: the last sentence describing Exhibit 3-2 is confusing as written.

Response: This sentence would have been rewritten. However, the Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-114: P. 3-6, fourth paragraph, last sentence: This makes no sense. Newer equipment having lower emissions would be unrelated to their potential for leaving PCE in solid waste. It is my understanding that the newer machines not only have lower emissions, but also remove more PCE from the waste streams before they are removed from the machine.

Response: The commenter misunderstood the sentence. The point of this sentence would have been clarified. However, the Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-115: P. 3-6, second paragraph, line 3: I could not find the source of this number 9,400 Mg/year or what the M stands for.

Response: The source and "Mg " would have been clarified. However, the Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-116: P. 3-6, second paragraph: In the Safety Kleen study, the 9,400 Mg should be

listed in kg to be consistent with other nomenclature. It is not clear whether the 9,400,000 kg is the total release (8%) or consumption (100%) value in this context. Either way, this represents another completely different consumption estimate and release estimate than earlier paragraphs. I admit to being fairly confused at this point. A table comparing various consumption and release estimates might give the reader some boundary conditions for these estimates. Right now they are all presented as sequential facts.

Response: The 9,400 amount would have been clarified and the consumption/ release comparison table would have been beneficial. However, the Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-117: P. 3-6, third paragraph: The 9,800 facilities listed does not compare with the number of facilities listed in Exhibit 1-9. Even 38% of the 1-9 number is over 11000 facilities.

Response: The number would have been corrected. However, the Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-118: P. 3-6: The CTSA states that there are discrepancies in the waste analysis. It also states that the differences could be attributed to newer equipment having a higher fraction of total PCE disposed in solid wastes. This would not reconcile the figures, however, because the absolute value would be the same.

The materials balance is a thorny issue and it gets the authors into trouble later because the CTSA is not assuming the right number of facilities, drycleaning machines or pounds of clothing cleaned.

Response: The Nationwide release estimates and issues have been removed from the CTSA, and this comment is no longer relevant.

Comment #3-119: P. 3-7, bullet 3: carbon should be capitalized.

Response: This typographical error was corrected.

Comment #3-120: P. 3-7 and 3-8: Delete PCE-D, PCE-E, PCE-I and PCE-J. Old technology, no more than 100 units in place nationwide, company is out of business.

Response: The updated CTSA has reduced the amount of information on "old and outdated technologies", and these configurations have been deleted.

Comment #3-121: P. 3-7, PCE-G: The description is misleading and inaccurate. The conversions really create two different configurations that should not be combined. When the internal conversion is made, this machine is now a PCE-K. When the external add-on is made, the machine is only equipped with refrigeration reclaiming during the cool-down or aeration cycle and the mileage is substantially less than an internal modification.

Response: No data or information could be found to validate or refute this contention.

Comment #3-122: P. 3-7, PCE-E & PCE-J: To the best of my knowledge, this combination was not common, nor can I locate anyone who remembers this configuration. The last sentence of both descriptions states the air stream flows to a carbon bed which may remove most of the remaining PCE before emitting the air stream. The previous sentence describes the system as recirculating!

Response: The updated CTSA has reduced the amount of information on "old and outdated technologies", and these configurations have been deleted.

Comment #3-123: P. 3-7: PCE-B: The description is misleading. This option uses an external refrigeration condenser connected with duct to the reclaimer. During aeration, air is recirculated through the RC and back to the reclaimer for the entire cool down cycle. One-pass operation occurs during door open for unloading the reclaimer.

Response: This description has been corrected.

Comment #3-124: P. 3-7: The analysis presents a large number of scenarios. I don't think this is productive. The only types of new machines being sold today are dry-t-dry closed loop. There are very few machines with azeotropic controls and the controls are not effective anyway. The footnote indicates that the manufacturer states that machines with azeotropic and carbon adsorber controls are closed loop. They are not. There is only one type of closed loop machine: a dry-to-dry closed loop machine with an internal refrigerated condenser.

Response: The updated CTSA has reduced the amount of information on "old and outdated technologies", and these configurations have been deleted.

Comment #3-125: P. 3-7 and 3-8: I have some real concerns, as outlined in my general comment C [Comment #G-75], regarding what, at this point, appears to be an endorsement of the CTSA for the solvation technique, which I believe is no longer being sold and commonly believed to not be effective. In the footnote on page 3-7, I believe the constant boiling mixture always exhibits a minimum boiling point.

Response: EPA has not endorsed any of the technologies. No recommendations are made in the CTSA; it is a comparative document. However, the azeotropic vapor recovery technologies have been excluded from the release assessment because they are not commonly used by the industry. Some azeotropes exhibit maximum boiling points. In the case of PCE and water mixture, the azeotrope has a minimum boiling point.

Comment #3-126: P. 3-7: Why are these different scenarios not included in Chapter 1?

Response: The equipment and processes were broadly described in Chapter 1. In this chapter, the equipment was combined into specific combinations to demonstrate differences in releases.

Comment #3-127: P. 3-8: The PCE - I&J control options, needs to be better described, and possibly combined. The dry-to-dry 2nd generation machines with azeotropic controls, but without

carbon adsorbers is extremely rare. For the last decade or more, virtually all azeotropic control systems have been built with carbon adsorbers that operate when the machine door is opened.

PCE-L. Many 3rd generation refrigerated condenser machines are equipped with door fans and small carbon adsorbers. Large carbon adsorbers is incorrect here, as a large carbon adsorber usually contains more than 100 pounds of carbon. Such controls are required to meet a 20 ppm PCE emission limit in New York.

PCE-M- while this description is correct, it would be useful to refer to this category as 4th generation-integral carbon adsorber. This section should also include supplemental vapor burner room enclosure ventilation controls that are required by EPA for large commercial units, and by New York and the Bay Area AQMD for mixed use settings.

Response: The PCE-1&J configurations would have been better described, however, these azeotropic vapor recovery technologies have been excluded from the release assessment because they are not commonly used by the industry. Regarding PCE-L and PCE-M (similar issue and response as 1-24 and others) , B = Agree. The descriptions of PCE-L and PCE-M have been improved or changed appropriately. EPA did not include room enclosures for PCE-M because EPA only requires these for transfer machines.

Comment #3-128: P. 3-8: There are no dry-to-dry closed loop machines with vented secondary control. Again, there appears to be confusion in the authors' minds about the difference between fugitive controls which are designed to prevent worker exposure and secondary controls which are designed to prevent PERC emissions. The fugitive control is often vented whereas the secondary control is not. Neither type of control involves a large amount of carbon. The carbon is generally desorbed with air after every cycle at the beginning of the next cycle. Thus a large carbon adsorber is not needed.

Again azeotropic systems or systems with carbon adsorbers are <u>never</u> closed loop systems.

Response: Different literature use the term "secondary" differently, resulting in misunderstandings. The use of the term has been minimized, and the technology has been described more in terms of the components. Regarding mixing worker exposure controls with emissions controls terminology, the terminology for these separate issues have been clarified. The Azeotropic vapor recovery technologies have been excluded from the release assessment because they are not commonly used by the industry.

Comment #3-129: P. 3-9: The authors are confused about the difference between dry-to-dry vented machines with controls and dry-to-dry closed loop machines. Vented machines with either a carbon adsorber or a refrigerated condenser have losses about twice that of a dry-to-dry closed loop machine. The CARB data are accurate; the NESHAP background document failed to make this distinction. The authors <u>must</u> understand this difference to present a credible analysis.

Response: Different literature use the term "secondary" differently, resulting in misunderstandings. The use of the term has been minimized, and the technology has been described more in terms of the components.

Comment #3-130: P. 3-9, first paragraph: "hazardous waste releases that result from each of the 13...". These waste releases do occur, so saying may downplays hazard.

Response: Some drycleaning facilities do not release PCE to water. This sort of conditional statement properly accents the variability within the population of facilities; hazard is not relevant to determination and estimation of releases.

Comment #3-131: P. 3-9, fourth paragraph: Not accounting for age of machine, configuration and controls in the CARB data is a serious omission which could possibly underestimate releases and exposure. This should be highlighted.

Response: This is not an omission, but rather an uncertainty. This uncertainty is of no greater importance than many other uncertainties in this CTSA.

Comment #3-132: P. 3-10, Exhibit 3-3: First, most earlier reporting has been in kg or liters and now switches to gallons. Second, it seems to be impossible to match releases in 3-3 with those in Exhibit 3-1. For example, in 3-1 there is a broad range of release values that do not correspond with the single value listed in 3-3. I spent 20 min. trying to calculate compared values before moving on and I'm sure the average reader would take far less.

Response: The Nationwide release estimates and issues, including inconsistency of units and release matching, have been removed from the CTSA. On the matching issue, as implied in the third full paragraph on this page, these sets were not intended to match.

Comment #3-133: P. 3-10, Exhibit 3-3: I spent considerable time in my review trying to find the volume of cleaning that is assumed for Exhibit 3-3. The only place I began to find a number was the 113 kg from 10 loads per day. Again, I have a real problem with what appears to be the endorsement of what is now called the azeotropic process. Please refer to general comment C [Comment #G-75].

Response: The volume is shown in footnote a of the Exhibit.

Comment #3-134: P. 3-10, Exhibit 3-3: Again I would prefer to see the raw data gleaned from the USEPA, CARB and other sources. This comment generally applies to Exhibits that follow when the raw data is not included in Appendix B.

Response: The raw data for CARB has been included in the Appendix. The USEPA data are not included because the Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-135: P. 3-10: Exhibit 3-3 has several problems. The emissions to air are grossly underestimated in nearly all cases. The amount of clothing cleaned is underestimated by all sources (CARB, EPA). This is because some drycleaners d not pay taxes on all or some of their receipts. Therefore they under report the amount of clothing they clean. Again, a typical drycleaning facility would clean about 1,500 pounds of clothing per week.

The footnote to the table indicates that the figures were taken from CEPA by the CARB report simply reports EPA NESHAP document figures.

Better estimates of air emissions in gallons per year for the 14 cases in Exhibit 3-3 are:

1	1,000
2	700
3	700
4	1,000
5	700
6	OK
7	OK
8	200
9	200
10	80
11	80
12	50

Again, there is no such thing as vented secondary control (option 11 above).

I assume, from the footnote, that the hazardous waste figures represent PERC plus other material. Assuming the waste is 40 percent PERC, the hazardous waste generated would be about 37.6 gallons pf PERC. This is probably a little high.

The estimate of 50 gallons of wastewater per year for machines with refrigerated condenser machines may be somewhat low. A better value is probably 150 gallons per year. I am the reference for the 50 gallons per year and, at this stage, I believe that is an underestimate.

The authors have added up the figures for releases to air, hazardous waste and wastewater to get the figure in the final column called "Total Hazardous Waste Volume" in Exhibit 3-3. Those are not the total hazardous waste volume; they are the total losses. This gets the authors in trouble later in the estimates of volume and cost of hazardous waste disposal (see comment in Chapter 6 below).

Response: Air emissions estimates were revised based on updated (higher) clothing throughput. The 1,500 lb clothing per week basis for the estimates provided by the commenter is higher than the updated clothing throughput generated for this CTSA.

With respect to the use of the term vented secondary control, different literature use the term "secondary" differently, resulting in misunderstandings. The use of the term has been minimized, and the technology has been described more in terms of the components.

The commentator appears to have misinterpreted the intent of the column on hazardous waste. The column header has been clarified. The value for wastewater volume has been incorporated into the CTSA. The column header for total losses has been clarified.

Comment #3-136: P. 3-10: Exhibit 3-3 on p. 3-10 puts a lot of good information together but it is not entirely clear. For example, the total "PCE" loss" is equal to the total air, water and hazardous waste releases but, this is not clear from the way the table is designed. The subheadings, PCE and

Total Volume, are confusing because the PCE releases are expressed as a volume.

Response: Column headings in this Exhibit have been clarified, and the footnotes improved to provide further clarification.

Comment #3-137: P. 3-10, Exhibit 3-3: Do the air emissions include fugitive emissions? Why are total hazardous waste volumes so much lower than those estimated in chapter 6?

Response: The footnote states that total air emissions are the sum of vented and fugitive emissions. The figures in Chapter 6 were revised to correspond to the figures in this section.

Comment #3-138: P. 3-10, Exhibit 3-3: This is an important exhibit and it should be accurate. I disagree with several of the assumptions mentioned in the footnotes to this exhibit:

a. The addition of the CA to Transfer and DTD Machines significantly reduced the emissions. During process venting (aeration cycle), the reclaimer of an uncontrolled transfer machine vents large amounts of PCE into the air stream. Fugitive emissions only occur during transfer and unloading of the reclaimer. Transfer emissions are not blown out of the stack as are process venting. To make the assumption that vented emissions are 50% of fugitive emissions is terribly inaccurate. Fugitive emissions from an uncontrolled vented DTD will be significantly less than the uncontrolled transfer.

"Vent control efficiencies were assumed to be 70% for RC one-pass, 84% for azeotropic, 95% for CA and 99% for Azeotropic and CA combined." I know of no "RC one-pass." Add-on RC's adapted to Transfer or DTD operate during the entire aeration or deodorization cycle and are exposed to 5-10 minute duration of recirculation.

b. and c. A vented 2° fan cannot possibly reduce emissions on a closed loop machine by 39%.

c. The amount of waste water generated by a machine is dependent on how much moisture is in the wheel and should be relatively the same volume regardless of the control.

e. Waste from a CA is not carbon waste, only waste water from the stripping operation.

General Comments: The numbers are out of line. PCE-B should use less PCE than PCE-C, D or E. A PCE-G (internal) will use less PCE than H,I, J.

Response: a. The commentator offered no recommendation for changing these assumptions, and no other information could be found to support changing these assumptions. However, the RC-one-pass has been removed from this exhibit because it is believed to be rarely used.

b. and c. The configurations shown in the exhibit and text have been changed.

c. Carbon adsorber desorption generates waste water which adds significantly to the amount of waste water from other condenser sources in a drycleaning facility.

e. Carbon eventually fouls and must be changed on an infrequent basis. The small volume of fouled carbon disposed has been averaged into the annual release.

General: Regarding PCE-B, EPA agrees. The updated exhibit reflects the commentator's contention. The exhibit already reflects the commentator's contention for PCE-G.

Comment #3-139: P. 3-11: What was done with PCE holds also for petroleum solvent cleaning technologies. By emphasizing the potential for environmental release from out-dated equipment projects a "hidden bias" against petroleum drycleaning. The usage numbers given in Exhibit 1-9 suggest an exorbitant and unrealistic solvent mileage of 54.6 lbs. solvent/100 lbs. cleaned. This corresponds to 15 lbs. cleaned/gal. In Chapter 3, page 3-11, emission estimates add up to about 26 lbs. solvent/100 lbs. This inconsistency needs to be resolved.

Response: Some estimates for "out-dated" technologies have been removed from the CTSA. However, some older data were the only data found for estimating releases, and some of those older data may also be valid. There is no "hidden bias." The best available information found has been used.

Comment #3-140: P. 3-11, *Nationwide Estimates:* There is no mention of the amount of waste that is generated from PS as there was for PCE.

Response: PS waste amounts are presented in the footnote to Exhibit 3-4. The commentator seemed to have trouble finding the PS amounts. The presentation of nationwide estimates for both PCE and PS would have been made more consistent. However, the Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-141: P. 3-11: The CTSA discusses the rate of emissions and how it can vary. All of the PS in the clothing is ultimately emitted, however, either at the drycleaning facility or when the clothing is at home or worn.

Response: PS can also be emitted from or permanently trapped in wastes after the wastes are removed from the facility.

Comment #3-142: P. 3-11: It became apparent at this point that there needed to be some consistency in regard to the tables in this section of Chapter 3. Some tables are in gallons per year, others in kilograms per day, and other in liters per year. Some consistency would certainly be appreciated.

Response: Although nationwide release estimates (intended only for nationwide risk) were not intended to be compared to comparative release estimates (intended only for comparing different machine types for a given solvent), the Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-143: P. 3-11: The use of a 1982 EPA document for the estimates of PS release rates seems even more astonishing. Are there not data for the Los Angeles Basin and other areas where VOC emissions are tightly controlled?

Response: Such regional information is not normally considered readily available for EPA's national

risk screening purposes, and may sometimes be biased based on regional regulations and issues (and therefore not representative of national trends). This may be particularly true if large segments of HC drycleaners are not in areas with tight VOC controls, yet data on facilities in tightly-controlled areas are used to represent them all.

Comment #3-144: P. 3-11, next to last paragraph: Dryer VOCs - These studies were conducted between 1975 and 1980, but it does not indicate what type of condenser and, if used, secondary vapor recovery device was used. Was either present? Fiber content should also be an important factor, but may have not been part of the three studies that were cited.

Response: Water-cooled condensers with no secondary controls were used. Fiber content was noted in the studies as a factor affecting emissions.

Comment #3-145: P. 3-13, fourth paragraph on Filters: This section should include a wider range of filters to include uncoated disks, powder coated disks, cartridges, etc.

Response: The descriptions of filtration systems for HC (PS) systems have been updated.

Comment #3-146: P. 3-14, first paragraph: The last sentence says that dry-to-dry machines were not considered yet the table and results include option PS-D, a dry-to-dry option.

Response: The last sentence referred to the nationwide estimates (what was meant by initial screening). This point would have been clarified. However, the Nationwide release estimates and issues have been removed from the CTSA.

Comment #3-147: P. 3-14: Bullet point 4 states that steam injection.....increases solvent recovery via azeotropic formation. The petroleum solvents used for drycleaning do not form azeotropes with water.

Response: The function of steam in dry-to-dry PS (HC) process could not be ascertained due to conflicting information received, and this issue was not addressed in the CTSA.

Comment #3-148: P. 3-14: PS-D - Why is stream injection the only technology designated differently? What about nitrogen or oxygen vacuum? By the time I reached this section of the CTSA, I began to believe that the authors had been convinced by sales jargon of the azeotropic process!

Response: A relative estimated ratio of solvent mileage was available only for PS dry-to-dry with steam injection relative to conventional PS. It was noted on page 3-16 that with the exception of water releases, releases from the oxygen-vacuum and nitrogen injection dry-to-dry technologies would be expected to be similar. This point would have been clarified in the earlier discussion of these technologies. However, the release estimation method was revised to use analogy to PCE technologies, for which some release and consumption estimates are published.

Comment #3-149: P. 3-14, PS-D: Steam injection is not for process control. See comment 1.2.2 **[p. 1-18, third paragraph:** "Alternatively, steam serves the same function as nitrogen." This is inaccurate and this inaccuracy has affected several of the key cost tables and assumptions in chapters 6 and 7. Steam injection on the PS Reclaimers and PS Dry-to-Dry machines is only a safety mechanism that is released when a fire or explosion takes place. Steam injection of any significant amount would damage most of the garments in every load.]

Response: The function of steam in dry-to-dry PS (HC) process could not be ascertained due to conflicting information received, and this issue was not addressed in the CTSA.

Comment #3-150: P. 3-14, PS-B: Same comment as 1.2.2 **[p. 1-17, third paragraph:** "Carbon Adsorption units such as those used in PCE facilities may also be applied to petroleum drycleaning facilities." I have visited many, many Petroleum plants and have never observed nor even heard mentioned the use of CA for primary vent control or fugitive control of PS vapor. If it were used, it would not be exposed to PS vapor at elevated temperatures since the carbon would not adsorb at these temperatures. When a CA is used in a PCE plant, it is not used during the heated dry cycle for the same reasons.]

Response: Some errors have been corrected regarding HC (PS) technologies, including eliminating carbon adsorption as a vapor recovery device.

Comment #3-151: P. 3-15, second paragraph: Section 3.1.3 describes a controlled PS process with a reference (Hill) to the steam injection system. Is this not similar to option PS-D in Exhibit 3-5. How do these systems compare in terms of the release estimate. Again, the difference in units makes comparison cumbersome.

Response: These are the same system. This section was intended to be combined into the previous section beginning on p. 3-14. This section 3.1.3 has been incorporated into that section and is no longer a stand-alone section. However, the Nationwide release estimates and issues, including inconsistency of units and release matching, have been removed from the CTSA. On the comparison issue, as implied in the third full paragraph on this page, these sets were not intended to be compared.

Comment #3-152: P. 3-15: Again, the numbers should be standardized in terms of units, and the table should include the volume of cleaning upon which the numbers are based. I have a hard time accepting that PS-A and PS-C are so close together. Please refer to general comment B [Comment #G-74] on condensers.

Response: The Nationwide release estimates and issues, including inconsistency of units, have been removed from the CTSA. Regarding the PS-A and PS-C comparison a new method was used to estimate these releases.

Comment #3-153: P. 3-16, first paragraph: Up to this time, numbers have been based on 250 days/year. This process is based on 270 days/yr.

Response: The value 270 is not in this paragraph.

Comment #3-154: P. 3-16: The authors assume that a PS system operates 312 days per year. This is inconsistent with the estimates for the PERC facilities which are assumed to operate 250 days per year. These estimates should be made consistent. PERC drycleaning facilities generally operate six days per week. This suggest that the 312 day per year estimate is a better one.

Response: This inconsistency needed to be better explained. For nationwide PCE and PS release estimates, the bases for the estimates from the original information sources were retained "as is" for the sake of consistency. This information included 250 days/yr operation for these facilities. However, the Nationwide release estimates and issues, including this inconsistency, have been removed from the CTSA.

Comment #3-155: P. 3-16, Section 3.1.4: In this section water is considered a solvent and then detergents are evaluated for releases. Why are detergents not even mentioned for drycleaning?

Response: Hazards and exposures to detergents from PCE and hydrocarbon technologies were assumed to be relatively minor compared to PCE and PS (hydrocarbon) solvents' hazards and exposures. Releases of detergents in solvent technologies generally go with hazardous wastes (lower public and environmental exposure) versus to water (higher potential public and environmental exposure) in aqueous technologies.

Comment #3-156: P. 3-16, section on Aqueous Based Processes: Under air releases, I think that moisture could be a potential concern for workers.

Response: The intent of the comment is unclear and no action was taken.

Comment #3-157: P. 3-17, second paragraph: Since the process has not gained commercial significance, too much emphasis is given to the potential release of the listed chemicals. Most locally applied chemicals would stay on the garments and the cleaners would not "fall to the floor and be swept up..." Drop Exhibit 3-6 and Appendix B, Exhibition B-1.

Response: The multi-process wetcleaning technology is no longer assessed in the CTSA.

Comment #3-158: P. 3-17, first paragraph under Machine Wet Cleaning: Estimates were based upon 17, 898 kg of clothing per year. I had a difficult time finding a similar base for PCE and PS technology. Are they all the same? It would seem necessary to normalize all of these figures to the same volume of cleaning.

Response: This figure (17,898 kg/yr) was used also in Exhibits 3-3 and 3-5, but units were expressed differently and one included a conversion error. This figure has been updated and presented consistently.

Comment #3-159: P. 3-18, Exhibit 3-7: Should say water release estimates for Machine Wet Cleaning and should go after the first paragraph of that section.

Response: The presentation of this section has been changed and this exhibit has been deleted. Revised release estimates have been incorporated into the text.

Comment #3-160: P. 3-18: Modeling on this exhibit was based on 312 days/yr. If release data is used on tables in following chapters, the inconsistency in days per year could influence the accuracy of the data.

Response: The comment is not clear as to what tables may be affected by the inconsistency referred to.

Comment #3-161: P. 3-18, Exhibit 3-7: Switches back to kg/site/day nomenclature vs. gal/yr. in earlier exhibits.

Response: Units have been made consistent throughout the release sections.

Comment #3-162: P.3-23, fourth paragraph: It has been my experience that workers in well maintained plants, using modern equipment, experience exposure well below the TLV or PEL (less than 10 ppm on 8 hr average). This assumption is significant to the results of this document and has no basis in fact. The alcohol content limit for drunk drivers is 0.1. We do not assume that all drivers are at 0.1 while they are driving.

Response: No assumption related to the TLV or PEL mentioned this comment is stated or implied in the fourth paragraph of p. 3-23.

Comment #3-163: P. 3-18, third line: 312 days per year would imply a 6-day work week?

Response: For this release assessment, 312 days/yr implies 6 operating days per week. The number of days worked by a given worker depends upon the facility's staffing.

Comment #3-164: P. 3-18, last paragraph, sixth and seventh line: I have assumed that a protective residue must be left upon the clothing prior to drying in order to machine dry wools without felting? In this paragraph it certainly should be pointed out that all soils removed from the fabric are released to water just as in laundering.

Response: The relevance of protective residue to this section is not apparent. As noted earlier in the CTSA, the only releases assessed for aqueous processes are detergents. This point about soils being released to water was covered in the process equipment section for machine wetcleaning.

Comment #3-165: P. 3-19. The analysis of carbon dioxide cleaning should not be conducted. It is completely speculative since the manufacturers do not even have a machine. It is not possible to estimate how it would operate or work at this time. It is difficult enough to draw conclusions about wetcleaning since so few cleaners use the process. At least, in wetcleaning, some cleaners are actually using the process. In contrast, no cleaners are using carbon dioxide. Vendors of technologies are unreliable sources because they are marketing rather than being critical. The

carbon dioxide technology should be treated as an emerging technology and should not be analyzed here in detail.

It is not clear why the assumption is made that carbon dioxide releases are similar to CFC-113 losses. CFC-113 was generally used in dry-to-dry machines in an entirely different process. Why would there by any similarity to carbon dioxide releases? This statement may have been made by the vendor but must have been meant qualitatively; otherwise it is ludicrous.

Response: Information on emerging technologies, including liquid CO_2, have been moved to a separate chapter. Specific release and exposure estimates have not been included.

Comment #3-166: P. 3-19: I really got frustrated beginning with the air releases on liquid carbon dioxide and had to put the CTSA aside and start fresh. This entire section makes no sense. I see no basis to compare CO_2 to CFC-113. CO_2 systems are operated at high pressure. I believe all of the section beginning with the second half of the first paragraph should be deleted. Consider the statement, *if none of the CO_2 were recovered or reused*. This would imply that cleaning is performed with CO_2 and the CO_2 is then released. If this occurs, no cleaning has been accomplished, and all of the soil remains behind in the fabrics. I believe the consensus of all of the CO_2 developers is that the CO_2 and suspended soil must be removed from fabrics in the liquid phase.

Response: Information on emerging technologies, including liquid CO_2, have been moved to a separate chapter. Specific release and exposure estimates have not been included.

Comment #3-167: P. 3-19: The subheading 3.1.5 "Liquid Carbon Dioxide Release Assessment" implies that liquid carbon dioxide is released. This is incorrect since carbon dioxide exists as gas only in the normal environment. What should be calculated is how much gas is generated upon evaporation and what concentration level of gas is encountered in the working place.

Response: Information on emerging technologies, including liquid CO_2, have been moved to a separate chapter. Specific release and exposure estimates have not been included.

Comment #3-168: P. 3-19, first paragraph: Why are spent PCE contains not mentioned while spent detergent ones are?

Response: The sources of solid wastes for solvent processes were not intended to be complete lists. More sources of these wastes are available to be listed for the drycleaning processes than for the wetcleaning processes. Also, these listings do not determine how releases are estimated in these sections, and lack of mention of a particular source in a list does not indicate that the source has not been included in the estimations.

Comment #3-169: P. 3-19: It is hard to believe that the total losses from the total process is only 0.08 kg carbon dioxide per kg clothes cleaned. This needs to be verified. The inference that CO_2 emission is comparable to CFC-113 is stretching it a bit. But if we assume this is to be possible, then one must also accept the fact that CFC mileage under commercial conditions was generally much poorer than that of PCE. This is because CFC-113 has a higher vapor pressure than PCE and

that seals of the machines were always leaking.

The density of liquid CFC-113 is about twice as high as liquid carbon dioxide, so weight losses of CO_2 may be about half. But the CO_2 vapor pressure is much higher than CFC-113, so it can be postulated that the fugitive weight losses may be equal. Under commercial conditions, CFC-113 losses of 10-12 lbs. solvent per 100 pound cleaned where very common.

Response: Information on emerging technologies, including liquid CO_2, have been moved to a separate chapter. Specific release and exposure estimates have not been included.

Comment #3-170: P. 3-19: If one assumes that CO_2 may become a viable alternative to conventional drycleaning, it is prudent to assess the release on actually measurements under commercial conditions. The figures estimated in this report are unrealistic and should not be used.

Response: Information on emerging technologies, including liquid CO_2, have been moved to a separate chapter. Specific release and exposure estimates have not been included.

Comment #3-171: P. 3-20: Solid Waste Releases - As with PCE, PS, and HC technology, the bulk of the solid waste that is produced is the soil that was on the fabrics, detergents and filter media.

Ultrasonic Cleaning Release Assessment, fifth line: I don't understand the statement expected to be less relative to the wetcleaning methods. It seems to be very related to wetcleaning in that the role of soil suspension in all aqueous process is dependent upon the chemistry in the water. Soil removal without soil suspension does not accomplish cleaning.

Response: Information on ultrasonic and liquid CO_2 technologies has been moved to a separate chapter on emerging technologies. No specific release or exposure estimates were made.

Comment #3-172: P. 3-20, sixth paragraph: Section 3.2 Exposure - Although I know there is some difference between health effects and exposure these two topics would seem more logical if presented together. As with release, the data would be easily understood in a single table of regulation, chemical, exposure standard. It is generally difficult to interpret the exposure values without a comparison of the levels thought to be probably carcinogenic. The LADD numbers all seem small but without comparison to toxicity data, OSHA standards, etc. the numbers have little or not value to the average reader.

Response: The CTSA has been reorganized to better present the material. However, this suggested change was not made. EPA believes that because the hazard and exposure information is complex, it makes the most sense to present the hazard and exposure information in separate chapters and then integrate that information in a separate risk chapter. It is important to be able to compare exposure numbers with some context. The chapter on risk, particularly as it has been revised, attempts to do this.

Comment #3-173: P. 3-21: No assumptions can be made about the amount of detergent used in a carbon dioxide process at this time.

The same comments hold for ultrasonic cleaning. Again, it is not a separate process. It is a wetcleaning agitation method. Like carbon dioxide cleaning, there is no machine so it should be treated as an emerging mechanical method for wetcleaning and it should not be carried through for analysis.

Response: Information on ultrasonic and liquid CO_2 technologies have been moved to a separate chapter on emerging technologies. Estimates of detergent use were not made.

Comment #3-174: P. 3-21, Section 3.2.2: Why is the CTSA citing the roundtable proceedings regarding characterization of exposure when these issues are better discussed in the SPC's guidance? I don't think this section defines the concepts of uncertainty and variability for reader that is unfamiliar with them and overall this section is somewhat misleading. Also, the statement that "The resulting range of exposures allows us to address uncertainty with a measure of consistency" is not true if the locations of the selected point estimates are not consistent. It is also not true that one must "typically assume the correct value." Instead, one can choose to represent one's uncertainty and to rely on distributions instead of point estimates, (see Thompson and Graham, 1997 for more discussion on the trouble with point estimates, and Thompson and Evans, 1997 for an example of using uncertainty distributions to characterize risks from PCE drycleaners.) Further, while the last paragraph (which spills over onto the top of page 3-22) does a good job explaining that the risk estimates in the draft may not reflect reality, it does not indicate that one could do better and that one needs to understand the likelihoods of different outcomes in order to improve decision making. Why should people care about the results if they may not be right? How are what-if scenarios helpful to decision makers if they don't know how likely they are to occur?

[Thompson, K.M. and J.D. Graham. 1996. Going beyond the single number: Using probabilistic risk assessment to improve risk management. Human and Ecological Risk Assessment. 2: 1008-1034.

Thompson, K.M., and J. S. Evans, 1997. The value of improved National Exposure information for perchloroethylene (Perc): A case study for drycleaners. Risk Analysis. 17:253-271.]

Response: A quantitative treatment of uncertainty is outside the scope of CTSA. The qualitative discussions of uncertainty have been rewritten to better clarify the issues.

Comment #3-175: P. 3-21, third paragraph: It is important to note that bounding estimates are only as good as the exposure data put into the model and are often inaccurate.

Response: Language has been added to clarify that bounding estimates involve professional judgement. The exposure assessor judges that the combination of input parameters will result in an estimate that is greater than actual exposures received by any individual. However, the commentator has offered no justification regarding the accuracy of these estimates.

Comment #3-176: P. 3-21: 3.2.2 does not appear to be necessary to this discussion or could at the least be limited to the second paragraph.

Response: This section includes the definition of exposure descriptors. It is important to include this language because the terms are repeatedly used throughout the chapter.

Comment #3-177: P. 3-21, first full paragraph: The sentence beginning with "ADCs, however,..." implies that these concentrations are averaged over a day. While there is ambiguity over this, ADCs are often averaged over the exposure period or over a year. What does the last sentence mean? Does it mean that appropriately averaged inhalation exposures are reported in units of mg/m^3, or that the averaging is done later?

Response: The language meant that ADCs were averaged over one day. However, the exposure chapter has been extensively revised, and the general-population acute exposure estimates have been eliminated. Discussion in the risk chapter (now Chapter 5) focuses on comparisons to specific indices that typically rely on lifetime average exposures. The potential for particular effects for more time-limited exposure is now discussed qualitatively.

Comment #3-178: P. 3-22: Exposure scenarios. Exhibit 3-8 should be modified to include oral ingestion of PCE in drinking water, later discussed on page 3-27.

Response: This has been included in the graphic showing exposure pathways.

Comment #3-179: P. 3-22, section on exposure scenarios: I don't believe that the argument that the "uncertainty associated with the estimate would be substantial" is a reason not to characterize it. Further, this section needs to include other significant sources of population risks.

Response: EPA believes that some scenarios are not appropriate for quantitative evaluation. These scenarios have been discussed qualitatively.

Comment #3-180: P. 3-22, Exhibit 3-8. Scenarios Presented in This Report. Two additional exposure scenarios might be petroleum solvents in breast milk and the aspiration potential of PS via oral exposure.

Response: There is not enough information to provide quantitative estimates of exposure for these scenarios. Aspiration may be a key toxicological feature of PS, which are volatile liquids. EPA did only look at Stoddard solvent, for which the aspiration data are more speculative.

Comment #3-181: P. 3-22, second paragraph: Why is only 1 contact per day considered. This is likely an underestimate as is the assumption that workers wash up at meal times or at the end of the shift. Washing may not be an important aspect in some foreign cultures.

Response: Although this assumption of one contact per day is considered valid, the issue should have been discussed. The discussion of the assumption has been added to the methodology discussion. Some CTSA reorganization has resulted in moving this methodology discussion to an appendix.

Comment #3-182: P. 3-22, Section 3.2.3: There are many exposure scenarios that are not presented. Which ones and the rationale about why these weren't chosen needs to be explicit. The fact that there is substantial uncertainty about an estimate does not mean that it is not

important exposure pathway. EPA has chosen to not deal with this difficult uncertainty by simply not analyzing the exposures. Some of the missing and potentially important exposure scenarios include: PCE contamination of groundwater and drinking water, spills and splashes, and ingestion of PCE by workers.

Response: The language has been revised to better describe exposure pathways, but that does not translate into quantitatively evaluating every pathway.

Comment #3-183: P. 3-22+ (3.3.1, 3.3.2): This section is very confusing. It may be easier to read if the example calculations were placed in the Appendix. Tables would also be helpful rather than a narrative discussion.

Response: The exposure section has been reorganized and much of the information, including example calculations has been moved to the Appendix.

Comment #3-184: P. 3-22: Exposure scenarios should also include ingestion of perc in food.

Response: The uncertainties involved in assessing this pathway make an exposure assessment difficult to perform. A qualitative discussion of this pathway has been added.

Comment #3-185: P. 3-23, last paragraph: It might be appropriate to let the reader know which data sets are being discussed by referencing them in the first sentence.

Response: The data sets have been referenced in one of the first sentences.

Comment #3-186: P. 3-23, last paragraph, last sentence: Are these DIs applicable to all data sets? Were the data collected by only one research team using only one technique?

Response: The issues raised in this comment were clarified in the CTSA by including the citations for data to which the DIs apply.

Comment #3-187: P. 3-23, last paragraph, third sentence: Why are short duration measurements not included in the PDR estimates when long term measurements are simply made up of successive short-term concentrations?

Response: This has to do with the exposures and hazards that are of concern. Since people are generally concerned about the cancer risk for PCE, the emphasis is on long-term exposures. There are risks associated with short-term exposures to PCE, but those risks tend to involve higher exposures than those received by the general population or co-located residents. Short-term monitoring data have been included for workers.

Comment #3-188: P. 3-23, first paragraph: Who says that screening level assessments are generally conservative. This is conjecture as the readily available data may underestimate risk. Please do not make this assessment seem conservative unless the assumptions that make it

conservative are clearly explained.

Response: The assumptions that make the worker exposure estimates "generally conservative" are clearly explained. A revised discussion of uncertainty, which includes factors that could lead to both over- and underestimates of risk, has been written.

Comment #3-189: P. 3-23, third paragraph: In explaining the NOES database, EPA mentions several uncertainties. The NOES is still considered the best database of occupational exposure and all exposure databases have uncertainties. Also, there is no indication that this database is conservative (please cite if you have information).

Response: The statement that NOES is conservative has been deleted.

Comment #3-190: P. 3-23, fifth paragraph: Why exposure peaks, which may be substantial in transfer machine operations, not considered and just averages taken? Peak exposures could be an important hazard.

Response: Short-term monitoring "peaks" have been included. While peak exposures may be a hazard to humans, we do not have a way to integrate their magnitude with our current form of dose-response relationship, which relies on a lifetime animal study from which only average exposure (or, rather, a function of cumulative exposure) and end-of-life tumor-bearing status are incorporated into a model. Even the pharmacokinetic considerations and studies so far examined by the Agency have not informed a model utilizing occupational peak exposures.

Comment #3-191: P. 3-23, fourth paragraph: All estimates of inhalation...assumption that workers will (again may is conditional). Why is an 8hr day considered. I would guess that drycleaners spend much more time than 8 hours in their establishments.

Response: The conditional "may", is not necessary in this case and has been changed. There are no data to indicate an average that differs from the 8 hr/day assumption. However, the possibility that more hours may be common has been included.

Comment #3-192: P. 3-24: Under dermal exposure, why is only 1 exposure event considered?

Response: Although this assumption of one contact per day is considered valid, the issue should have been discussed. The discussion of the assumption has been added to the methodology discussion. Some CTSA reorganization has resulted in moving this methodology discussion to an appendix.

Comment #3-193: P. 3-24, Inhalation Exposure: It is not clear that this assumes 100% uptake.

Response: This issue is answered for each worker dermal exposure estimate in the CTSA. These estimates are each followed by the phrase "available for dermal absorption." Now that the methodology discussion (in an appendix) follows presentation of the estimates, this clarification is not necessary.

Comment #3-194: P. 3-24: "Dermal Exposure": The assumption of 1 exposure event per day seems low to me especially since page 3-4 sites 10 loads/day/site. If it is indeed a credible estimate, some comment on the thought process that led to this value may be appropriate. Alternatively, a few phone calls to some drycleaning facilities might yield a better estimate.

Response: Although this assumption of one contact per day is considered valid, the issue should have been discussed. The discussion of the assumption has been added to the methodology discussion. Some CTSA reorganization has resulted in moving this methodology discussion to an appendix

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Comment #3-195: P. 3-24, third paragraph: Example calculations for inhalation and dermal exposure should be closure to the exhibits and pages they reference, or in the notes/footnotes.

Response: EPA has moved these example calculations to an appendix.

Comment #3-196: P. 3-24: "Inhalation Exposure": This section involving the "calculation" of inhalation concentrations is somewhat of a misnomer. The EC is not calculated since it is derived directly from another reference(s). It is, however, converted to units used in this report. Wording such as the following may be more appropriate. "Inhalation ECs were taken from the literature and converted to mg/m3 using the ideal gas law. ... An example of this conversion follows:

> 58 ppm PCE (from reference) X (Mol. Wt. of PCE = 165.8) X (conv. factor = 0.041 mg/m3/ppm) = 400 mg/m3 PCE"

Response: The term "calculation" has been replaced by the term "conversion". Also, because the data point in this "unclear" sample calculation has been replaced by other data in the updated CTSA, the equation has been revised and updated.

Comment #3-197: P. 3-24: The CTSA uses a figure of 58 ppm for worker exposure from a transfer machine. This seems far too low.

Response: This data is from a published study and is supported by other available data, particularly some additional data which has been included in the updated CTSA.

Comment #3-198: P. 3-24, inhalation exposure example: The reference needs to be included and the 165.8 g/mol of PCE/24.45 m^3/mol of air at STP conversion factor should be explained. Why are the exposures here not averaged over the worker's lifetime and why aren't they reported as LADCs and ADCs?

Response: The equation has been revised and clarified. Regarding averaging, LADCs and ADCs, C = No action required. The units used for LADCs and ADCs were those requested by the risk assessors for this CTSA.

Comment #3-199: P. 3-24, fifth paragraph: The dermal exposure model is calculated on a 1 exposure event/day scenario yet the release estimates (see 3-4) are based on a 10 load per day scenario. This would seem to underestimate exposure by an order of magnitude compared to release if this model persists throughout the analysis.

Response: Although the assumption of one contact per day is considered valid, the issue should have been discussed. The discussion of the assumption has been added to the methodology discussion. Some CTSA reorganization has resulted in moving this methodology discussion to an appendix. EPA finds the assumption appropriate and disagrees that it will result in the underestimation of exposure.

Comment #3-200: P. 3-25: In Chapter 3, Section 3.3 EXPOSURE ASSESSMENT METHODOLOGY, Subsection 3.3.2 should be located in the Appendix or left as a reference only so that the purpose of the section and results are more evident.

Response: This section has been placed in an Appendix.

Comment #3-201: P. 3-25, equation 3: There is a typographical error, it should be 0.001 mg/μg.

Response: This has been corrected.

Comment #3-202: P. 3-25: Section 3.3.2 should be titled "Non-Dry Cleaning Worker Populations." There are two potentially exposed groups in addition to residents in the same or adjacent buildings: non-working relatives of drycleaning workers physically present on the premises of the facility, and workers in businesses in the same or adjacent buildings. These potentially exposed populations are not considered in the CTSA. Some estimate of the size of the co-located worker population could be obtained by estimating the percentage of drycleaners located in malls or multi-tenant commercial buildings, or in apartment buildings with other businesses, in comparison to the percentage of drycleaners in free-standing single-tenant buildings with no other buildings nearby.

Response: Demographic data were included in the reviewed studies and such an analysis is outside of the scope of the CTSA.

Comment #3-203: P. 3-25, Exhibit 3-5: Footnote e does not exist. Are the total solid waste volumes estimated hazardous or not?

Response: The missing footnote has been added. Discussion of whether hydrocarbon solid wastes are hazardous or not has also been included in several places in the CTSA.

Comment #3-204: P. 3-26, Section 3.4.1, first paragraph: "Workers experience skin contact..." Not may – they do experience skin contact with PCE, not only from clothes but also in maintenance, changing filters, cleaning machines, spills, etc. This will underestimate risk.

Response: The wording has been changed. However, not all workers will have dermal contact

from some activities listed in the comment because not all workers engage in several activities.

Comment #3-205: P. 3-26, second paragraph: This and the third paragraph should be combined.

Response: The general-population exposure sections have been extensively revised and rewritten to make the language clearer and less repetitive.

Comment #3-206: P. 3-26, last paragraph: I would drop or qualify any mention of diffusion through building materials as an important transport mechanism. Airborne transport will clearly dominate PCE transport to residences, no matter where the residence is. I would either drop the discussion about diffusion or clearly let the reader know that diffusion is a very minor transport mechanism in this case.

Response: The language has been revised.

Comment #3-207: P. 3-26, second to last paragraph, first sentence: Add "gaps/leaks in the building shell" to the list of things PCE can travel through.

Response: This language has been revised, and this paragraph is no longer present.

Comment #3-208: P. 3-26, Section 3.4.1: This section misses several exposure scenarios as discussed above. Also, the second and third sentences sound funny. Where do owners report these? Why not just say that "PCE is released into drycleaning facilities and is a source of exposure to workers and non-workers that enter the facility. Workers may also be exposed to PCE via dermal contact." The CTSA should also cite other exposure studies that show residual levels from clothes off-gassing in homes (Thomas et al., 1991 and Tichenor et al., 1990 (which is based on EPA, 1988)).

[Thomas, K.W., Pellizzari, E.D., Perritt, R.L. and W.C. Nelson, 1991. Effect of dry-cleaned clothes on tetrachloroethylene levels in indoor air, personal air, and breath for residents of several New Jersey homes. J. of Exposure Analysis & Environ. Epi. 1:475-490.

Tichenor, B.A., Sparks, L.E. and M.D. Jackson. 1990. Emissions of Perchloroethylene from Dry Cleaned Fabrics. Atmos. Environment. 24A:1219-1229.]

Response: The language has been revised. A discussion of the additional studies has been included.

Comment #3-209: Sec. 3.4.1: Section is too large, should be sub-divided.

Response: The section has been revised to improve the presentation.

Comment #3-210: P. 3-26: Exposure estimates. General. It should be emphasized that people living in co-located buildings are exposed up to 24 hours per day for prolonged periods. This is very important to demonstrate that PCE levels in residences play a very great role in chronic

exposure of the residents, including pregnant women, nursing mothers, infants, children, the elderly and infirm who may spend a great deal of time at home (Schreiber et al., 1993).

We are particularly concerned about exposures of infants and children who live in buildings with operating drycleaners. The EPA, ATSDR and Centers for Disease Control and Prevention (CDC) as well as the National Research Council have all pointed out the need for protection of infants and children who differ from adults in susceptibility and exposure to chemicals. These aspects should be elucidated and described in the CTSA.

Response: The discussion of potentially vulnerable subpopulations, including children, infants, and the elderly, has been expanded.

Comment #3-211: P. 3-27, last line: the number of days that people work in drycleaners may be available from the new National Survey being completed by Robinson under USEPA sponsorship (Dr. William Nelson of the Exposure Branch, at RTP, NC is project officer) and some data may also exist in the long form on the US Census or via Geographic Information System (GIS) data bases

Response: This source was not considered to be a readily available source of information.

Comment #3-212: P. 3-27: The NOES data set from NIOSH underestimates the number of exposed workers in drycleaning. This underestimation is due to the sampling frame used for the survey which missed most small commercial drycleaning facilities.

Response: The statement that NOES is conservative has been deleted.

Comment #3-213: P. 3-27, first sentence: Include dermal showering and bathing (see discussion about Page 3-45 Para 4 [Comment #3-300]) and contaminated soil gas entry into homes above contaminate aquifers (analogous to radon home penetration)

Response: A discussion of dermal showering and bathing has been included. An analysis of contaminated soil gas entry into homes above contaminated aquifers is outside the scope of the CTSA.

Comment #3-214: P. 3-27, Occupational Exposures: It should be noted that for well operated and maintained state-of-the-art 4th generation PCE dry-to-dry-refrigerated condenser, integral carbon adsorber machines, background levels of 1-2 ppm PCE have been found in many New York State DEC and Dept. of Health DOH investigations.

Response: This information has been included based upon the NIOSH study data and related information. This inclusion is in the updated Worker Inhalation Exposure section for PCE.

Comment #3-215: P. 3-27, Occupational Exposures, second paragraph: There is a discussion of regulation and recommended limits for perchloroethylene (PCE). There is no mention of the IDLH, Immediately Dangerous to Life and Health Concentrations. In fact, for PCE, the previous level of 500 ppm was revised in 1995 to 150 ppm. This is based on acute inhalation toxicity data in

humans as cited in NIOSH (www.cdc.gov/niosh/127184.html.) A copy is also enclosed.

Response: IDLH information has been included.

Comment #3-216: P. 3-27: Occupational exposures. As pointed out at the bottom of the page, 'some worker subpopulations (e.g., some "mom and pop shops") could be expected to be exposed for more than 250 days per year, although no data were found to support any quantification of this expectation.' To this, we would add that some portion of the people who work in these 'mom and pop shops' live in the same building in which they work. In these cases, the exposure is combined occupation and 'residential' exposure since the men and women would be exposed during the course of their workday followed by exposure in their home (usually upstairs from the shop). We do not know of any estimates of the numbers of people who would be in this category, but are aware of some anecdotally. We have also observed several instances of young infants in drycleaning shops who accompany their parent(s) during working hours.

Response: No information was found in the literature sources for a combined occupational and residential population.

Comment #3-217: P. 3-27: The NOES survey covered only establishments with more than 8 workers. We recommend that EPA use the "Total Employees" figures in the attached table.

Response: The data from the table, which is copied from the 1997 NIOSH reference in the updated CTSA, has been modified, and the modified data included.

Comment #3-218: P. 3-27: The CTSA contains the statement that "In some cases, PCE releases to land are not considered to be solid waste." I have no idea what that could mean. What lese would they be?

The CTSA indicates that nine employees work at a typical drycleaning facility. I think this number is too high.

Response: The language has been revised to reflect that PCE releases to land could be considered hazardous waste and disposed of under RCRA authority in some cases. The estimate of the number of workers has been revised.

Comment #3-219: P. 3-27, second paragraph: In terms of landfill releases, EPA notes that because of uncertainty no exposure estimates are performed. This underestimates the risk (if it is uncertain, it must not be a risk mentality). EPA should make some qualitative judgment in the absence of data.

Response: In place of reporting a modeled estimate, measured data collected by New York and California are used. The CTSA has been revised so that qualitative discussions of exposure pathways are included when the assessors judge that a quantitative estimate is not feasible.

Comment #3-220: P. 3-28: Inhalation Exposures: A number of other data sets exist that can be

used to supplement the three data sets presented. Thomas (sic, Thompson) and Evans (1993) ' Workers breath as a source of perchloroethylene (PERC) in the home' J Expos Anal & Environ Epidem 3 (4) 417-430 quote several sources in their Table 2 that provide personal air sample (TWA) measurements. One is a report by the International Fabricare Institute from 1990 (I do not have a copy of the report to supply but have sent the paper by Thomas (sic, Thompson) and Evans), which is listed as having made more than 3000 measurements of operators and non-operators who use either dry to dry and transfer machines. Several other smaller studies are also cited by Thomas and Evans 1993. Overall the values reported in that article are somewhat higher than provided in exhibits 3-9 to 3-11.

There are three studies done outside the US which may also be useful for comparison and completeness. While the level of emission control and maintenance of the machines may be less optimal than in the US, many older, smaller operations in the US may also be below the preferred standard for emission and maintenance, so these foreign studies provide information on the high end exposure concentrations. They include Aggazzotti et al. 1994 'Occupational and environmental exposure to perchloroethylene (PCE) in drycleaners and their family members' Archives in Environmental Health 49 (6) 487-493, Skender et al. 1992 'A comparative study of human levels of trichloroethylene and tetrachloroethylene after occupational exposure' Archives in Environmental Health 46 (3) 174-178. and Abo El Ata et al. 1996. 'Environmental and health monitoring study in dry cleaning Departments' Int. J. Environ. Health Res. 6, (3) 221-231.

Response: The Thompson and Evans reference contains data which are useful and have been incorporated. The IFI data were found in other published sources and have also been included. The other three references provided did not contain the types of exposure data and information required for this section.

Comment #3-221: P. 3-28, second paragraph: There is no empirical evidence that OSHA data may be higher than actual data for the total population. This unfounded statement leads to an underestimate of risk. In fact, there is evidence that workplaces where OSHA makes compliance inspections (or complaint inspections) are more often unionized and generally have better health and safety conditions. So, these data may actually be underestimates of actual Ecs.

Response: No evidence is presented to support this argument. Such uncertainties are well established in the text.

Comment #3-222: P. 3-28: The most helpful tables are 3-9, 3-10, 3-11. These demonstrate that median exposures to all but managers (roughly equivalent to geometric mean) are 5-15 ppm, while average exposures over the population as a whole (excluding managers) and for cleaners ran about 50 ppm. For cleaners, the median (approximated by the geometric means) as also about 10 ppm, showing that the average is being pulled upwards by a few outliers. Managers, a minority of the workforce and likely of higher social class, had about twice the median and average exposures. These exposure data are important for interpreting epidemiology studies in light of extrapolated risk assessment from animal data.

Response: Observed exposures have been used in the risk chapter (now Chapter 5) together with unit risks and other risk measures to gauge the range in which risks to occupational populations may lie. The risks reported in occupational epidemiologic studies are best interpreted in light of exposures measured in their own populations. While the figures from OSHA and NIOSH may well

pertain to the same worker populations (Ruder et al. (1994), for instance, cite the NOES data base), older numbers are more likely to correspond to the historical exposures that would bear on health outcomes published several years ago, whereas more recent numbers (as shown in the exposure chapter) provide information on the potential for future occurrence of adverse health effects. The epidemiology in the CTSA is insufficient to derive specific comparison values from human data - the Ruder et al. study, for instance, provides relative, not extra, risk. The data bases themselves are established as sources of descriptors of the conditions under which workers labor, and do not provide disease incidence information. Only careful enumeration and study can address the likelihood of an association between the two. As identified in response to such comments as #2-79 and #2-96, IARC's analysis of the epidemiology, together with animal studies, has brought it to conclude PCE is probably carcinogenic to humans.

Comment #3-223: P. 3-28, first paragraph: Same comment as page 3-23. [**p. 3-23, fourth paragraph:** It has been my experience that workers in well maintained plants, using modern equipment, experience exposure well below the TLV or PEL (less than 10 ppm on 8 hr average). This assumption is significant to the results of this document and has no basis in fact. The alcohol content limit for drunk drivers is 0.1. We do not assume that all drivers are at 0.1 while they are driving.]

Response: No assumption related to the TLV or PEL mentioned in this comment is stated or implied in the fourth paragraph of p. 3-23. No changes have been made.

Comment #3-224: P. 3.28, section on inhalation exposure: This section needs to represent the data in a way that is relevant for decision makers. In particular, it must separate the data for transfer machines from those dry-to-dry machines and for different types of workers. My own analysis of occupational data and the analyses of others suggest that these should be split into dry-to-dry machines and transfer machines and operators and non-operators (see Thompson and Evans, 1993, table 2). Also, the CTSA is missing the data reported by Petreas et al., 1992 and Moschandreas and O'Dea 1995.

I am very concerned with the use of the data supplied by OSHA as a basis for estimating occupational exposures without further analysis. First, the data are not classified by the machine type and since other exposure studies have shown exposures to be significantly different based on machine type, these data are unhelpful. Second, the data represent repeat measurements at the same facility so that averages and geometric means of the data are not very meaningful in estimating the averages for the industry overall. In particular, although I have not spent much time looking at these data, I did notice that the facility with the highest measurement (Smitty's Clean Scene) of 744 ppm sampling a drycleaner on 7/15/91 also had drycleaner measurements of 0, 0, 0, 0, 2.3, 2.5, 3.3, 3.4, 3.4, 3.6, 4.4, 6.0, 8.4, 10.7 on that same day. These data points make me suspicious that we don't understand all of the sampling that went on that day and that the high value is probably not representative of the typical workplace concentration in that facility (i.e., it should not be used to estimate typical workplace exposure values.) Note also that a maintenance man servicing the facility a week later had measurements of 105.2 and 127.7 ppm and this may suggest that something was wrong. The same problem appears at Mr. Todd Dry Clean where measurements made on 2/11/92 included 71, 92, 140, 161, 170, 291, and 627 ppm for the manager (whatever that means), 0, 30, 67, and 94 for the assistant manager, 60, 67, and 67 ppm for the supervisor, and 34 and 64 ppm for the pantpresser. This is also a problem for the next one up in the data, the Roxy United Drycleaners, where drycleaner measurements on 8/16/93 included

0, 0, 87, 108, 162, 246, 265, 388, and 516 ppm and drycleaner measurements on 7/14/93 included 0, 9, 12, and 31. These data should not be used in the CTSA until further analysis is performed to ensure that they represent the information relevant for the industry. (As an aside, before doing this analysis, the data between 1994 and the current date should also be included). Also, it is unusual to report data as the "as study from the University of Michigan" when it appears in the peer-reviewed literature. The citations should be to Solet et al., 1990 throughout (including at the bottom of Exhibit 3-11 instead of AIHA, 1990) and in general citations should be given to the authors of the original research. The data from PEI, 1985 are too outdated to be of any use, besides the fact that they are also not disaggregated by machine type. These data should be dropped entirely.

[Thompson, K.M., and J. S. Evans, 1997. The value of improved National Exposure information for perchloroethylene (Perc): A case study for drycleaners. Risk Analysis. 17:253-271.

Petreas, M.K., Rappaport, S.M., Materna, B.L., and D.M. Rempel. 1992. Mixed-exhaled air measurements to assess exposure to tetrachloroethylene in drycleaners. J. of Exposure Analysis and Environ. Epi. Supp. 1:25-39.

Moschandreas, D.J. and D.S. O'Dea, 1995. Measurement of perchloroethylene indoor air levels caused by fugitive emissions from unvented dry-to-dry cleaning units. J. Air and Waste Manage. Assoc. 45:111-115.]

Response: The worker exposure data have been expanded to include additional differentiated data and the Thompson and Evans data. The associated exposure issues have also been better explained. The Petreas and Moschandreas references were not found to include the types of data and information required for this assessment. Although many uncertainties exist for the OSHA data, these uncertainties are explicitly stated, and many other data sources have been included to give a broader perspective on the variation in exposure levels. Regarding the Solet citation, the data from this source has been replaced by a larger body of data. This larger body includes the Solet data, and the citation has been properly presented in the updated CTSA. The PEI data has been dropped from the CTSA and replaced by newer and more differentiated data.

Comment #3-225: P. 3-28, Exhibit 3-9: The geometric and arith. mean exposure of the manager is considerably higher than the cleaner. This does not seem realistic unless the manager also acts as the owner. If this is the case, it should be noted.

Response: The data are correct, and whether the manager acts as owner was not available. This issue has been discussed briefly in the updated CTSA.

Comment #3-226: P. 3-29, dermal exposures: Why bother giving these if they are not characterized later? Same question applies to top of page 3-49 for PS and on the top of page 4-19.

Response: No action required. Risk characterization is not a prerequisite for exposure assessment. EPA has rewritten this section. These estimates were not used for quantitative estimates of risk, however, were used qualitatively.

Comment #3-227: P. 3-29, last paragraph: Why are other dermal exposures (non-transfer workers) not considered? Couldn't these workers have exposure from machine maintenance, changing filters, pouring solvent, etc.?

Response: Dermal exposure to "non-transfer" workers are covered in the sentence immediately following that on "transfer" workers.

Comment #3-228: P. 3-29, first paragraph: A good percentage of exposure studies are based on small numbers (due to the cost of these studies), so that the difficulty in making statistical conclusions is almost always the case.

Response: Additional studies with data based on larger samples have been included. In some instances, that has permitted their authors to make statistical conclusions that EPA has used. Comparisons across studies remain qualitative, but EPA has added a discussion regarding apparent tendencies.

Comment #3-229: P. 3-29: The CTSA cautiously states that exposures seem to be higher for transfer than for dry-to-dry machines these tentative statements are made in several places in the document. It is obvious that exposure for transfer machines is highest because of the nature of the machine. Exposure for dry-to-dry vented machines is next highest and exposure for dry-to-dry closed loop machines is lowest. This is obvious since dry-to-dry machines were designed to control emissions better than transfer machines. This conclusion could be drawn without analyzing all of the data from co-location studies.

Response: The CTSA shows many of the commenter's points.

Comment #3-230: P. 3-29, first paragraph: the Michigan and NIOSH studies need references in the text.

Response: These citations were overlooked in the text. All data citations have been included in the updated CTSA.

Comment #3-231: P. 3-31, first paragraph: For all of the general population data it would be useful to have a table in the text that lists OSHA occupational values in mg/m^3 and ppm for reference. The population values are generally quite small but they should be put in context. An extremely useful number would be the human olfactory detection threshold limit for PCE. PCE has a distinctive odor and is detectable at concentrations well below those thought to pose a health risk. However, the perception is that detection = hazard.

Response: EPA did not do this because of issues with the use of occupational data. The OSHA values are based in part on factors not directly related to health issues, such as best available technology. In the risk chapter, language is included which puts the general population values in context.

Comment #3-232: P. 3-31: How many control homes were used? How does this number affect the overall value of the study? This section describes the control homes that should have been outliers, but does not discuss the control homes that were not outliers.

Response: A more extensive discussion of control homes has been provided.

Comment #3-233: Sec. 3.4.1, p. 3-31, third paragraph: Second sentence: punctuation missing.

Response: This has been corrected.

Comment #3-234: P. 3-31, last paragraph: The listed range for the control homes includes the outliers. It would be more appropriate to report the range without the outliers and then report the outlier results individually.

Response: This change has been made.

Comment #3-235: P. 3-31 and throughout: The "methodology" section should precede the "results" section in describing any study results.

Response: This change has been made.

Comment #3-236: P. 3-31 to 3-33: General population. Capital District Survey. The New York State Department of Health study in the Capital District was conducted to evaluate PCE levels in indoor and outdoor air of all buildings where there were occupied apartments and an operating drycleaning facility using PCE. As such, the study is representative of all co-located apartments in the Capital District area of New York (the cities of Albany, Schenectady and Troy). We disagree with your statement on page 3-32 that because the intent was to measure the highest level in these residences and the small number of apartments, that these results are not representative of all co-located apartments. It should be noted that none of the residents of these apartments detected PCE odors (neither did the NYS DOH staff) nor complained to health or environmental officials prior to the study. The lack of odor detection is an important point to make in the CTSA because odor detection for PCE is an inadequate warning of its presence in air. Concentrations of PCE that can results in recognizable odors should be added to the CTSA.

Regarding the air results for apartments above non-vented dry-to-dry machines mentioned on page 3-33, we can provide clarification of which facilities/apartments were also studied by Consumers Union in their (separate) assessment.

Response: The discussion of this scenario has been revised and the language regarding representativeness is no longer present.

Comment #3-237: P. 3-31: PCE Concentration Monitoring Data. "co-located residents are exposed to elevated levels (they are not potentially exposed, this study did find high levels)." Measured concentrations are highly variable in all exposure studies. To state that this one is variable downplays the results.

Response: The problem is due to the extrapolation of a small number of data points to a larger population. EPA disagrees that stating that this study is highly variable will downplay the results.

Comment #3-238: P. 3-31: The NYSDOH study cited has been published as Schreiber et al. 1993 'An investigation of indoor air contamination in residences above drycleaners' Risk Analysis 13, 335-344, which may be available than the original NYSDOH report and worth adding to the reference list.

Response: This citation has been added to the list of references.

Comment #3-239: P. 3-32, fifth paragraph: The fact that people were not asked to keep their windows closed is a large caveat which potentially would lead to underestimates of exposure.

Response: This point has been made.

Comment #3-240: P. 3-32, section on previously unpublished data from NY: A summary of the results is needed here for ranges as they relate to different types of machines and control. Instead of the list given in Exhibit 3-12, the CTSA should strive to come up with generalized estimates that apply to different machine types and control types (they should be independent of sampling times and locations).

Response: The presentation of these data has been revised. There are now fewer exposure scenarios, and the data are grouped by machine type for each study.

Comment #3-241: P. 3-32, fourth paragraph: I do not believe that evacuated canisters provide accurate sampling for the low levels that are being measured. The velocity of sample air flowing into the canister is much higher at the beginning of the sampling period than at the end.

Response: EPA has reported the information from studies, critique, and debate over the validity of the conduct of the studies are not within the scope of the CTSA. Specific adjustments for bias and measurement error were not available for use in the CTSA.

Comment #3-242: P. 3-32, sixth paragraph: a verb is left out of the phase.

Response: This has been corrected.

Comment #3-243: P. 3-32, sixth paragraph, last line: ...there are only...

Response: This change has been made.

Comment #3-244: P. 3-32, first paragraph: At a minimum, the range of outdoor values need to be reported in this paragraph.

Response: This information has been included.

Comment #3-245: P. 3-33, second paragraph: Sampling of residence because of complaint. Where are sample results of the other 3,000 plants that had no complaint?

Response: Although some of the samples are based on complaints, other studies are census-based or are focused on specific types of machines. In addition, the samples taken in response to complaints are not necessarily higher than other measured values.

Comment #3-246: P. 3-33, first paragraph: What is the concentration range with the outlying poor machine removed? How does removal of this outlier affect the results of the study?

Response: The language has been revised to provide this information.

Comment #3-247: P. 3-33, third paragraph: The fact that the samples were based on complaints provides no clear indication that these places were not representative of others. Also, EPA assumes that the closed facilities had lower concentrations after reopening. Was resampling done?

Response: The language regarding representativeness has been deleted. Yes, resampling was done in many cases. In general, lower concentrations were found after reopening.

Comment #3-248: P. 3-33, eighth paragraph: Facility had no fans. Unusual circumstances to say the least. A drycleaning plant without a fan is designed for failure and is in violation of most State and local building codes.

Response: EPA has reported the results of the studies and conditions under which they were conducted (to the extent known). It is outside of the scope of the CTSA to critique or debate the conduct of the studies.

Comment #3-249: P. 3-33: In the San Francisco study involving dry-to-dry machines, from the tables of machine types from chapter 1 this would not appear to be a realistic situation.

Response: The study was conducted to look at "new machines with advanced controls".

Comment #3-250: P. 3-34, fourth paragraph: Consumers Union was not able to identify any drycleaning machine referred to in their study. Thus, there is much uncertainty about whether the 3rd generation refrigerated condenser machines had supplemental controls. It appears that no 4th generation machines were present in this study, nor were there any proper vapor barrier room enclosures. (Personal conversations with B. Warren, Consumers Union, 1995). The NYS DOH, Consumers Union have never tested a residential apartment above a drycleaner, having state-of-the-art 4th generation equipment, and a proper vapor barrier room enclosure, as per NYS DEC part 232 requirements, with an air change every 5 minutes. I helped a New York City landlord develop a special environmental lease for his drycleaner tenant, located in a mixed use building in Manhattan. This required an air change every 2-3 minutes in the vapor barrier room enclosure, VBRE for a 4th generation Permac machine that had negligible PCE emissions (background of 1-2 ppm in the VBRE). This facility has yet to be tested by the NYS DOH, and should be fully studied

to demonstrate that such new facilities can be properly controlled to minimize health risks of PCE in mixed use, co-located, buildings.

Response: EPA has reported the results of existing studies. Undertaking a new study is beyond the scope of the CTSA.

Comment #3-251: P. 3-34, second paragraph: There is no need to put the goal of the Consumers Union study. Were there any peak concentrations noted in the averaged samples? Why are no conclusions of this study provided?

Response: EPA has revised the discussion and believes the study is adequately characterized.

Comment #3-252: P. 3-35, last paragraph: For completeness there is another German study (Gulyas and Hemmerling 1990, 'Tetrachloroethylene air pollution originating from coin-operated drycleaning establishments' Environmental Research, 53 (1) 90-99) that included apartments above drycleaners, including a temporal examination of one after the drycleaning machines had been removed from the premises. Elevated levels were found for extended time periods, presumable due to absorption and subsequent release from the cement.

Response: An analysis of coin-operated facilities is outside the scope of this assessment.

Comment #3-253: P. 3-35: Concentrations measured in Germany and Netherlands. It is not believed that the data cited includes the aforementioned Hamburg Germany mixed use drycleaner, using 4th generation PCE equipment, and the positive air pressure vapor barrier ceiling that this writer saw in April, 1997; and which will be described in more detail later in these comments.

Response: An analysis of these new European data is outside the scope of the CTSA.

Comment #3-254: P. 3-35, sixth paragraph: What is so special about the 0.100 mg/m3 value mentioned in the second sentence? Page 3-27 cites much higher levels of concern.

Response: This was the New York Department of Health concern level for exposures to PCE, based on their analysis of non-cancer health effects. An explanation has been added to the text.

Comment #3-255: P. 3-35, last paragraph: Why weren't the Dutch and German data used in this assessment? They provide important information in terms of similar exposures from vented and non-vented dry-to-dry

Response: These data were not used in order to limit the assessment to concentrations measured in the United States.

Comment #3-256: Sec. 3.4.1, p. 3-35, seventh paragraph: European data show no difference between vented and non-vented machines, but are levels higher or lower than in the U.S.? Why were these data not used?

Response: European data tend to be similar to levels found in the U.S. These data are briefly discussed, but not used because EPA believes that an assessment of the U.S. data is sufficient.

Comment #3-257: P. 3-35, fifth paragraph: Is 0.100 mg/cubic meter the acceptance criteria for levels in apartments? Where was this taken?

Response: This is the New York Health Department concern level for exposures to PCE.

Comment #3-258: P. 3-36, sixth paragraph: The estimate of 1.5-2 years of residence is very low, especially in established neighborhoods, where people might spend more than 20 years. Even the upper bound estimate of 8 years is by no means an upper bound. I suggest surveying of individuals living in co-located residences for better information. Why are children not considered in this upper bound?

Response: A survey of individuals living in co-located residences is a good idea, but is beyond the scope of this assessment. Information provided in the Exposure Factors Handbook (USEPA, 1997) has been used in the estimation of residence time. EPA recognizes that this is an underestimate of residence time for some individuals; this has been noted in the text. A discussion of exposures to children has been included.

Comment #3-259: P. 3-36, second paragraph: "PCE based on emissions from (not to) transfer machines."

Response: This change has been made.

Comment #3-260: P. 3-36, fifth paragraph: Isn't the estimate of one drycleaning machine per co-located building low? Earlier EPA mentions 2 machines.

Response: The study descriptions showed that there was one machine per facility.

Comment #3-261: P. 3-36: Again, the tentative conclusion that transfer machines expose workers more than dry-to-dry machines is drawn and again, it is inherently obvious.

Response: Some conclusions, that may be obvious to some, are presented for completeness.

Comment #3-262: P. 3-36: Co-located Residents: Exposure Scenarios. The assumption that the average number of years in residence at the same apartment ranges from 1.5 to 2 years appears to be an underestimate. The upper-end duration of eight years appears to be more reasonable. Particularly in New York City (where apartments are hard to find) many families reside in one apartment for decades. We would point out that for an infant living in such an apartment since birth, eight years represents a period in his or her life when the child is most vulnerable for many of the adverse health effects associated with PCE exposure, and therefore these exposures should carry additional weight in risk assessment.

Response: Refer to the answer to comment number 3-258.

Comment #3-263: P. 3-37, Exhibit 3-12: There appears to be no rationale for the arrangement of exposure scenarios. Please provide some rationale for this. Also, the comments that assessments were made in response to complaints is non-relevant (leads one to think the results are not typical) and should be omitted.

Response: The exposure discussion has been reorganized to better present the material. The influence of complaints on measured values is unclear, however, it suggests that these samples are not necessarily random. This point is made in the revised discussion. EPA believes that it is worthwhile to mention that some samples were based on complaints.

Comment #3-264: P. 3-37/38: While the intent is to give a picture of co-location exposure this data and all of the caveats required to justify it's presentation is very questionable. The data is a collection of case studies with single point sources. The examples are so varied and the conditions so uncontrolled that it is nearly impossible to draw any conclusion. This is a great example of a university research project with good controls waiting to be conducted.

Response: Both the data and the descriptive language have been reviewed by a statistician to ensure that the results are appropriately presented. EPA believes that the data presented is useful and informative.

Comment #3-265: P. 3-38: Under entries I and J in Exhibit 3-13, the machine types are called "non-vented dry-to-dry" and "non-vented dry-to-dry with refrigerated condensers." All dry-to-dry closed loop machines contain integral refrigerated condensers. It is not clear why they are distinguished in the exhibit.

Response: The presentation of the data has been revised to eliminate this distinction.

Comment #3-266: P. 3-39, sixth paragraph: It is obvious that residents will have differing levels of exposure depending on the number of drycleaners in the city.

Response: This scenario has been removed.

Comment #3-267: P. 3-39, fifth paragraph: The model of general population outdoor exposures could easily be eliminated. The model appears to be based on an equation that takes the number of dry-cleaning units and calculates a release per unit. If this is the data reported in Exhibit 3-16 it is not called out in the text. One must assume that there are multiple urban sources for perchloroethylene compared to a rural setting. This section adds no value.

Response: This section has been removed.

Comment #3-268: P. 3-39: See Thompson and Evans (1997) for an alternative way to characterize exposure via ambient emissions. The CTSA needs a citation for the "OAQPS Study."

Also, see Wallace (1989) for a more synthesized view based on TEAM data. I find this section to be very unhelpful to the average cleaner. In addition, if one is using box models to estimate LADCs for individual risk, then one will miss the highest individual LADCs that occur for people living very near the source. I believe that the Human Exposure Model should be considered here, since it at least attempts to consider dispersion around the source. If one is concerned that two facilities are too close together, then test the hypothesis to see if it matters. The control estimates of "no control" and "best control" are meaningless since they are not related to the current distribution of machines. In particular, since not all facilities have uncontrolled transfer machines, this gives an incorrect view of the status quo. Finally, using the concept of exposure efficiency (see Evans and Thompson, 1997) one can estimate the population exposures easily from these sources. Note that TEAM study data are both relatively old and that they do not distinguish between different sources of PCE or pathways of exposure.

[Thompson, K.M., and J. S. Evans, 1997. The value of improved National Exposure information for perchloroethylene (Perc): A case study for drycleaners. Risk Analysis. 17:253-271.

Wallace, L.A. 1989. The Total Exposure Assessment methodology (TEAM) Study: An analysis of exposures, sources, and risks associated with four volatile organic chemicals. J. of Am. College of Tox. 8:883-895.]

Response: The Wallace paper has been used to provide a better description of the TEAM study results. There is some attempt to distinguish among different sources of PCE.

EPA has decided that a detailed modeling analysis of ambient exposures for PCE is not needed, given the many monitoring studies available.

Comment #3-269: P. 3-39, fourth paragraph: Why was an infant exposure duration of 1.75 years chosen? Please be explicit. While the 70 year lifespan is usually chosen for risk assessments, it should be updated with current mortality statistics for men and women. Why are workers in businesses adjoining drycleaners not considered in this analysis?

Response: The discussion of infant exposure has been revised and the exposure duration value of 1.75 years no longer applies. The 70-year lifetime has been retained because it is consistent with assumptions implicit in the unit risk value. A reevaluation of the unit risk (and hence, the 70-year lifetime) is beyond the scope of this assessment.

Comment #3-270: P. 3-39, first paragraph: While adults may spend 69% of their time outside the home, what about small children, mothers protecting those children, and child care providers. Mothers staying home with children will spend up to 100% of their time in their home.

Response: More information on exposures to persons spending most of the day at home has been provided.

Comment #3-271: P. 3-39, last three paragraphs: The modeling approach for the outdoor air provides a reasonable first estimate of localized outdoor air concentrations for cities, but has the implicit assumption that the area considered has a uniform concentration. This is not true as proximity to drycleaners (i.e., being within one to two blocks) can result in ambient concentrations that are higher than more distant locations. (US EPA/902/R-93-001 Vol 4 - Staten Island/New Jersey Urban Air Toxics Assessment Project Report, January 1993).

It is expected, however, that this non-uniformity will have only a small impact on the population exposure since other sources of exposure (visits to drycleaning shops, transporting, storing and wearing drycleaned clothes) will be much greater. Proximity may impact a portion of the population that would otherwise have lower exposures. A sentence or two acknowledging this inherent assumption in the model of outdoor air concentrations and that real gradients in ambient air concentrations exist should be included.

Response: The section on modeled ambient air exposures has been removed. Data on general-population exposures as summarized in the TEAM study are discussed. The language has been revised to make the point that ambient air exposures vary with distance from drycleaning facilities.

Comment #3-272: Sec. 3.4.1, p. 3-39, third paragraph: Perhaps a measure of variability would be helpful.

Response: EPA does not believe there is enough data to accurately calculate it.

Comment #3-273: Sec. 3.4.1, p. 3-39, first paragraph: "divided up between" is colloquial.

Response: The language has been revised.

Comment #3-274: P. 3-40: Typographical error on p. 3-40: 24 hour samples, not 4 hour samples, were taken in Study I.

Response: The reviewer is correct in pointing out this error. The discussion of the co-located exposure scenario has been revised to provide clearer descriptions of the studies and less complicated tables. This table has been substantially revised.

Comment #3-275: P. 3-40, Exhibit 3-14: It would be useful to be explicit about how the high end exposures were determined. These could be low based on the time percentages presented.

Response: The language has been revised to more clearly document assumptions used in the exposure calculations.

Comment #3-276: P. 3-40, Exhibit 3-14: There are really too many issues relating to the development of this table to completely discuss here. Here are the highlights. One, there appears to be some rounding or other error in the LADC columns. I calculated 0.09 and 0.41 for scenario A's average and high end values, respectively, and 0.10 and 0.46 for scenario E's average and high end values, respectively. You might want to check other values as well.

Two, I do not believe it is proper to use the geometric mean to get an "average daily concentration" using the rationale that "geometric means are not as easily influenced by outliers." If the measurements truly contained outliers (which I don't believe they do), you should remove the outliers and recalculate the distribution average. It is more likely that the co-located residences were not randomly sampled, thus causing the statistical means to be biased. However, correcting for this bias is not easy and probably not within the scope of your project. It might be easiest to

change your rationale for using the geometric mean. One rationale for using the geometric mean (GM) is that in log-normal distributions, the GM is very close to the median of the distribution. I suggest wording such as " ... because geometric means are closer to the median, i.e., 50th percentile, of log-normal distributions than the arithmetic mean and many of these data sets are more log-normal than normal." -- see paragraph 2 on page 3-39.

Three, high end concentrations in Exhibit 3-14 should be influenced by more than the number of years a person spends in an apartment. High end concentrations should also be influenced by the higher-than-median concentrations as well as higher-than-median apartment stays. I would suggest using the 80th percentile of the log-normal distribution which is easily calculated from the GM and geometric standard deviation of the concentration distributions.

Response: 1) The reviewer is correct in identifying rounding errors. All calculations have been rechecked and revised as needed.
2) EPA agrees that the use of the word "outlier" was not correct in this context. However, the arithmetic means are now used in the general-population exposure calculations.
3) This change has not been made. The exposure assessment involves extrapolations from short-term measured values to long-term estimates of exposure. EPA does not agree that it is appropriate to use high-end concentrations in estimating high-end exposures.

Comment #3-277: P. 3-41, Equation: Why was an exposure duration of 18 years chosen?

Response: This scenario has been removed.

Comment #3-278: P. 3-41: I don't think using an ED of 18 years is appropriate for this urban analysis. It assumes one would move to a pristine area after 18 years. In fact, they may move to an urban area with greater or lesser PCE in the air. (This situation is different for co-located residents who are unlikely to move to another co-located apartment.) I would drop the Lifetime part of this analysis and just report expected urban concentrations.

Response: This scenario has been removed.

Comment #3-279: P. 3-42, second paragraph: What does personal activities mean in this contact (sic). This places blame on individuals for their exposures, as if they could control them.

Response: Personal activities include things like bringing drycleaned clothes home. This discussion has been revised to provide a more complete explanation

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Comment #3-280: Sec. 3.4.1, p. 3-42, fourth paragraph: The relative contributions from various sources might parallel the distribution of end-uses for PCE.

Response: Additional information on relative contributions is described in the exposure chapter.

Comment #3-281: P. 3-42, last paragraph: Modeling only infant exposure through breast milk will most certainly underestimate risk to infants. Infants will also be exposed to PCE through

inhalation, just as any adult (and this inhalation exposure will likely be more important for children given their increased breathing rates).

Response: A discussion of infant inhalation exposure has been added to the CTSA.

Comment #3-282: P. 3-42, section on maternal exposure scenarios: This exposure pathway is relatively unimportant and I think that the CTSA is giving it too much emphasis. I'm not saying that it shouldn't be included, but it should appear last on the list. In addition, the para-occupational exposure of workers to their families via their exhaled breaths (Thompson and Evans, 1993) is likely to be more significant.

[Thompson, K.M. and J.S. Evans. 1993. Workers' breath as a source of perchloroethylene (Perc) in the home. J. of Exposure Analysis and Environmental Epidemiology. 3:417-430.]

Response: EPA disagrees; there is a great deal of concern for infant/child exposure. The occupational/home breath pathway has been discussed.

Comment #3-283: P. 3-42 to 3-44: Maternal exposure scenarios and infant doses. In addition to the summary of studies by Schreiber (1992 and 1993), additional information is also available. Schreiber (1997) is attached for your information, and Fisher et al. (1997) "Lactational Transfer of Volatile Chemicals in Breast Milk" (attached) provides additional information on PCE in breastmilk.

[Fisher, J.F., D. Mahle, L. Bankston, R. Greene and J. Gearhart. 1997. Lactational Transfer of Volatile Chemicals in Breast Milk. Am. Indust. Hyg.Assoc. J. 58: 425-431.

Schreiber, J. 1997. Transport of Organic Chemicals to Breast Milk: Tetrachloroethylene Case Study. IN: Environmental Toxicology and Pharmacology of Human Development. Edited by Sam Kacew, Ph.D., George H. Lambert, M.D., Chapter 5, pages 95-143.]

Response: The findings of these studies are discussed in the CTSA.

Comment #3-284: Sec. 3.4.1, P. 3-43, third paragraph: Last sentence is key. Expound. Also important to note that most inhaled PCE is exhaled as PCE.

Response: Additional language has been added to make these points.

Comment #3-285: P. 3-43, last paragraph: This paragraph is confusing and unnecessary.

Response: The description of this scenario has been rewritten. This language has been removed.

Comment #3-286: P. 3-43, Exhibit 3-18: APDR is not defined. Do these scenarios include infant inhalation exposure?

Response: This scenario has been revised, and the previous APDR estimate is no longer applicable. A discussion of infant inhalation exposure has been added.

Comment #3-287: P. 3-43: An exposure is calculated for an infant from PCE in breast milk when the mother is exposed to high levels of PCE in an apartment co-located in a building with a drycleaner. It should be noted that the infant also breathes the air in the same apartment as the mother and therefore the total exposure to the infant is the sum of the ingestion exposure from the breast milk and the inhalation exposure in the apartment. These two exposures cannot be separated and both need to be calculated for the infant's exposure in the designated scenario and included in the risk section when comparing the risks (Page 4-16 and 4-18).

Response: A discussion of infant inhalation exposure has been added to the CTSA.

Comment #3-288: Exhibits 3-18: The source of the exposure numbers for scenarios C,D, and E is unclear. If I refer back to the previous tables on apartment exposures, there are only a small number of exposures concentrations in the same range as scenario C. The basis for these exposure levels should be defined.

Response: This scenario has been revised, and the previous APDR estimate is no longer applicable. A discussion of infant inhalation exposure has been added.

Comment #3-289: P. 3-43, consumers: This section also needs to consider population exposure and consumers' exposures when going into workplaces. Other data on PCE residuals on clothes include Thomas et al., 1991 and Brand et al., 1997. Again, these estimates of consumer exposure should be disaggregated by machine type and control type if these distinctions are relevant.

[Thomas, K.W., Pellizzari, E.D., Perritt, R.L. and W.C. Nelson, 1991. Effect of dry-cleaned clothes on tetrachloroethylene levels in indoor air, personal air, and breath for residents of several New Jersey homes. J. of Exposure Analysis & Environ. Epi. 1:475-490.

Brand, K.D., Jang, C.J., Park, J., Serrano, D.L., Weker, R., Lee, K. and Y. Yanagisawa. 1997. Residual perchloroethylene in dry-cleaned acetate: the effect of pressing and extent of inter dry-cleaner variability.]

Response: The Brand and Thomas studies are discussed in the CTSA.

Comment #3-290: P. 3-44, fifth paragraph: "set of samples from USEPA's study (which study??)." This is also an incomplete sentence. Why are PCE concentrations from the closet not used. Closets are frequently opened and closed and many contain slats in the doors or gaps that would allow the PCE to enter the bedroom.

Response: The scenario has been revised, and this language is no longer applicable.

Comment #3-291: P. 3-44, fourth paragraph: Drycleaning consumers are (not can be) exposed to PCE..."

Response: The language has been revised.

Comment #3-292: P. 3-44, third paragraph: These scenarios are always uncertain, not just this

one.

Response: That is correct.

Comment #3-293: P. 3-44: The consumer exposure summary on p. 3-44 does not include a study done by Consumers Union in 1996 which is unique because it evaluates personal exposure of drycleaning consumers. (The study is enclosed) Also, the Austrian Environment Ministry commissioned a study on releases from garments, worker exposure to PCE released from 6th generation machines and exposure to petroleum solvents. (This study was referenced in a memo from a colleague -- I will forward it when I obtain a copy.)

[Wallace, D.N. and E. Groth, III. 1996. Perchloroethylene exposure from dry-cleaned clothes. Consumers Union of U.S., Inc. Yonkers, Inc.]

Response: The Consumers Union study results have been included in the CTSA.

Comment #3-294: P. 3-44/3-45: This section attempts to estimate the median contribution to the portion of the general population who wears drycleaned clothing. It assumed exposure within one's home, in particular in a bedroom after dryclean clothing is placed in the closet, is the primary location of the exposure. An USEPA study that measured indoor air concentrations after the clothing had been handled in one of three ways was used to evaluate the exposure. The results from that study are counterintuitive, since it found that airing out of a garment before hanging in a closet resulted in higher indoor air concentrations, both immediately after placing the garment in the closet and for several days afterwards, than was found after hanging the garment in the closet within the plastic bag. These two conditions both resulted in higher concentration than was found after hanging the garment in a closet after removing the plastic bag. Any comments explaining these results, either in the appendix where they are summarized or in the text, would be welcome.

The text also says that the den (and presumable the other rooms within a house, other than a bedroom which contained the closet in which the drycleaned clothes were hung) was not included in the exposure analysis since the air concentration was at background levels. However, the appendix shows that the air concentration in the den was approximately one half of the air concentration in the bedroom, with the initial concentration in the den being as high as 20$\mu g/m^3$, well above the background concentrations. Since individuals who do not work outside their home spend almost twice the amount of time indoors not in the bedroom (~16 hours) than the eight hours quoted for time spent in the bedroom, and even the individuals who work outside the home may spend an average 8 hours per day in rooms other than the bedroom, the inhalation exposure indoors in rooms other than the bedroom could be expected to be between 50 and 100% of the value calculated for the bedroom, as presented in Exhibit 3-19. Thus these should be included in the exposure estimate.

Other concerns with the estimate include no information on the number of articles placed in the closet of the test home, as several articles of clothing are often retrieved at a single time from a drycleaners, and no distribution of how often people go to the drycleaners are given, as the mean number provided may not be adequate to estimate the 90th percentile exposed population. The value calculated can be compared to estimates obtained from the TEAM study. Wallace (1989) 'The Total Exposure and Methodology (TEAM) study: An analysis of exposures, sources, and risks associated with four volatile organic chemicals' J. Of the American College of Toxicology 8 (5) 883-895, suggests that 5$\mu g/m^3$ as an average in-house exposure from drycleaned clothes, which is

similar to the values for the 30 and 50 year exposures calculation. However the 5$\mu g/m^3$ was for the entire study population and not just those individuals who wear drycleaned clothes, thus is expected to be low. This is seen by the indoor air concentration average being 25% greater than the two sites where more drycleaning may be expected, NJ and LA, compared to Contra Costa. Thus values greater than 8$\mu g/m^3$ may be more realistic for indoor environments impacted by drycleaned clothes across all rooms of a home, with higher values for individuals who have more items drycleaned. In addition, the contribution that is expected at work or from wearing freshly drycleaned items were not included. As pointed out on Page 3-45 Para 2, a number of uncertainties exist with these exposure analyses, and it may be worthwhile indicating the potential magnitude of the uncertainties.

Response: The reviewer raises several good points. The quantitative exposure estimates based on the drycleaning study have been removed. The information from this study is summarized qualitatively. The TEAM study is still used.

Comment #3-295: Sec. 3.4.1, p. 3-44, third paragraph: Unintelligible sentence.

Response: The language has been revised.

Comment #3-296: Sec. 3.4.1, p. 3-44, seventh paragraph: What about exposure concentration decay? Constant over 7 days?

Response: See the answer to comment number 3-294.

Comment #3-297: Sec. 3.4.1, p. 3-44, fourth paragraph: What about process determinants? What about weather conditions, especially temperature, air movement and possibly humidity?

Response: See the answer to comment number 3-294.

Comment #3-298: P. 3-45, fourth paragraph (and p. 4-5): It is stated, without a reference, that the dermal pathway during showering/bathing with PCE contaminated water is negligible. Current literature suggests otherwise. This skin permeability coefficient of PCE from aqueous solutions is greater than for either chloroform or trichloroethylene (Bogen et al. 1992 ' Dermal absorption of dilute aqueous chloroform, trichloroethylene and tetrachloroethylene in hairless Guinea Pigs' Fundamental and Applied Toxicology 18 30-39) and the dermal uptake during showering and bathing for both of these compound have been shown to be comparable to inhalation during showering, greater than inhalation during bathing and being approximately equivalent to a 2-liter ingestion of water (Jo et al. 1990 'Routes of chloroform exposure and body burden from showering with chlorinated tap water' Risk Analysis 10 (4) 575-580, Jo et al. 1990 'Chloroform exposure and the health risk associated with multiple uses of chlorinated tap water' Risk Analysis 10 (4) 581-585, Weisel and Jo 1996 ' Ingestion, inhalation and dermal exposure to chloroform and trichloroethylene from tap water' Environmental Health Perspectives 104 (1) 48-51).

Response: The reviewer is correct. The statements on dermal absorption have been revised.

Comment #3-299: Sec. 3.4.1, p. 3-45: Exhibit 3-19: Aired out has highest LADC?

Response: Yes, the authors speculated that this had to do with the drycleaning process used, rather than airing out the garments. See the answer to comment number 3-294.

Comment #3-300: P. 3-45, fourth paragraph: The exposure assessment for groundwater use was based on a 5ppb concentration because the Californian data base used reported 5ppb when levels exceeded MCL of 5 ppb for the state. A value of 5ppb underestimates the water concentration when water contamination has occurred and therefore underestimates the resulting exposure by ingestion, inhalation and dermal absorption. Page 3-46 says "if these effluent flows (from drycleaners) are not sent to a POTW, it is possible that the PCE could be present in surface water in excess of the CC." The CC is 70 ppb. Even though "Anecdotal data suggest that most drycleaners discharge their effluent to a POTW" it is likely that some do not and thus these higher water levels exist. Values of 180ppb have been found in drinking water in Finland, though it is unclear whether drycleaner were the sole source of the contamination (Vartainen et al. 1993 'Population exposure to tri and tetrachloroethylene and cancer risk: Two cases of drinking water pollution' Chemosphere 27 (7) 1171-1181). A higher groundwater concentration than 5ppb should be used for the proposed scenario, possibly 70 ppb, the quoted CC.

Response: An analysis of groundwater contamination in Finland is not necessarily representative of conditions in the United States. Although U.S. data also show that high contamination levels can be found, in general these problems are cleaned up. For the purposes of assessing chronic exposures, EPA believes that 5 ppb is not unreasonable. For more information, please see chapter 4 and Appendix E of the CTSA.

Comment #3-301: P. 3-45, Exhibit 3-19: Again, I would like to see the "average daily concentrations" and not just the lifetime average daily concentrations. Throughout this whole section, we've had exposure durations of 1.75, 8, 10, 18, 30, 50 and possibly other number of years. The reader would like to know how concentrations from different environments vary (in-laundry, co-located residences, urban shed, in-house with drycleaned clothes, etc.) and these values cannot be easily compared without factoring out the sometimes arbitrary dilution factor of exposed days versus lifetime days. Although exposure durations are important to risk assessment, there seems to be an underlying assumption in all of these calculations that one is exposed to near-zero PCE concentrations during the time not included in the exposure duration (ED), which is unrealistic in some cases. With the exception of the breast-feeding scenario which has a relatively well defined ED, I would at least present the ADC along with the LADC.

Response: The exposure chapter has been revised to make the presentation of scenarios clearer.

Comment #3-302: P. 3-45, fourth paragraph: Since the MCL in many States with high population concentrations is 1 ppb, why not use that for the LADC's?

Response: See response to next comment.

Comment #3-303: P. 3-45: People do not receive doses of 5 ppb PERC in drinking water. When a well contains that high of a concentration, it is generally closed. Sometimes water contaminated at

the 5 ppb level will be diluted with other uncontaminated water to reduce the PERC concentration. It is not legal to deliver drinking water with more than 5 ppb so the CTSA should assume a lower level of contamination for the exposure assessment.

Response: The section on groundwater contamination has been rewritten to provide more details on the California findings as well as data from New York. Since 5 ppb contamination level is documented in the study, and the New York findings show that it is possible to have short-term contamination levels in excess of this number, the exposure assessment is still based on 5 ppb.

Comment #3-304: P. 3-45: it is stated that "5 ppb was the only concentration level reported in a data set that, by my reading, included PCE levels in 20 out of 260 wells tested. I do not understand where this 5 ppb number came from and why it is used -- especially when there is evidence that PCE in drinking water is associated with elevated rates of cancer. Please clarify.

Aschengrau, A., D. Ozonoff, C. Paulu, P. Coogan, R. Vezina, T. Heeren, Y. Zhang. 1993 Cancer risk and tetrachloroethylene-contaminated drinking water in Massachusetts. Arch. Environ. Health 48: 284-292.

Response: The study provided results as PCE ion counts, with higher counts correlating to higher concentrations. The statement made was that an ion count of 100,000 correlates to a measured concentration in water of 5 ppb.

While the Aschengrau et al. study finds an association between crude incidence of certain cancers and modeled relative PCE exposure, specific exposure levels are not provided. The Massachusetts concentrations quoted are based on within water system sources and probably not a good level for estimating risks that may be associated with drycleaning exposures.

Comment #3-305: P. 3-45, third paragraph: It was said earlier that exposure in groundwater was not going to be modeled.

Response: What was meant was that exposures resulting from estimates of disposal of PCE to landfills would not be modeled. The groundwater contamination results from PCE release to surface water.

Comment #3-306: P. 3-45: considering the uncertainty underlying the assumptions, how helpful is the table?

Response: This section has been revised; the table is no longer present.

Comment #3-307: P. 3-45, PCE in groundwater: Using the MCL of 5 ppb alone is inappropriate since this does not reflect actual data, because groundwater contamination with PCE may arise from non drycleaning sources, and because these values are not released to control strategies. Since this is presented as a what-if value, why not estimate it for a range of values?

Response: Rather than estimate exposures to a range of values, the description of the scenario has been expanded and information on database searches has been provided.

Comment #3-308: Sec. 3.4.2, second paragraph: Dr. DiNardi's data should be invaluable for this purpose.

Response: DiNardi did not respond to an EPA inquiry. However, the updated CTSA has incorporated information from a NIOSH study. NIOSH studied some factors, such as drycleaning worker tasks, which the commenter describes DiNardi as having investigated.

Comment #3-309: P. 3-46, first paragraph: Solubility in water of 200 ppm should be 150 ppm (see comment Exhibit 3-2). [**p. 3-5, Exhibit 3-2:** 200 ppm is used for the solubility of PCE in water. On page 2-48, 3rd paragraph, the solubility of PCE in water was 150 ppm.] The daily release is based on 250 days/yr.

Response: The reviewer is correct. This change has been made.

Comment #3-310: P. 3-46: Occupational exposure of PS. This is an amazingly long discussion given the extremely limited data set available. Again, the table would be more useful if compared to the OSHA standards from 2-51. The bottom line is that it takes several pages to say that we know very, very little about this case.

Response: Although there is no extraneous information in this section, the OSHA comparison has been included.

Comment #3-311: P. 3-47, third paragraph: It should be stated that no data is available on PS public inhalation exposure. In the absence of any data at all the exposure estimates that follow are simply speculation and add little to our understanding. The same is true for the subsequent sections on aqueous based technologies and multiprocess cleansers.

Response: Yes, that's true, but that would require the CTSA to take a very different approach.

Comment #3-312: P. 3-47, PS Exposure section: I have similar concerns here to those mentioned above for PCE with respect to the age of the occupational data and the use of the OSHA data, with the lack of characterization of the fire hazards, and with the presumption of zero toxicity limiting the exposure assessment. It seems reasonable that similar to PCE sources, PS cleaners could contaminate co-located residents, and be a source of exposure to consumers.

Response: Newer OSHA data have been included. Although many uncertainties exist for the OSHA data, these uncertainties are explicitly stated However, fire hazard is not relevant to this section and is mentioned elsewhere in the CTSA.

Due to the flammability issues, EPA believes that co-location of residents with hydrocarbon drycleaning facilities are minimal.

Comment #3-313: P. 3-47, Exhibit 3-21: Something is wrong with the "Presser" data. All seven data points would need to be 3.5 if the GM, the AM, and the maximum are all to be 3.5.

Measurement error alone would preclude this from happening.

Response: The measurements were all below the detection limit. This issue has been included.

Comment #3-314: Sec. 3.4.2, p. 3-48, third paragraph: Under what circumstances (or based on what assumptions) are the OSHA data better than the NIOSH data?

Response: Differences in data characterization and times of collection, in addition to many other factors, can make data from one source "better" than data from another source.

Comment #3-315: P. 3-48, last paragraph: Here it is said that estimates of dermal exposure to PCE are not used for risk calculation, but earlier it says they will be (or at least they are estimated). Dermal exposures should be modeled.

Response: Dermal modeling was completed for this section and discussed in the risk chapter.

Comment #3-316: P. 3-49, second paragraph: Why not use the same model for PS as for PCE? Why does it matter that they are currently used less often? This seems inconsistent.

Response: Because PS (hydrocarbons) are used less often, there is less of a likelihood that multiple drycleaners will cause elevated exposure to PS. This makes an area source model unnecessary.

Comment #3-317: P. 3-49, Exhibit 3-23: Use only one significant figure for the '4'in the Width Control ADC column.

Response: This scenario has been removed, so this comment is no longer applicable. Throughout the chapter, attempts have been made to improve the presentation of significant figures.

Comment #3-318: P. 3-49: How does ubiquitous exposure to petroleum products from gasoline and other hydrocarbon sources affect the PS exposure estimates?

Response: These exposures likely affect the exposure numbers presented here, but an analysis is outside the scope of the CTSA.

Comment #3-319: P. 3-49: Inhalation Exposure: I assume that only one inhalation scenario is provided for the petroleum solvents to the general population because of the limited data set available. While there are no petroleum solvent data available to evaluate the exposure directly for the additional scenarios done for PCE, the highest general population PCE exposures were estimated for the other scenarios. Therefore, it seems prudent to try to estimate the same scenarios for the petroleum solvents. The co-located residential exposures could be estimated by assuming that the loss of PCE and petroleum solvents to walls and furnishings as the vapors are transported within a building would approximately equivalent (a reasonable assumption for the time period transport that occurs continuous so that steady state exchange with materials could occur)

and therefore the ratio of the concentration in apartments co-located with drycleaners to that in the drycleaners would be the same for PCE and petroleum solvents. A first approximation of the apartment petroleum solvent concentration could then be obtained by multiplying the PCE concentrations in the apartments (Exhibits 3-13 & 3-14) by the petroleum solvent concentration in the drycleaners (Exhibits 3-22) and dividing by the PCE concentration in the drycleaners (Exhibit 3-9, 3-10,3-11). Since the concentration of PCE and petroleum solvents are at a similar order of magnitude, the concentrations predicted in the apartments would be similar as well. Granted, this approach has a number of broad assumptions but it will provide a first order estimate to determine whether there should be concern for individuals living above drycleaners using petroleum solvents.

Response: EPA does not believe that residents typically are co-located in the same building as drycleaners using PS (hydrocarbons), because of the flammability issue.

Comment #3-320: P. 3-50: The major reason petroleum solvents are not widely used anymore is the problem of fire and explosion. The CTSA performs the full analysis on PS but does not include the risk from fire and explosion. Why perform the full analysis at all if the fire or explosion risk is not included?

Response: EPA has included some information on flammability consideration associated with hydrocarbon solvents, however, it was not possible to quantitatively assess these risks.

Comment #3-321: P. 3-50, last paragraph: Why is it mentioned here that "wet cleaning process are expected to result in exposures", why PCE processes only "may" result in exposure. This is a double standard, which makes wetcleaning seem more dangerous than it is. Contaminated drinking water is the exposure pathway, but how often are drinking water and discharge water sources the same? Isn't drinking water treated before ingestion?

Response: Drinking water is treated before ingestion, but the available data indicate that drinking water treatment plants vary greatly in their removal efficiency. Therefore, EPA did not dismiss this exposure pathway.

The current version of the CTSA does not provide drinking water ingestion estimates, because the human health discussion has been revised and there are no longer concerns for exposures via this pathway.

Comment #3-322: P. 3-50, third paragraph: Conventional Petroleum plants maintained large UST's. This was needed because of the large amounts of Petroleum solvent that was needed since reclamation was not used. Some of the most expensive Environmental clean-ups have been repairing the soil and groundwater damage created by these UST's leaking over long periods of time. Depending on the soil condition, leaking solvent can travel to the groundwater and create high levels of Petroleum Hydrocarbons as well as other contaminants depending on the additives used by both the manufacturer of the solvent as well as the plant operator. Older Petroleum plants often used a septic system for disposal of distillate residue even though the plant was always connected to a POTW. Obviously this system has caused significant damage to soil and groundwater. Therefore I disagree with, "Estimated LADC's and PDR's are not needed because migration of both Stoddard and 140°F solvents to groundwater is estimated to be negligible."

Response: An analysis of UST's is outside the scope of the CTSA.

Comment #3-323: P. 3-50: Spotting of garments often occurs before washing. This is known as "Wet Side" spotting. Since wetcleaning is less effective on inorganic stains, the chemicals used to remove these spots should be evaluated along with the standard additives to the wetcleaning processes. This does not appear to have been considered.

Response: Assessments for spotting agents are outside of the scope of the CTSA.

Comment #3-324: Section 3.4.3: Exhibits 3-24 and 3-25: scientific notation (concentration) may be confusing to general reader.

Response: These numbers are no longer expressed in scientific notation.

Comment #3-325: P. 3-51: The CTSA states that estimates were made for the constituents of wetcleaning detergents but says they are not presented. Why not? Of what value was the analysis if there are no results?

No water volume estimates from machine wetcleaning are presented. It would be of value to know the discharge rate to estimate costs POTWs would charge for discharge. It might also be important in areas where water shortages are common.

Response: Much of the data for machine wetcleaning is proprietary. EPA has attempted to provide example formulations to provide a sense of the potential exposures associated with machine wetcleaning detergents.

Comment #3-326: P. 3-51: Why is sodium carbonate not removed in waste water treatment.

Response: Because it is not expected to biodegrade, sorb to sludge, or volatilize.

Comment #3-327: P. 3-51, first paragraph: There is no need to mention that water is not assessed here. Why are exhibits 3-24 and 3-25 not presented on this page. In the calculation DC is used - is this not wetcleaners?

Response: This section has been rewritten and reformatted to make the presentation more clear.

Comment #3-328: P. 3-52/3-53, Exhibits 3-24/3-25: One, the "Q" and "F" need to be explained in a footnote not just in the text. The 3E-4 values should be expressed consistently with data from other parts of the report (i.e., 3×10^{-4}). This also applies to the text where these tables are discussed (see page 3-55).

Response: This scenario has been extensively revised. The new scenario is based on Standard Industrial Classification (SIC) code data. In the revision, EPA has made the expression of data more consistent.

Comment #3-329: P. 3-52, first paragraph: This paragraph does not belong in the exposure section and should be placed in chapter 1.

Response: These activities affect worker exposures, and therefore, belong in this section.

Comment #3-330: P. 3-55: How does this scenario account for general consumer use of detergents?

Response: It doesn't. An analysis of this scenario is outside the scope of the CTSA.

Comment #3-331: P. 3-56, second paragraph: Information on liquid CO_2 and ultrasonic has been moved to a separate chapter on emerging technologies and exposure information is not included.

Response: This issue has been mentioned in the CTSA.

Comment #3-332: P. 3-56, fifth paragraph: While the cleaning data on CO_2 is just being generated, numerous other professions routinely use it. A simple check of OSHA standards would provide a great deal more information here. Moreover, for both CO_2 and ultrasonics is unlikely that the detergents and surfactants added to the process will be much different than those added to perchloroethylene or PS and they will be added for the same operational reasons.

Response: Information on liquid CO_2 and ultrasonic has been moved to a separate chapter on emerging technologies and exposure information is not included.

Comment #3-333: Section 3.4.6, second paragraph: Second sentence: reasonable assumption?

Response: Information on microwave drying is not included in the CTSA.

Comment #3-334: P. 3-57: The last paragraph on p. 3-57 leaves the reader with the impression that electric and magnetic field exposure from microwave drying cannot be estimated because specific information has not been supplied by manufacturers. This seems to be a data gap that could be filled easily. Has this been reviewed by Joseph Bowman and his colleagues at NIOSH?

Response: This entire section and the associated issues have been excluded from the CTSA.

Information on microwave drying is not included in the CTSA.

Chapter 4

Comment #4-1: The level of detail required to understand the presented tables may exceed the limits of the average reader. An important comparison would be risk index's for the background level. That is, when the carcinogenic value of different scenarios is presented in the tables we can only compare them to each other and not to an average population rate without PCE.

Response: The CTSA has been written for a technical audience and is designed to provide information that assists relative comparisons of cleaning technologies. Therefore, the presentation of information in the tables is appropriate. EPA expects to develop additional documents that will be less technical and more applicable to a broader audience. Because these are estimates of individual excess lifetime risk (that is, risk beyond that ordinarily sustained by the general population with no particular exposure to the chemical, as described in CTSA section 5.1.2), these calculations already incorporate and are not in the same scale as average cancer rates for the population.

Comment #4-2: Risk Assessment. I have addressed these issues through my report, so will not comment on it again. Since the potential risks associated with PCE have been studied more than with any other chemical listed in this report, does this imply that any other listed chemical is less "risky" to use for cleaning clothes? Drycleaners would like to have an authoritative answer to this question. They are in no position to get it on their own.

Response: The chapter has been revised to indicate that the comparisons of health risk between the various technologies can only give a "ballpark" type of comparison. It does not imply that any chemical other than PCE is "less risky". (For example, it indicates that although it was not possible to quantify the risk of fire from HC solvents, the risk would be greater than that from PCE).

Comment #4-3: <u>Risk Assessment for Perchloroethylene (perc)</u>. Chapter 4 lacks an explanation of the details concerning the methodology used to derive the cancer risk from perc. The implicit message that the risk of cancer for perc drycleaning operators is 1/100 or even higher requires a more thorough and detailed explanation of the assumptions made to arrive at that conclusion. It would be more appropriate to present a risk range based on worst case and best case scenarios. In addition, no epidemiological studies are presented to support the estimated risks, and the animal studies used appear to be somewhat dated and thus of questionable relevance. Additional studies that could be included in this discussion are:

Aschengrau A, Ozonoff D, Paulu C, et al. [1993]. Cancer risk and tetrachloroethylene-contaminated drinking water in Massachusetts. Arch Environ Health 48(5):284-292.

ATSDR [1995]. Toxicological Profile for Tetrachloroethylene (Update). U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry, 1995.

Bois FY, Zeise L, Tozer TN [1990]. Precision and sensitivity of pharmacokinetic models for cancer risk assessments: Tetrachloroethylene in mice, rats, and humans. Toxicol Appl Pharmacol 102:300-315.

Byczkowski JZ, Fisher JW [1994]. Lactation transfer of tetrachloroethylene in rats. Risk Analysis 14(3):339-349.

Dallas CE, Muralidhara S, Chen XM, et al. [1994]. Use of a physiologically based model to predict systemic uptake and respiratory elimination of perchloroethylene. Toxicol Appl Pharmacol 128:60-68.

Hattis D, White P, Koch P [1993]. Uncertainties in pharmacokinetic modeling for perchloroethylene: II. Comparison of model predictions with data for a variety of different parameters. Risk Analysis 13(6):599-610.

Response: As identified in the peer review draft and in the final CTSA, the CTSA is a compilation, not a risk assessment *de novo*. The Risk chapter (now Chapter 5) has been restructured to make the conclusions more apparent in light of the preceding information. While the text does not cite particular models used to derive the unit risks for PCE, it is hoped that the language is clearer in describing the underlying assumptions. Methodology is outlined at what is now Appendix D, and the cited EPA documents provide detailed discussion of the derivations. The papers suggested by the commenter are insufficient to derive specific comparison values from human data - the Aschengrau et al. study, for instance, has many modeling assumptions in order to estimate exposure levels and provides relative, not extra, risk, and the several pharmacokinetics papers examine models in different contexts, exploring their utility. Papers by some of these authors (e.g., Bois, Hattis, Fisher), however, have been included in several parts of the revised exposure and risk chapters, as well as in the revised dose-response appendix. Interestingly, another paper coauthored by Hattis (Hattis, D., S. Tuler, L. Finkelstein, Z. Luo, 1986. A Pharmacokinetic/Mechanism-Based Analysis of the Carcinogenic Risk of Perchloroethylene. Report to the National Institute for Occupational Safety and Health and the National Institute for Environmental Health Sciences. MIT Center for Technology, Policy and Industrial Development. Report No. CTPID 86-7. NTIS PB88-163 209. Cited in Comment #G-35) states "Even at 10 ppm, however, our best estimate is that the annual increment to an individual's risk would be over one in ten thousand, and that the working lifetime risks would be over .5% [i.e., 1/200]. Upper limit calculations suggest that the risk could be as much as twenty times more than these 'best estimates.'"

Comment #4-4: The risk assessment successfully accomplishes its objectives.

Response: No response is necessary for this comment.

Comment #4-5: The effects characterizations in Chapters 2 and 4 are mutually consistent and appropriately informative.

Response: No response is necessary for this comment.

Comment #4-6: The risk tables are sufficiently clear.

Response: No response is necessary for this comment.

Comment #4-7: To my knowledge, the sources of uncertainty are adequately covered.

Response: No response is necessary for this comment.

Comment #4-8: The risk assessment discussions clearly convey the disparity in availability of toxicity information for the different cleaning processes.

Response: No response is necessary for this comment.

Comment #4-9: To my knowledge, the risk-related sections of the report are not inconsistent with the "Guidance for Risk Characterization".

Response: No response is necessary for this comment.

Comment #4-10: The dose-response modeling appears to be straightforward, but as discussed above, a bit speculative. Also as mentioned above, readers are probably more interested in synthesized evaluative material rather than source or detailed information.

Response: No action appeared to be required by this comment.

Comment #4-11: The risk assessment does highlight the riskier situations, but these may be recognized already, and reinforced by more intuitive means. Basically, if there are health hazards (and these, except for carcinogenicity, are relatively well known for PCE and to a lesser extent for PS), then environments where greater concentrations of these substances pose the greatest threats to health.

Response: No response is necessary for this comment.

Comment #4-12: Chapters 2 and 4 somewhat overlap. It is unclear whether this is necessary, and if not, would represent an opportunity for tightening the document. Why not summarize relevant health effects in Chapter 2 only?

Response: This is a good suggestion which has been incorporated into the revised risk chapter.

Comment #4-13: The risk tables tend to be numerous and complex. While some of this appears necessary, some simplification seems possible, and desirable.

Response: This is a good suggestion which has been incorporated into the revised risk chapter.

Comment #4-14: Purpose: I am not clear on the true objective in this chapter, primarily because there is confusing language on pp. 4-1 and 4-2 about the nature of the quantitative estimates and whether they can be compared. If the purpose of using a common numerical yardstick is not comparison, then what is it? Is this a portrayal of the nature of the risks for each process and some general idea of order of magnitude or likelihood? This needs to be stated more clearly.

Response: The language has been changed to better reflect the idea stated in the comment of a portrayal of the nature of the risks for each process and some general idea of order of likelihood.

Comment #4-15: Mostly clear, but a number of problem spots, noted below.

Response: No response is necessary to this portion of a comment.

Comment #4-16: Tables are good.

Response: No response is necessary for this comment.

Comment #4-17: I'm not sure if tables and text are consistent. That is a mechanical process a proofreader/copy editor can do.

Response: The text and tables have been revised and checked for consistency.

Comment #4-18: Here again, there are very few actual citations to the reference list so it is difficult to know upon what the statements in the text rely. This is a serious omission.

Response: Citations to the reference list have been added to improve clarity.

Comment #4-19: The sources of uncertainty, while sufficiently described, tend not be carried forward to the interpretations and conclusions. IF they were, it might become clear that the models tend to have at least as much uncertainty and limitations as the more relevant human evidence.

Response: It is agreed that exposure models have as much uncertainty and limitations as the human data. The text has been changed to indicate this.

Comment #4-20: This was addressed above. Clearly there was a bias related to the availability of information available, and this might ultimately undermine the balanced evaluation of the alternatives from a health perspective. At an extreme, it raises the questions as to whether such a CTSA assessment, though compelling in many ways, could reasonably be made at this time. Again, a more direct and simple approach might have been more effective, and possibly the most prudent limit at this time.

Response: It is agreed that there is a bias related to the availability of information.. However, it is thought that this does not negate the usefulness of the entire CTSA.

Comment #4-21: Toward Better Risk Management Based on Risk Assessment PCE to humans implies a high value to further research that might clarify the risk of PCE exposure to humans. In the meantime, it should be recognized that high exposures, at the level of up to nearly 200 milligrams per cubic meter (mg/m^3) in indoor air near drycleaning facilities, pose many orders of magnitude higher danger to exposed individuals than the PCE levels of the order of .001 mg/m^3 occurring in outdoor urban air (exhibits 3-15,16,17, p.3-41,42). Therefore, an appropriate risk management focus is identifying and correcting situations in which PCE leaks are causing high exposures to nearby residents in indoor air. A much less urgent risk management focus is the replacement of PCE-based drycleaning by considerably more expensive or less effective cleaning methods, motivated by the highly uncertain but small risk posed by low-level exposure to PCE from modern, well-maintained drycleaning facilities.

Comments from this reviewer commenting on a 1996 draft PCE report for the State of New York is attached. These comments emphasize points about appropriate use of risk assessment for risk management on PCE, which are essentially the same as have been stated in the previous paragraph. The New York State report, Tetrachloroethylene Ambient Air Quality Criteria Document, should be included among the references for the CTSA report. The publication status of this NYSDOH report should be available from Dr. Nancy Kim, Office of Public Health, Department of Health, State of New York, Albany, NJ, tel: 518-474-2084.

Response: It is agreed that taking immediate active risk management measures to lower PCE exposures can effectively reduce risk. This does not, however, preclude the discussion of alternative technologies as in the CTSA.

Comment #4-22: I personally found the Risk Index to be more informative and intuitive than the Margin of Exposure on most of the risk tables. If other reviewers agree, and it is easy, you might want to make the Risk Index the last column on these tables.

Response: This has been done for most tables.

Comment #4-23: The guidance provided to peer reviewers requested comments on whether the discussion of perchloroethylene dose-response modeling is straightforward, and its sources clear, for those readers who want more details. As currently written, this discussion needs some clarification. Page 4-11 of the CTSA lists a unit risk of 0.00071 per mg/m^3, but fails to state the source of the unit risk estimate. Appendix C, page C-1, states that the dose-response modeling relies on analyses published in the Addendum to the Health Assessment Document, and cites USEPA [1986a]. Page C-2 states that human equivalent metabolized doses were used in modeling the mouse and rat tumor data, but also states that "The numbers are not the same as in USEPA [1986a]...." This is somewhat confusing. Based on footnote 2 on page C-2, it appears that the 1986 analyses were not actually changed in any way, but that only a subset of the 1986 results was averaged to get the unit risk estimate cited in Chapter 4. If this is what is meant by the statement "The numbers are not the same as in USEPA [1986a] . . .," then this should be stated explicitly, along with the impact of this change on the unit risk estimate. The clearest way to do this would be to quote the four individual upper-bound risk estimates from 1986 that were used so that the reader can easily verify that the new unit risk estimate is simply the geometric mean of the four individual risk estimates. The old unit risk estimate from 1986 should also be quoted for comparison.

Response: The text of what is now Appendix D, Dose-Response Assessments, has been changed to clarify the derivation. While the counterpart to what was Exhibit 4-3 (now Exhibit 5-3) retains the unit risk as a footnote, Exhibit 5-2 shows its value is discussed in Appendix D.

Comment #4-24: There is an additional issue in the characterization of cancer risk attributable to perc; no mention is made in the CTSA of the wide range of carcinogenic potency estimates which have been derived for perc. A recent analysis by Thompson and Evans [1997] notes that there is a 447-fold range of upper-bound carcinogenic potency estimates for perc. Although it is not unusual for central estimates of carcinogenic potency to differ widely for low exposures, it is somewhat unusual for the upper-bound estimates to vary so greatly. The existence of such a range of potency estimates provides a vivid demonstration of the fact that unit risk estimates are simply

estimates which may vary widely under differing assumptions. Chapter 4 of the CTSA explores the impact of varying exposure assessments on the cancer risk estimates for perc, but does not discuss the impact of varying estimates of carcinogenic potency. A full discussion of the sources and implications of this variability in carcinogenic potency estimates is beyond the scope of the CTSA, but some mention should be made of the existence of these widely varying potency estimates. The simplest way to do this would be to add Thompson and Evans' reference number 6 (Proposed Identification of Perchloroethylene as a Toxic Air Contaminant Technical Support Documents, August, 1991 and Revisions, April, 1992, California Air Resources Board and the Department of Health Services, Sacramento, CA) to the list of references in Chapter 4, along with the range of carcinogenic potency estimates.

[Thompson KM, Evans JS, 1997. The value of improved national exposure information for perchloroethylene (perc): A case study for drycleaners. Risk Analysis 17(2):253-271.]

Response: This comment makes an interesting and important point. We agree that full discussion is beyond the scope of the CTSA. The numeric span of upper bound excess risk estimates has not been explicitly included, however, since the chapter has been extensively revised and it is hoped the new tone of the discussion will convey the idea that differing assumptions can strongly influence the estimates, as noted in the comment. While different researchers' estimates for PCE carcinogenic potency have varied greatly, the scenarios on which the CTSA places most focus remain those with highest potential for highest exposures.

Comment #4-25: Finally, it does not seem appropriate to imply that the margin of exposure (MOE) approach is an alternative to the use of linear models, as is done in the last paragraph on page 4-3. The MOE is based on the ED_{10}, which can be calculated from a model which is nonlinear in the range of the observed data. However, the MOE itself is derived by simply dividing the ED_{10} by the estimated exposure, which is clearly a linear procedure.

Response: This paragraph and the corresponding references have been removed.

Comment #4-26: It is unclear whether the purpose of this chapter is to provide risk information for each process or develop a quantitative metric that can be compared across technologies. This should be clarified. Also, organization of the chapter is hard to follow and often repetitive. The chapter might be easier to follow if it were broken up by risk groups (workers, co-located residents, etc.) rather than cancer and non-cancer effects. Subsections should all be numbered and included in the chapter contents box. Tables should occur on the same or adjoining page from where they are referenced. Encountering tables several pages after they are mentioned is confusing.

Response: As stated in Comment 4-14, the language has been changed to better reflect that the chapter is a portrayal of the nature of the risks for each process and some general idea of order of likelihood. Also, the suggestions concerning format have been incorporated in the revised chapter.

Comment #4-27: In the introduction, the word potential risks should be eliminated. Risks are by nature the odds of a potential harm. By adding the word potential, the risk is downplayed.

Response: It is agreed that the word, "risk", implies a potential for harm. The word, "potential" has therefore been eliminated in many cases in discussing risk in the chapter. However, since the

concept of risk is not always easily understood, there are instances where the word, " potential" has been included for clarity. It is not thought that this downplays the risk.

Comment #4-28: Children not considered in this analysis. Also, are all of the adults considered healthy adults? It must be assumed that some percentage of those living above drycleaners are elderly or have other conditions which would increase their risk of disease from exposure to PCE

Response: EPA has added sections to include the concern for children and the elderly.

Comment #4-29: In response to a peer review question, the paucity of health effects data on substances other than PCE is obvious from review of the document. However, I am also more familiar with this scientific literature than many of the potential users of this document. I believe that the assessments made of these other substances (e.g., other than PCE) are sound. However, this may not be reflected in some of the summary tables and presentations, some additional "caveats" would be helpful.

Response: The tables and text have been revised to make the presentation clearer.

Comment #4-30: Risk numbers should be more clearly presented – eg., 1 in 100 drycleaners are expected to get cancer. If the goal of this document is to inform drycleaners so that they can make better decisions, EPA needs to be more straightforward and explain what these results mean, not just leave that analysis up to the reader.

Response: The text has been revised to include discussion of the tables. However, a risk of 1 in 100 does not mean that 1 in 100 drycleaners are "expected" to get cancer.

Comment #4-31: This chapter needs a separate glossary of terms in the appendix so that the reader can follow abbreviations repeated through the text.

Response: In the revised chapter each new term and acronym is defined or identified the first time it is used in the chapter. Also, a list of acronyms has been added. This approach was less cumbersome than adding a glossary, and should serve the technical audience well.

Comment #4-32: In comparing risks, there is no effort to consider the differing amounts of exposure between PCE and wetcleaning chemicals. Risk is a function of toxicity and exposure, but if exposure.

Response: The comment is not complete. EPA is unable to respond to the comment without speculating what was the commenter's intent.

Comment #4-33: The chapter needs a more complete assessment of uncertainties and variability in terms of PCE risks. With more than 30,000 establishments, work practices, operations, processes, and equipment condition will vary substantially. This great variation, termed indeterminacy, may tend to underestimate exposures and thus risks.

Response: The commenter's point is a valid one, and the revised chapter takes note of the variations in establishments, such as variations in work practices etc. However, at a screening level of assessment, a complete assessment of the uncertainties and variability associated with PCE risks was not possible.

Comment #4-34: By the time this reviewer had reached Chapter 4, there was just an overwhelming amount of health and environmental information and a strong urge to move on the operations of the alternative technologies. The chapter was much too technical and drawn out unless the reader is a toxicologist or of similar background. Serious thought should be given to compressing this chapter and making it more readable. And again, the dispersion of environmental impacts and human impacts made it all the more confusing. Lacking expertise in this area, it is difficult to prioritize the relevance and magnitude of information for this reviewer and no recommendations are evident. It is apparent that the objective is to highlight which sorts of situations pose greater risk of experiencing adverse effects but it takes a long time in doing so. It does not take an expert to understand the impact of poor facility maintenance, lack of emission controls, effect of exposure as proximity of source changes, etc. yet an overwhelming amount of information is provided to the reader to convince them of these issues (some of which are quite obvious).

Response: The chapter has been revised in an attempt to make it more readable.

Comment #4-35: Throughout this chapter there is a section titled "Strengths/weaknesses". These are not adequately presented in most cases. Frequently only one strength is given, i.e., p. 4-24, and no weaknesses. Rarely are the studies weaknesses adequately addressed. A weakness that should be listed for all of these citations is that there is only one study or two studies for each one. This is a very poor base from which to be drawing conclusions. The strengths and weaknesses need to be adequately outlined.

Response: The revised chapter no longer contains this section.

Comment #4-36: This chapter like others is seriously lacking in citations where required.

Response: This has been corrected in the revised chapter.

Comment #4-37: Risk Assessment: 6. I am unfamiliar with the EPA's, "Guidance for Risk Characterization."

Response: The EPA Administrator issued a memorandum on the "EPA Risk Characterization Program" on March 21, 1995. It included "Guidance for Risk Characterization" from the EPA Science Policy Council, Feb. 1995.

Comment #4-38: Risk Assessment: 5. The disparity between the amount of information between PCE and the other compounds and procedures is explained adequately. I detected no hidden biases.

Response: No response is necessary for this comment.

Comment #4-39: Risk Assessment: 4. The uncertainties associated with the risks assessed are carefully explained and are appropriate.

Response: No response is necessary for this comment.

Comment #4-40: The discussion of PCE dose-response modeling is reasonably straightforward. However, it does fail to convey the large amount of uncertainty surrounding this estimate and it does not cite any documents that would provide a discussion of the controversy for people who are interested in that. For example, it could cite Drye (1993) or Thompson (1997) for a discussion of this. Also, I believe that Jean Parker at EPA (not the Jean parker associated with DfE, but the other one who wrote the Response to Issues EPA document cited as references 369, 370, and 373) has issued a final version of this document that includes a point estimate of 4.8×10^{-7} per $\mu g/m^3$ for PCE which differs slightly from the value used in the CTSA of 7.1×10^{-7}. The reason for this difference should be made obvious in the text.

Response: It is important to give some feeling for the fact and magnitude of uncertainty and variability as possible. Some uncertainties also bear public health weight, relating to their perceived consequence and historical consideration and not to their size. We hope extensive revisions in the discussion throughout the CTSA have made this clearer. Regarding, however, the point estimate in the recently finalized "Response to Issues," we know no changes were made in that document between 1991 and this date. The two sentences referring to 4.8×10^{-7} per $\mu g/m^3$ indicate they are based on the oral studies. The other figures reflect the redundant use of the mouse carcinomas from the inhalation data. This is currently explained in what is now Appendix D.

Comment #4-41: The text does a reasonably good job discussing the available data, but could improve its discussion of the controversies. However, I believe that EPA has updated its earlier assessment with respect to a quantitative point estimate of the unit risk (and for the ED_{10}) and these differ from the numbers used in the CTSA. Review of Appendix C suggested that the difference is due to selection of different data sets, but the text needs to make this clear. More importantly, I disagree that an updated risk assessment is not considered essential for the purpose of this document because it leaves the user (who is supposed to make decisions about relative risk and alternative technologies) with incomplete information.

Response: As discussed in our response to #4-40, regarding the point estimate in the recently finalized "Responses to Issues," we know no changes were made in that document between 1991 and this date. The two sentences referring to 4.8×10^{-7} per $\mu g/m^3$ indicate they are based on the oral studies. The other figures reflect the redundant use of the mouse carcinomas from the inhalation data. How these calculations differ is currently explained in what is now Appendix D. The CTSA is not an assessment. The Agency will be undertaking a full assessment under the auspices of the Office of Research and Development within about a year.

Comment #4-42: 2. and 3. (regarding the questions on page 6 of the guidance to peer reviewers): There is good linkage between the health effects that are given in chapter 2 and risks estimated in chapter 4. However, since several sources of population exposure are not considered (as noted

above), the assessment is incomplete. The CTSA needs to do a better job of placing the exposures and risk into context. I think that the risk tables are generally clear.

Response: The revised chapter has been reorganized to better place exposures and risk into context. While it is agreed that inclusion of additional sources of population exposures would add to the total picture of risk, it was not possible given that the CTSA is presenting only a screening level risk assessment.

Comment #4-43: 4. and 6. Regarding characterization of uncertainty, I believe that the CTSA does a good job pointing out some sources of uncertainty, but needs to do a better job characterizing it and exploring and explaining its implications. In addition, the draft needs to do a much better job discussing variability between sources that might influence decisions. In these respects, the CTSA needs to be improved in order to satisfy the principles detailed in the SPC's Guidance on Risk Characterization, even at the screening level at which the CTSA is written.

Response: The revised chapter includes more discussion of uncertainty. However, it is beyond the scope of the CTSA risk chapter to elaborate on variability between sources that might influence risk management decisions.

Comment #4-44: 5. There is a lop-sidedness in the CTSA with respect to the presentation of information. I believe that restructuring the draft as suggested above would go a long way in conveying the different amounts of information available and make the draft easier for the reader to follow.

Response: EPA has reorganized the CTSA based upon many comments. The risk chapter has been included in this reorganization.

Comment #4-45: Risk Assessment: 3. The risk tables, though complex, are clear if read carefully.

Response: No response is required for this comment.

Comment #4-46: Risk Assessment: 2. The effects characterized in chapters 2 and 4 are consistent.

Response: No response is required for this comment.

Comment #4-47: Risk Assessment: 1. The situations that pose the greatest risk are explained at great length and in several places.

Response: No response is required for this comment.

Comment #4-48: Exposure Estimates: 1. The discussion of PCE dose-response-modeling is well done and the sources clear.

Response: No response is required for this comment.

Comment #4-49: Q-6: There are several relevant references missing. Some of them are already referenced above, others are not. Here is a brief listing of references which can be used either to expand this chapter(s) or to give the reader comprehensive treaties on the subject and a better understanding of the issues concerning risk:

1. Cohrssen JJ. and Covello, V.T. "Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risk." NTIS Document PB 89-137772 (1989).

2. "Improving Risk Communication." National Research Council, National Academy Press, Washington, DC (1989).

3. Glickman, T.S. and Gough, M., Editors. "Readings in Risk." Resources for the Future, Washington, DC (1990).

4. Stern, P.C. and Fineberg, H.V., Editors. "Understanding Risk-Informing Decisions in a Democratic Society." National Research Council, National Academy Press, Washington, DC (1996).

Response: It was not the intent of the risk chapter of the CTSA to include all references covering guidance on risk assessment. In an effort to keep the CTSA at a reasonable size only references directly utilized in the chapters are listed.

Comment #4-50: Q-5: As listed above, updated information about risk, EPA's proposed carcinogen classification scheme, new hydrocarbon technologies and carbon dioxide are available and should be included in this chapter.

Response: New information on hydrocarbon technologies have been included. Reference is made to EPA's proposed cancer guidelines, but as stated in response to Comment #4-49 the risk chapter was not intended as a resource for risk references. Information on carbon dioxide has been moved to a chapter on emerging technologies and risk has not been included due to the emerging status of this technology.

Comment #4-51: Q-4: There are no apparent inconsistencies between text and table. However, the statements about the lack of data on hazard and risk of carbon dioxide is incorrect.

Response: This has been corrected.

Comment #4-52: Q-3: Before presenting exposure and risk numbers, it would be useful to include tables about the average response of people to inhalation of PCE vapors (Source: The Safe Handling of Perchloroethylene Drycleaning Solvent, Center for Emission Control, Washington, DC), Petroleum Solvents (Source: Exxon) and Carbon Dioxide (Source: NIOSH Document PB-266-597 and Carbon Dioxide document, Compressed Gas Association, Arlington, VA)

Response: The risk chapter is supposed to combine measured or expected exposures with known or expected hazard values. This risk characterization includes descriptions of this analysis and whether it pertains to low, mid or high exposure scenarios\hazards and associated risk.

Comment #4-53: Q-2: My recommendation is that the content of this chapter should be split into two chapters.

The first chapter should focus on risk and review briefly the status of this emerging discipline, state its strength and weaknesses, describe its role in defining regulatory and societal strategies and policies and provide clear information about the assumption and limitations of theoretical models. The fact that cancer risk can be zero, and that the linearity assumption at low exposure concentration is not universally accepted, must be noted.

Campbell and North published a paper (referenced below) on perchloroethylene which demonstrated that risk numbers for drycleaners and other workers differ widely if different methodologies and mathematical models are used. These findings, along with other references, led to the statement in a 1985 publication of the Conservation Foundation (under the Presidency of William K. Reilly, later EPA Administrator) on "Risk Assessment and Control" that "risk assessment is as much art or philosophy as science." Acknowledging and explaining these issues in the context of this document would allow readers to understand the controversy and differences about risk among the various stakeholders of the DfE program.

Since risk numbers given in this chapter are potentially devastating for the fabricare industry, it is paramount that responsible risk communication is included. Flow charts linking input and output information together and identifying endpoints and decisions derived from it would help readers understand this complex topic. While reviewers are not to comment on policy issues, I would like to add that the agency should seriously consider to withhold the quantitative risk number. There are sufficient incentives for the industry to move towards more environmentally friendly technologies as they emerge.

It is important to explain why risk experts think that comparative and quantitative risk information and risk numbers about our daily actions or exposures are not valid. There should also be a discussion about perception and reality of risk. The acceptance or rejection of voluntary and involuntary risk by various segments of our population could be explained also. The methodologies for arriving at qualitative and quantitative cancer risk, human health endpoints and ecological risk should follow. All assumptions should be clearly stated.

The reference to cancer risk should also cover EPA's proposed guidelines for carcinogen risk assessment and the new classification scheme for carcinogens (FR April 23, 1996, p 17960 ff.). This is especially relevant since one of the seven case studies used to explain the new system is "a chlorinated alkene solvent used in drycleaning."

The other chapter should focus on the risks associated with the present and future fabricare technologies. The information presented in this document need to be updated and expanded to include safety and pollution prevention measures. References to stringent state regulations (NY, CA) may help.

Response: This chapter has been rearranged to align with the technologies under consideration. While some discussion of concepts has been included to assist in making the CTSA

comprehensible, the volume is not intended as a primer. Consequently, this chapter will continue to resemble more what this commenter saw as a second chapter in a split of the original contents.

Comment #4-54: Q-1: This chapter is undoubtedly the most controversial one. Environmentalist will welcome it and the fabricare industry will respond to it very vocally and negatively. The present content and format does not adequately cover this controversial subject matter. It is of utmost importance that this chapter is as objective as possible. I trust that credible experts in this field are among the reviewers and that they will offer a broader and clearer version of this emerging new scientific discipline and methodology.

I don't consider myself an expert in this field. But I have studied generic risk literature in scientific, popular and trade journals. I have attended one of Harvard's School of Public Health (John Graham) seminar on risk analysis, assessment and management and their application and use in policy and decision making...I have also lectured about it at universities and addressed fabricare conventions on risk assessment, management and communication. Therefore, I have some knowledge and experience of how the general public and the industry responds to this controversial subject matter.

Response: It is agreed that the communication of risk information is very difficult. However, the reviewer did not specify in what way the chapter did not adequately cover the topic of risk assessment. The risk chapter has been revised in order to be clearer and more readable.

Comment #4-55: This reviewer believes the strength of evidence for health risks of PCE exposure is significantly understated in this document, carrying forward from the Appendix A, to the Risk Chapter, to the summary. Understatement applies to interpretation of bioassay data, cancer epidemiology, and reproductive health effects. The characterization of risk leaves it to the "user" to "do it yourself" without disclosing EPA's position.

Response: The risk chapter has been revised to more clearly present the characterization of risk.

Comment #4-56: The risk charts in Chapter 4 contain a great deal of information, but get too complicated.

Response: Most of the tables in the risk chapter have been revised in an effort to make them more readable.

Comment #4-57: The risk characterization for cancer and non-cancer risk are assessed for one route of exposure. We suggest that the total cancer and non-cancer risk from multiple routes of exposure also be also assessed. For example, the CTSA assesses an infant's risk from ingesting breastmilk contaminated with PCE, but fails to assess the total exposure and risk of an infant from all routes of exposure.. Such a multi-media exposure and risk analysis is important because such infants may be getting a much higher PCE dose through the air (see comment on pages 4-28 and 4-29).

Pages 4-28 and 4-29. Given the recent recommendations of the NAS and current US EPA Policy on Evaluating Health Risks to Children, we suggest that the focus of this section be on infants (and

children), and not a route of exposure (i.e., breastmilk). We recommend that the special characteristics of children are used to explicitly assess the risks to children living in apartments co-located with drycleaning facilities. The NYSDOH Criteria Document illustrates one way to conduct such an assessment of non-cancer risks (pages 71-79)

[NYSDOH (New York State Department of Health) 1997. Preprint Draft. Tetrachloroethylene Ambient Air Criteria Document. February 1997. Bureau of Toxic Substance Assessment. Albany, N.Y.]

Response: The chapter has been revised to emphasize the fact that exposures can be from several routes, and that the risks from these exposures are additive. A section on infants has been added summarizing some of the information on breast feeding models, and exposures in co-located residences. The exposure chapter (Chapter 4) has been revised to include inhalation estimates, and it discusses children's exposures in greater detail than in the original draft. However, it was felt that it was beyond the scope of this CTSA to attempt to explicitly assess the risks to children living in co-located residences, other than in a qualitative manner.

Comment #4-58: The discussion of the uncertainties associated with cancer potency estimates and RfC estimates are found only in the section on occupational exposure for dry-cleaning workers. These uncertainties (and others) apply to all risk estimates and could be discussed in a single section dealing with the uncertainties and strengths/weaknesses common to all exposure scenarios.

Response: The chapter has been revised, and an attempt was made to indicate in the individual uncertainty sections that many of the uncertainties applied to all the exposure scenarios.

Comment #4-59: The CTSA needs to better characterize risk. For example, MOEs of 3.5 - 43 between LADCs for workers and the ED10 were characterized as "low" (page 4-18) and MOEs 0.28 - 5.3 between the same LADC and the occupational LOAEL were also characterized as "low" (page 4-20). Both were considered "indicative of concern for potential risk". What were the criteria that were used to classify the MOEs as "low" and "indicative of concern for potential risk?". However, MOEs of 80 - 700 between the LADC for residents of apartments near dry-cleaning facilities and the ED10 are characterized as "marginally low" (page 4-23). What are the criteria to separate "low" MOEs from "marginally low" MOEs.

We found it difficult to associated numerical risk levels or MOEs with qualitative descriptors of risk. We recommend a formal presentation of the relationships and the criteria used to generate the risk descriptors for both non-cancer and cancer effects. There should also be a discussion of the factors that are considered when determining whether a risk levels or MOE is "cause for concern." Such factors would include, the for example, the severity and nature of toxicity endpoints used in the MOE analysis and the strength of the toxicological database.

Response: The chapter has been revised to clarify the use of the ED_{10} MOE approach. However, at the present time there is no agreement as to criteria to link a quantitative MOE number for the ED_{10} with a qualitative statement of "concern for risk". Therefore, the terms "low" or "marginally low" concern have not been used. The revised text emphases that the ED_{10} is an alternative approach which gives a measure of how much margin there is from the expected exposure level to the ED_{10} level (the level in human equivalents at which 10% of the animal study population showed excess tumors.)

Comment #4-60: 1. Is the discussion of perchloroethylene dose-response modeling straightforward? Are its sources clear? 2. Are you aware of human health effects information...that should have been included in the summaries? The revised summary discussion of PCE cancer risks is substantially improved over the versions that were put in various places in the document. Still there is a need to make two key points that appear nowhere in either the current text or the revision:

• Despite the unsupported allusions to the possibility of a "threshold" in perchloroethylene cancer risk (top of p. 4-8), the available animal cancer dose response data have if anything, a convex (saturating) shape. That is the higher doses tested generally show a less-than-proportional increase in observed tumors as a function of dose. This is understandable, and has been modeled, as the result of the observed saturation of the activating metabolism of PCE near the bioassay concentrations in the animals tested. This is a principal motivation for the development of PBPK models for PCE, such as the ones I developed over ten years ago, and which have more recently been extended by Bois* and the State of New York. It is depressing to see this whole body of work ignored in the current document.

*Bois, F.Y., Gelman, A., Jiang, J., Maszle, D.R. Zeise, L., and Alexeef, G. Population toxicokinetics of tetrachloroethylene. Arch Toxicol 1996;70(6):347-355.

• The recent analysis of human epidemiological data by the State of New York projects overall cancer risks that, if anything, are at the high end of the range of projected risks from the animal data. My original analysis from 1986 offered a "least unlikely" estimate of PCE cancer potency that translates to a unit inhalation risk of about 0.4 E-6/μg/m^3. My "plausible upper limit" estimate (influenced importantly by uncertainties in the rate of PCE metabolism in people) was 20-fold higher at slightly less than 8 E-6/μg/m^3. Central-estimate projections by the State of New York from the Ruder et al. (1994) and Blair et al. (1990) epidemiology studies range from 3-6 E-6/μg/m^3 each for a few different sites, and somewhat more for an aggregate "all cancers" category. These projections from the human epidemiology are still quite tentative and subject to revision as more data accumulate. But the reader of the CTSA document has a right to be informed that there is no basis to suggest that the human experience so far does not indicate a comparable (or somewhat higher) degree of hazard as was originally projected from the animal data.

You do not have to create your own de novo updated PCE risk assessment in order to at least refer to the substantive conclusions of the newer assessments done by others.

Response: We agree that the shape of response has motivated a number of PBPK models; now some of these are identified in Chapter 3 (Exposure), in keeping withe the concept of using PK to derive a dosimeter, and others in Appendix D. The word 'threshold' on peer review draft page 4-8 was not intended to suggest these particular data might conform to such a model, and the extensive revisions to the risk chapter have removed the allusion. As for the epidemiology, ordinarily, when human data cannot be used directly to estimate excess risks, it is because some limitation in design or circumstance has provided a study that is not positive. In such a case, nonetheless, it may be possible to get a abound based on the sensitivity of the study. In the case of Ruder et al., risks were seen. This, however, is not the hindrance to deriving an incremental risk estimate; the authors' use of employment location and duration as surrogates for exposure is. In order to make its projections, NYSDOH made assumptions about the exposure levels that pertained in specific occupational settings. Rather than make additional exposure assumptions to derive further possible incremental risk relationships *de novo*, the CTSA has included a revised discussion of uncertainties. The commenter should note that whether the potential adverse effects are cancer

or other toxicities, the scenarios on which the CTSA places most focus remain those with highest potential for highest exposures.

Comment #4-61: 1. (numbering out of order as in instructions, p. 6) Does the risk assessment accomplish the objective of highlighting which sorts of situations pose greatest risk of experiencing adverse effects from exposure to each cleaning process? Generally, although I think it is a great shame not to produce some usable information about the fire/explosion risks from the petroleum based technologies. The discussion as it stands leaves the reader with a gaping question mark about this potentially serious source of risk. Surely it would be possible to pursue insurance and fire accident sources to get some approximate quantification of the fire and fire casualty rates from the current use of this technical option. OSHA, faced with a similar question about possible hazards of flammable substitutes for methylene chloride in furniture stripping reportedly was able to come up with reasonable data on the hazard in reasonably short order.*

*Dr. Adam Finkel, OSHA Director Standards, U.S. Department of Labor, personal communication.

Response: EPA was not able to identify information that would allow a quantitative estimate of the risks of fire/explosion. The CTSA does contain a qualitative discussion of these risks.

Comment #4-62: 2. Are the effects characterizations in chapter 2 and chapter 4 consistent with one another? I didn't notice any inconsistencies.

Response: No response necessary.

Comment #4-63: 3. Are the risk tables clear? As mentioned earlier, the risk tables include a fundamental error in the use of geometric means of the exposure data for estimation of lifetime average concentrations/doses. This leads to an understatement of central tendency risks by about 2-4 fold. This must be corrected.

Response: The exposure and risk tables have been revised; where possible, the arithmetic mean has been provided. Discussion of the distinction can be found in the exposure chapter.

Comment #4-64: 4. Are sources of uncertainty sufficiently covered in the Risk Assessment sections? The uncertainty discussion tends to misleadingly minimize the likelihood that risks from perchloroethylene are likely to be very much less than estimated or absent entirely. In particular, EPA must remove the red herring of the alleged absence of glutathione based metabolic activation of perchloroethylene in humans. There is every reason to expect that at least some of the carcinogenic action occurs by mutagenic mechanisms, and therefore any suggestion that there is likely to be a threshold for PCE carcinogenesis should be removed.*

*Hattis, D., "Pharamacokinetic Principles for Dose Rate Extrapolation of Carcinogenic Risk from Genetically Active Agents," Risk Analysis, Vol. 10 pp. 303-316, 1990.

Response: The summaries of cancer hazard and dose-response have been eliminated from this chapter as a result of reformatting. Generally, EPA has revised the discussion of uncertainty. The language originally used, however, was not meant to indicate that "threshold" and non-linear" were synonymous, but to contrast those two circumstances to a linear one where the steps in

modeling are more straightforward. The text does not allege an absence of glutathione-based metabolic activation as such, but the allusion to the utility of the Green et al (1990) data has been changed for clarity in the revised Appendix C and Birner et al. (1996) (see comment A-16, for instance) has been added. Appendix D discusses both the linear at low dose, and the non-projection approaches in detail.

Comment #4-65: 5. Do the risk assessment discussions for the petroleum solvents and wetcleaning chemicals clearly convey the fact that there was a disproportion amount of information... Yes. But, as indicated above, I think you should make a greater effort to gather quantitative information on the fire and explosion risks from petroleum solvents. One good fire could well cause greater emissions (and probable damage to human health/safety) than 1000 years of normal operation of a petroleum solvent based drycleaner. Therefore it is a serious omission to leave the fire-related risks unquantified. Even though the reader is made aware of the presence of these risks, the impression still is left that they are not important relative to the emissions that are quantified. There is a human tendency to count what is easy to count, and then mistake what is counted for what counts.

Response: The comment is a valid one; however, in the context of the CTSA it was not possible to do a quantitative analysis of the risk of fire. The revised text emphasizes that the risk for fire is an important concern.

Comment #4-66: 6. Adherence to recent EPA guidance on risk characterization: There is an almost complete lack of quantitative treatment of variability and uncertainty. This I think is not ideal in the light of the Agency's recent guidance on the use of sophisticated distributional techniques in analyzing exposures and likely risks. Some quantitative treatment of uncertainties in the economic cost estimates would also be helpful. At the very least, the cost numbers should not be expressed to five significant figures.

Response: The EPA guidance on risk characterization focuses on achieving the qualities of transparency, clarity, consistency, reasonableness in EPA risk assessments. It emphasizes including discussion of uncertainty and variability associated with the assessment. However, it does not require quantitative treatment of variability and uncertainty in screening level assessments. The sections on uncertainty have been revised for this chapter and for the exposure chapter (chapter 4).

Comment #4-67: <u>**Petroleum Solvents.**</u> The interpretation of hydrocarbon toxicity information is complicated and controversial. Gasoline is carcinogenic in rats and mice: gasoline can be thought of as a mixture of Stoddard/140F solvent with lighter, less toxic components. However, EPA and others have discounted the male rat kidney tumors observed, and give lesser weight to mouse liver tumors (even in females) observed in those studies.

Response: No response appears to be necessary.

Comment #4-68: The Discussion of the Carcinogenicity of PCE should Reflect the Revised EPA Guidelines for Carcinogen Risk Assessment and Not Just the 1986 EPA Guidelines. The August 18th issue of *Risk Policy Report* has a news article story (attached) on the CTSA report and on

another forthcoming EPA document: "Common Questions on Drycleaning." While the source of this study is unknown to the reviewer, the story itself reinforces questions about potential misinterpretation about the classification of PCE under EPA's 1986 cancer guidelines as a "possible" versus a "probable" carcinogen. This reviewer would like to be on record as deploring these terms associated with EPA's 1986 classification scheme. The authors of the CTSA report should avoid these terms, except to state historical facts involving the history of PCE evaluation by EPA and by IARC.

The switch in classification by IARC described in the August 6, 1997, "Clarification for CTSA Peer Reviewers of EPA's Position on the Carcinogenic Potential of Perchloroethylene" is not, to this reviewer's knowledge, based as much on new scientific information as reinterpretation of information that was available in 1991. As is evident from the discussion in Appendix A, the recent epidemiological studies provide little or no additional support to the hypothesis that PCE is carcinogenic in humans.

The EPA Science Advisory Board report of August 16, 1991 (attached) should be referenced on page ES-3 of the Executive Summary in addition to the references to the 1991 EPA "Response to issues and data submissions on the carcinogenicity of tetrachloroethylene (perchloroethylene)" and the 1995 IARC monograph on PCE. This reviewer strongly commends to the authors of the CTSA report the language on page 2 and the first two paragraphs of page 3 of the August 16, 1991 letter to the Administrator. This language does an excellent job of summarizing the issues on the carcinogenicity of PCE and its implications for EPA. The terms "probable" and "possible" carcinogen are simply labels adopted by EPA for weight-of-evidence categories B2 and C under the 1986 cancer risk guidelines. The SAB points out that "perchloroethylene...is an example of a chemical for which there is no compelling evidence of human cancer risk but for which reductions in unnecessary human exposure might well be prudent." The SAB goes on to stress the need for further research to clarify the extent of human cancer risk posed by PCE and "other chemicals that present similar ambiguities of interpretation."

The focus of the CTSA document is not on the carcinogenicity of PCE, which is an area of great uncertainty and longstanding scientific debate. Rather, as the "Clarification" of August 6 indicates in the last paragraph, the document provides a comparison of exposure scenarios. The document needs to communicate clearly and succinctly that while PCE is known to induce tumors in rodents, it is not known at present whether PCE even at very high levels induces any form of cancer in humans. The risk estimate used of 0.00071 per mg/m^3 is, according to the language of EPA's 1986 guidelines, a "plausible upper bound." The plausible lower bound is zero, meaning that there could be no cancer risk, even with high levels of PCE exposure. (Note: this is stated in the CTSA report on 4-19; such language should also appear in the Executive Summary. Stating the risk estimate to two significant figures conveys an inappropriate appearance of precision that Is potentially misleading to readers. Either only one significant figure should be used in Exhibits 4-1 or explanation should be added in this portion of the report (i.e., p.4-7,8) that the risk estimate is highly uncertain.

An extensive discussion of methodology for carcinogen risk assessment is beyond the scope of this review. The methods and estimates used in the CTSA report and in its Appendix A are conventional EPA practice for "screening-level" risk assessment and risk characterization using the 1986 Guidelines. In this reviewer's judgment, Chapter 4 and Appendix A are reasonably well done, and there is some recognition of the ideas in the new EPA Guidelines. The need for refinement in the 1986 Guidelines is set forth in the National Research Council report, *Science and Judgment in Risk Assessment*, 1994. EPA has responded to this National Academy of Sciences report with new guidelines, which are in the final stages of SAB review and expected to be issued

shortly. The April 1996 version of these new guidelines included an Appendix A, which in Narrative #1 includes a chemical with substantial resemblance to PCE. The recommendation in this Narrative #1 that the dose response assessment include both nonlinear and linear default approaches under the new guidelines seems to this reviewer quite appropriate for PCE.

This reviewer is pleased to note the reference to the April 1996 version of the new EPA Guidelines on page 1 of Appendix C. The discussion there implies that given current limited knowledge on mechanism, PCE should not be assumed to have a low-dose linear dose-response relationship, even if PCE is a carcinogen in humans. As a consequence, low-dose PCE exposure could have negligible risk even if PCE is later determined to be a human carcinogen. However, as pointed out by the SAB in 1991, high-dose PCE exposure could pose significant cancer risk to the individuals so exposed. Use of the margin-of-exposure (MOE) approach is helpful, but a clear, non-technical explanation should be added to the text about p.4-8 on the implications of a non-linear dose response function. (The discussion on p.4-19 is inadequate and too far away from the overly precise risk estimate in Exhibit 4-1.) The discussion in Appendix C is good but may be difficult to understand for a reader not familiar with cancer risk assessment.

Response: Much of this comment does not require specific action. The CTSA has been extensively revised, however, and the new discussion should clarify those points made in paragraphs 2-5 of the comment. The SAB discussion reflects studies published no later than 1991. Several of the studies on which the IARC classification is based, and ones included in the CTSA discussion, date subsequent to that time, and add substantial support to inferences on PCE's carcinogenic potential.

Comment #4-69: p. 4-1: Chapter 4 presents worker exposure data from Occupational Safety and Health Administration (OSHA) databases. OSHA data are biased and not representative of most drycleaning shops because they are usually collected from those workplaces with exposure problems. If the OSHA data are used, appropriate caveats should be stated in the document.

Response: The worker exposure data has been updated. Data from OSHA and other sources are utilized. Appropriate caveats accompany the OSHA data.

Comment #4-70: p. 4-1: Chapter 4 summarizes the hazard dose/response, and exposure assessments from other chapters and integrates the information into "screening level" risk assessments for each cleaning process. The assessments thus give only a "rough" or "crude" idea of the potential risks. The latter terminology is more descriptive than "general" as used in 4.1.1, para 2, line 3.

The next sentence should read "...the *process-specific* assessments are not directly comparable *to one another...*"

Response: The text has been revised to reflect this comment.

Comment #4-71: p. 4-1, second paragraph: Dose/response is not described in any other chapters - it is contained in an appendix.

Response: Where available, dose-response figures have now been included in Chapter 2 (hazard), with a reference to their derivation and explanation in what is now Appendix D.

Comment #4-72: p. 4-2: Statements on developmental toxicity are too weak. As discussed below, the combination of the human data from Eskenzi, with the animal data, support a conclusion of strong evidence for a risk.

Response: The particular statement on developmental toxicity has been eliminated in the revised chapter as part of eliminating duplicate discussions of hazard. However, a developmental toxicity risk is acknowledged in the risk conclusions.

Comment #4-73: p. 4-2: The intent is "to allow clothes cleaners to better understand the potential implication of technology choices." The document is awfully long and technical. Will clothes cleaners have the tenacity and patience to wade through it? I think not, except in special cases. Executive-type summaries for each chapter should be highlighted in some way and made easy to find (e.g., include as separate items in the index). These will be read if they are readable. The balance of the document will serve primarily as reference material.

Change *1) Hazard Assessment*...to read "...exposure to a chemical, ***possibly only at extremely high levels,*** can cause...".

2) Dose response...The term "toxicity value" has no useful meaning. Change the second and following sentences to read "From the quantitative dose-response relationship, ***the likelihood of adverse effects occurring in humans at different anticipated exposure is established. The risk characterization step includes these estimates as well as explanations of key...".***

Response: In defining Hazard Assessment, it was not felt that the qualifier was necessary. "Toxicity comparison values" is used in the absence of a better name.

Comment #4-74: p. 4-2: The methods used to estimate cancer risks are <u>upper bound</u> estimates of lifetime risk.

Response: It is true that most times EPA's methods give upper bound estimates of lifetime risk and the revised text indicates where this applies.

Comment #4-75: p. 4-2, para at bottom of page: The phrase "the human health point of concern" appears but is never defined. I have never seen this before. What does it refer to?

Response : It is an error. The phrase should read, " human health endpoint of concern".

Comment #4-76: p. 4-2, last paragraph: The last sentence, going into page 4-3 is unclear.

Response: EPA made a change in the text by replacing this sentence and the start of the next with "Risk estimates for adverse effects other than cancer are not expressed as probabilities of occurrence; instead, a concentration or dose associated with presence or absence of a specific

toxic endpoint of concern is compared to an estimated dose or exposure level for the population being considered. This comparison is expressed as a ratio, which is an indicator...."

Comment #4-77: p. 4-3, seventh line from bottom: Substitute "increments over background" for "excessive". "Excessive" has other connotations that are not intended here.

Response: Agreed. The new text reads, "These risks are identified as incremental over background."

Comment #4-78: p. 4-3: The term commonly used to describe calculated cancer risks is additive risk. The third sentence in the third full paragraph should read - *These risks are called additive, that is they are in addition to the cancer risk in the general, unexposed, population.*

Response: Additive as used on page 4-3 denotes how risks combine across chemicals. For a single chemical, extra risk, which is calculated for the CTSA, is, in fact, not additive to background, which is the sense meant by the commenter. Extra risk is a scaled value: (P(d)-P(0))/(1 = (P(O)). An explanatory clause has been appended in the text of Chapter 5.

Comment #4-79: p. 4-3: In line 1, the term "comparison value" has no useful meaning. Change to read "ratio of a toxicologic *exposure level* to an estimated...". In line 2, strike from "nearness" through the end and replace with "indicators of the *margin by which exposure would have to be increased before adverse effects might reasonably be expected to occur."*

Response: This text has been extensively rewritten and now appears in section 5.1.2.

Comment #4-80: p. 4-3, third paragraph, line 3: "in terms of the estimated *incremental* upper-bound excess lifetime risk per..." Note that is the only place where the phrase *upper-bound* is used to characterize the unit risk. Since the ED10 and not the LED10 is used for the MOE approach, Exhibit 4-1 presents "apples and oranges". I suggest that wherever "unit risk" is used throughout the document, it be qualified as *upper-bound* unit risk.

Response: EPA made the change regarding "incremental." The Agency uses "unit risk" in a large number of documents to indicate an upper bound estimate of the relationship; this change was not made. EPA, however, clarified that excess lifetime risks calculated using unit risk are "upper bound."

Comment #4-81: p. 4-3, third paragraph, line 4: "Unit risk is a *similar* measure..."

Response: This change has been made.

Comment #4-82: p. 4-3, third paragraph, line 7: Replace "consistent" with *proportional*. Strike "Thus,".

Response: This change has been made.

Comment #4-83: p. 4-3, fourth paragraph, line 1: *"Excess cancer risk* is...".

Response: This change has been made.

Comment #4-84: p. 4-3, second full paragraph: The description of the slope factor includes the common but misleading suggestion that it is conservative in the sense of being an upper confidence limit. This is only true for the particular model used (presumably the linearized multistage model), but not for some other equally biologically plausible model like the Weibull model, which for PCE predicts risks orders of magnitude larger, I believe. This paragraph should make clear that the estimates are only good as far as the model assumption is good, and the model assumption is neither the most biologically plausible nor the most conservative one available. The same comment applies to the last paragraph on the page, where the "appropriateness" of the linear model is called into question. The context and later text implies that the linear model may be too conservative, but in fact it may be not conservative enough if a Weibull model is the correct one.

Response: EPA agrees that steeper-than-linear dose-response relationships, were they used, could produce higher estimates. Text has been added to identify the origin of the upper bound nature of the estimates.

Comment #4-85: p. 4-3, first paragraph: There is indeed evidence of non-cancer end points showing a no-threshold level for effects, such as immune system effects and endocrine disruption. The authors have been too quick to assume this hypothesis.

Response: No change has been made. These are issues that are currently under debate in the scientific community.

Comment #4-86: p. 4-3, paragraph at top of page, last sentence: Here it is baldly stated that any non-cancer effect is assumed to have a threshold. While this is not uncommon to see, I know of no substantiation for it. It is merely an assumption, and one, moreover, not likely to be true. Also, there should be some differentiation between a *practical* threshold, which may just be related to the level of detection, and a theoretical threshold.

Response: Most of the discussion on risk characterization does not, however, hinge on issues of experimental resolution that seems to be the commenter's second point.

Comment #4-87: p. 4-3: The margin of exposure approach should be explained in more detail in the text rather than just referring to the Appendix.

Response: In revising the CTSA based on overall peer reviewer comments, technical explanations, formulae, and extensive tables were placed in the appendices in order to make the document more readable.

Comment #4-88: p. 4-3, fourth paragraph, line 7: Strike "other".

Response: The sentence has been revised.

Comment #4-89: p. 4-3, end of first full paragraph: It would be worthwhile to add a sentence before the last sentence that notes that controversy regarding PCE classification is one motivation for the new classification system.

Response: EPA does not believe the discussion would benefit from such additions.

Comment #4-90: p. 4-3, fourth paragraph, line 5-6: Replace "excessive" with *excess risks; i.e., risks* beyond those...by the population." Strike "with no particular exposure to the chemical."

Response: This sentence has been changed as discussed in Comment #4-77.

Comment #4-91: p. 4-4: The background discussion here is good, especially the third paragraph on the page.

Response: No response is necessary for this comment.

Comment #4-92: p. 4-4, first paragraph: This paragraph does a much better job of explaining risk assessment than does the corresponding paragraph on p. 4-3 and 4-3.

Response: The paragraphs previously on page 4-3 have been extensively revised.

Comment #4-93: p. 4-4, first paragraph: As described and used the MOE approach does have a built in linear-type assumption. In evaluating MOEs it is generally assumed that a 10-fold decrease in exposure would be 10 times more risky than a 100-fold decrease in exposure. This means that the MOE approach really doesn't account for potential nonlinearities in dose-response.

Response: The extensive revisions of the risk discussion, with the use of MOE in conjunction with the cancer endpoint in a fashion that should clarify the limits of the concept, make it unnecessary to include this observation.

Comment #4-94: I found the explanation of the MOE on p. 4-4 confusing. In particular, the statement that, "interpretation of MOE employs the same approach to uncertainty as the RfD does" did not make sense to me. The MOE is a ratio and the RfD is not a ratio. If the MOE's are meant to highlight scenarios that warrant the most attention, perhaps they should be put in a separate table from exhibit 4-5 and in ranked from smallest to largest. Explanatory text could point out the exposure scenarios with the MOE's of greatest concern.

Response: This text has been revised to eliminate the lack of clarity and confusion of the text expressed by several commenters.

Comment #4-95: p. 4-4: cascade of factor 10--based on unstated assumptions, can be understood only with careful attention to Appendix C.

Response: A revision of paragraph 4 has eliminated this language.

Comment #4-96: p. 4-4, second paragraph: Technically, the 10-fold factor for variation in human sensitivity is not accounting for uncertainty but adjusting for an expected occurrence.

Response: The within-human sensitivity uncertainty factor is intended to account for the wide variation in possible human responses, recognizing that we may not know its limits. No change appeared to be necessary.

Comment #4-97: p. 4-4, third paragraph, lines 5-6: A quotient of 0.001 does not mean... ." What *does* it mean?

Response: The text has been revised to explain that it means, . . . "that the event is very unlikely to occur".

Comment #4-98: p. 4-4, fourth paragraph: The use of the MOE is not equivalent to calculating an HQ based on the RfD. An MOE of 1000 is not the same as a hazard quotient of 1000 because the RfD has adjustments of (usually) 100-fold built in. In fact an MOE of 1000 is more likely equivalent to an HQ of 0.1 (if RfD would have 2 ten-fold adjustments) or even an HQ of 1.0 (if starting from LOAEL so RfD would have 3 ten-fold factors). It would be more useful to calculate a quasi-RfD by applying the appropriate factors to the data used in the MOE calculation. See comments on page 4-38 below [Comment #4-324].

Response: Agreed. This paragraph has been extensively revised, and no longer makes this comparison.

Comment #4-99: p. 4-4, first paragraph: Some readers may get confused by the ED_{10} mentioned in the first paragraph of page 4-4 and the ED, exposure duration, used in Chapter 3. Either change one of the abbreviations or clearly delineate the changing use of "ED."

Response: Agree, the text has been changed to delineate the changing use.

Comment #4-100: p. 4-4: Why is 10% chosen for the MOE approach? (stability of the estimate?). Then why not use 50%? (I'm not suggesting it is appropriate, only pointing out the arbitrary nature of the choice). Comparing doses to the 10% level flies in the face of public health precedence, in my view and is of doubtful value. I wouldn't use this kind of an MOE at all.

Response: Choosing 10% is generally believed to place the user toward the end of the range of responses typically observable in experimental systems, but above the boundary of the range where responses become difficult or impossible to measure or observe reliably, regardless of type of effect. This may be why it has been selected as the basis for the method recommended in the

proposed revisions (1996) of the EPA Carcinogen Risk Assessment Guidelines, which are being used as guidance for preparation of this CTSA. No change has been made in the text.

Comment #4-101: p. 4-5, fourth full paragraph: Be specific about the developmental toxicity. The last sentence contradicts the last sentence of Paragraph 3 below.

Response: Reformatting has eliminated this text. Text on developmental toxicity is found in Chapter 3 and Appendix C.

Comment #4-102: p. 4-5, fifth full paragraph: "The *findings in* human studies have *generally been consistent with those* in the animal studies.

Response: Reformatting has eliminated this text. Text on developmental toxicity is found in Chapter 3 and Appendix C.

Comment #4-103: p.4-5, fourth paragraph: Developmental toxicity in laboratory animals is a good indication of potential developmental toxicity in humans. Human data are almost always inconclusive and as such animal models are relied upon. This lack of conclusive evidence is not indicative of a lack of effect. The authors downplay the importance of the data with such statements.

Response: EPA disagrees that the statement that "the human data are inconclusive as to the potential of PCE to cause developmental and reproductive effects" downplays the importance of such data. However, reformatting has eliminated the text from this chapter. A summary of the animal and human data is given in Appendix C.

Comment #4-104: p. 4-5, third full paragraph: Be specific about the toxic effects, e.g., CNS depression, etc. The term *dysfunctioning* is awkward and uninformative.

Response: Reformatting has eliminated this text.

Comment #4-105: p. 4-5, Section 4.2.1: "Human data indicate that PCE is *rapidly* absorbed into the body via inhalation...but *only* poorly *absorbed* through the skin. Strike *also* in the next sentence.

Response: Reformatting has eliminated this text.

Comment #4-106: p. 4-5, second paragraph: There is no indication in this document that PCE is poorly absorbed through the skin. Skin contact could be a large route of exposure and shouldn't be ruled out as the authors have. There is human evidence of much more than neurotoxic and kidney effects from PCE exposure in humans (e.g., immune system).

Response: The document has been revised to indicate risks due to dermal contact and absorption of PCE. However, EPA does not agree that effects, such as those reported for the immune system,

have been well documented. The effects reported for the immune system have not been specifically and uniquely associated with exposure (for example, *Immunotoxicology and Immunopharmacology*, eds. JH Dean, M Luster, A Munson, I Kimber. 1994, Raven Press). Other information (EPA 8EHQ-96-13799) has not demonstrated that an association exists.

Comment #4-107: p. 4-5, Ecological Risk paragraph: The term "concern concentration" is awkward jargon.

Response: Reformatting has eliminated the text in this chapter, however, the term , "concern concentration" is defined and used in Chapter 3 and Appendix B, and is standard language used in ranking hazards to aquatic organisms.

Comment #4-108: p. 4-5, first paragraph under "human health": You should also note here that there is some human epidemiological evidence of carcinogenicity for PCE.

Response: Reformatting has eliminated this text. A summary of epidemiological data is given in Appendix C.

Comment #4-109: p. 4-5, second paragraph under "human health": What does "high to moderate levels" mean? Also, in the 3rd line, "dysfunctioning" is not a proper word. Substitute "dysfunction".

Response: Reformatting has eliminated that text. High, low and moderate are intended simply as relative terms.

Comment #4-110: p. 4-5, second last paragraph: What does it mean to say the human data are "inconclusive"? Does anyone EXPECT the data to be conclusive? Again, this is just a way to deflect the force of the data without presenting any valid supporting argument and should be avoided.

Response: Reformatting has eliminated this text. There is considerable discussion in Appendix C clarifying the utility of human data.

Comment #4-111: Section 4.2.1, p. 4-7, paragraph 5: Strongly disagree with general presumption that human data should be discarded in favor of potentially irrelevant animal data.

Response: The text referred to in the comment has been eliminated in this chapter; however, it is used in Appendix D. As indicated in Appendix D, (1st paragraph under heading, "Cancer") the first step in establishing a specific dose/response assessment entails reviewing the epidemiological data to see if it is sufficient to establish a quantitative relationship. In the case of PCE, the epidemiological data were not sufficient. EPA did not discard the human data, it simply was not modeled.

Comment #4-112: p. 4-6, second paragraph: Why is neurological dysfunction not considered as a critical effect.

Response: Reformatting has eliminated this text. The revised Dose-Response Appendix, now Appendix D,(Section, Additional Comments/Studies for the RfC) discusses reasons why neurobehavioral endpoints were not considered as critical effects.

Comment #4-113: p. 4-6, first paragraph: The sentence on the literature on human studies having gaps is disingenuous in that all human studies have gaps.

Response: Reformatting has eliminated this text. The intent was to highlight that extensive testing has been done in animals, compared with limited study of humans. It was not meant to obfuscate.

Comment #4-114: p. 4-6: Summary of Dose/Response Characterization - Noncancer effects: The term "medium confidence" is an "IRISism" that needs explanation.

Response: Reformatting has eliminated this text. The term, "medium confidence", is however, introduced in Appendix D, along with a section, "Discussion of confidence in the RfC".

Comment #4-115: p. 4-6: Cal/EPA has recommended an acute non-cancer Reference Exposure Level (REL) of 12 mg/m^3. [CAL/EPA, Determination of Acute Toxicity Exposure Levels, Appendix C. Draft for public Comment.] This is based on the Stewart 1970 study showing 3 hour LOEL for CNS effects of 100 ppm (678 mg/m^3). Uncertainty factor of 10 to estimate a NOEL from the LOEL, and an additional uncertainty factor of 10 applied to account for intraspecies differences. An equivalent to the 1 hour exposure was calculated from the 3 hour exposure: $c^n * T = K$ where $n = 2$. An acute non-cancer REL of 6.8 mg/m^3 has been established by the California Air Pollution Control Officers Association. Also, an occupational 'health-based exposure limit' (HBEL) guideline has been calculated for Perchloroethylene of 0.11 mg/m^3 for non-cancer effects, and 0.01 mg/m^3 for cancer. See Health-Based Exposure Limits Committee, Chemical Exposure Guidelines, Version 9, Santa Clara Center for Occupational Safety and Health, October 1995, p. 95. (Enclosed and available also at http://152.3.65.120/oem/chem-exp.htm).

Response: While the CTSA did rely on a provisional derivation for its own purposes, in presenting those of others it has been limited to final analyses or published papers as much as possible. The HBEL values are cited as being derived from IRIS and the HEAST, which would be circular sources. The HBEL quoted for effects other than cancer is about the same as the provisional RfC in the CTSA and approximately one-tenth the provisional occupational comparison level.

Comment #4-116: p. 4-6, Exhibit 4-1: Reorder either the table to be consistent with the text: noncancer first, cancer second. I would also want to see the NOAELs and LOAELs upon which the RfD and RfC were based. Also be more specific about the critical effects: "liver" and "renal" are not particularly informative. Also include the study cites in the table.

Response: The table has been revised (Table 5-2) for clarity, and includes many of the points in the comment. The aim was for clarity and ease of reading, and therefore, some information such as discussion of the critical effects, NOAELs and LOAELs are discussed in Appendix D.

Comment #4-117: p. 4-6, Exhibit 4-1.: The note at the bottom should indicate that the values here differ from those given in EPA (1991) and should provide a reason for this.

Response: Exhibit 5-2 (corresponding to the previous Exhibit 4-1) has been enlarged to include a footnote identifying the data source for each of the toxicity values used. Appendix D details the derivations.

Comment #4-118: p. 4-7: the general tone of the hazard characterization is overly cautious and filled with caveats. This section should be rewritten in the style of the August 6 "Clarification" for reviewers. The epidemiologic evidence for carcinogenicity of PCE has clearly gotten stronger over the past ten years but this draft does not reflect that development.

Response: Reformatting has eliminated the text on hazard characterization. EPA agrees regarding the epidemiological evidence. The SAB discussion reflects studies published no later than 1991. Several of the studies on which the IARC classification is based, and ones included in the CTSA discussion, date subsequent to that time, and add substantial support to the inference that PCE is a probable human carcinogen.

Comment #4-119: p. 4-7, fourth paragraph: Yes, there are uncertainties about the dose-response data. This is not peculiar to PCE but is true for every chemical, as the dose-response part of the curve is unobservable at the dose levels to which humans are exposed, so this is scientifically meaningless but misleading to the average reader.

Response: Reformatting has eliminated this paragraph. Discussion of the cancer data and dose-data are presented in Appendices C and D.

The extensive revisions to the risk chapter have removed this section.

Comment #4-120: p. 4-7, fourth paragraph and p. 4-8, second paragraph: The same caution about getting this right so as not to alienate readers applies here. The CTSA should mention lack of SAB agreement and IARC classification of PCE drycleaning as "possibly carcinogenic to humans."

Response: Reformatting has eliminated these paragraphs; however, Appendix C includes statements concerning the SAB review and IARC classification of PCE.

Comment #4-121: p. 4-7, first paragraph: There is some disagreement from some quarters about the relevance of the animal tumor data, but it comes primarily from those who don't like the answer. The fact remains that animal bioassay data is generally accepted to be relevant to humans. Period. (Same comment goes for the next paragraph).

Response: Reformatting has eliminated these paragraphs. Appendix C reviews the cancer data.

Comment #4-122: p. 4-7, last paragraph: The data neither point to nor away from a linear effect at low dose. See previous comment and comments about the correct model to use. This too is scientifically meaningless but misleading.

Response: Reformatting has eliminated this paragraph.

Comment #4-123: p. 4-7, second paragraph: Several mechanisms have been proposed to explain the liver and kidney tumors observed in animals, but the relevance to humans is questionable.

Response: No response appeared to be necessary and no discussion of this now appears in the text.

Comment #4-124: p. 4-7, first paragraph: You must mention the human evidence of carcinogenicity of PCE here. I assume all four paragraphs here will be revised in accordance with the new statement that was mailed to us. In addition, of course, I have made some additional suggestions for amplification above.

Response: Reformatting has eliminated this paragraph. The human and animal data on PCE are discussed in Appendix C.

Comment #4-125: p. 4-7, second to last paragraph: I believe it is overstating matters to say that "human epidemiology is insufficient to define the relationship" between PCE exposure and the incidence of cancer. Studies in humans have given us an idea of just how much increased cancer risk might occur in PCE exposed employees, and for which types of cancer that risk might be elevated. Cancer is not an etiologically homogeneous condition. There are many different forms of cancer with distinctive causal pathways leading to them. It is likely that if PCE exposure does have the potential to cause cancer in humans, it does not do so for all cancer sites. The results of the epidemiologic studies, particularly those of Blair et al. and Ruder et al., suggest that it is cancers of the bladder and esophagus that would be of the most concern. It does not appear that the CTSA takes this etiologic heterogeneity into account.

Response: Reformatting has eliminated this paragraph. The epidemiologic studies indicated in the comment have been included in the section on cancer/ human data in a revised Appendix C.

Comment #4-126: p. 4-7, last paragraph: I believe the first sentence misstates the facts. Kidney tumors have been observed in male rats exposed to PCE, but not female rats.

Response: The commenter is correct; however, reformatting has eliminated this paragraph. These data are discussed in the section on cancer/animal data in a revised Appendix C.

Comment #4-127: p. 4-7, third paragraph, line 1: Strike *single.*

Response: Reformatting has eliminated this paragraph.

Comment #4-128: p. 4-7: The repeated statement that the "mechanisms by which PCE induces these endpoints are not clearly understood" would apply to any cancer of any type induced by any agent. It is useless for analysis and should be deleted any place it appears in the entire document. The discussion of genotoxic versus non-genotoxic mechanisms again only tells the reader to "do it yourself" for hazard identification. It would be more appropriate to quote EPA's risk assessment and the SAB comments at this point, not to paraphrase.

Response: EPA agrees with the commenter. Reformatting has eliminated this paragraph. A discussion of human and animal data and the overall evidence on cancer is presented in the revised Appendix C.

Comment #4-129: p. 4-7,8: See points under General Discussion, above. The uncertainty in the risk estimate, first line of Exhibit 4-1 should be discussed explicitly. The SAB report of 1991 should be explicitly referenced and language from it might be quoted.

Response: Reformatting has eliminated this text. A revision of the discussion of uncertainties has been added to the chapter.

Comment #4-130: p. 4-7, last sentence: Although additivity to background processes does suggest linearity of response, it does not follow that the slope of this line will be proportional to the slope at high doses.

Response: This text no longer appears in the risk chapter. It is true we do not know what the slope of a linear response at lower doses may be. We can only hope that the modeling done near the transition from higher to lower doses, where we have data with which to anchor the curve, will reflect the lower dose behavior.

Comment #4-131: p. 4-7, fourth paragraph, line 5: "...for carcinogenicity *"at least in heavily exposed laboratory animals."*

Response: Reformatting has eliminated this text.

Comment #4-132: p. 4-7, fifth paragraph, line 3: Strike *First, an attempt is made to predict.* Replace with *If feasible,* this relationship *is estimated using data* from...

Response: Reformatting has eliminated the text in this chapter, however, the wording is present in Appendix D. It has not been changed, since, as it stands, the text indicates that there is always a first attempt made to utilize human epidemiological data. This emphasizes the importance placed on finding and using human data whenever possible.

Comment #4-133: p. 4-7, second paragraph, last line: Strike *exact.*

Response: Reformatting has eliminated this text.

Comment #4-134: p. 4-7: The US EPA 1996 proposed guidelines for carcinogen risk assessment contains a case-study example of PCE in the section on classifying weight of evidence, where PCE is classified as a "Likely Human Carcinogen." This case-study summary should be used in the CTSA, perhaps as part of the CTSA's Summary of Hazard Characterization - Cancer. In particular, the case-study provides a better summary of the weight-of-evidence on the human carcinogenicity of PCE than the CTSA summary.

Response: Reformatting has eliminated this text. Appendix C summarizes the data on human carcinogenicity. See 4-130.

Comment #4-135: p. 4-7, paragraph 1, last line: "*of* each tumor type".

Response: Reformatting has eliminated this text.

Comment #4-136: p. 4-7, line 4: Remove excess s from "in males rats".

Response: Reformatting has eliminated this text.

Comment #4-137: p. 4-7, fourth paragraph: Uncertainties in dose response of PCE are common with every other chemical that has been studied. This statement again undermines the importance of the data.

Response: Reformatting has eliminated this text.

Comment #4-138: p. 4-7, first paragraph: Animal models are accepted as good predictors for humans. The statement about uncertainty about the human relevance of each tumor is completely out of place and should be omitted. This is an argument put forward by those who don't like the results of the positive studies. Similarly in the next paragraph, there are few chemicals for which we have adequate information about mechanism and those have been studied intensively for decades. Asbestos is a known human carcinogen, though its mechanism of action is still not certain. These statements undermine the importance of the data. The fact that we do not know the exact mechanism of action of a chemical does not mean that it does not pose a risk or does not harm individuals.

Response: Reformatting has eliminated this text.

Comment #4-139: paragraph 1: Text reference to 4.2 should specify PCE.

Response: The comment is unclear, EPA is unable to respond without additional information.

Comment #4-140: p. 4-8, second paragraph, line 4: Change "effect" to *effects*, and strike "in affected tumors,".

Response: Reformatting has eliminated this text.

Comment #4-141: p. 4-8, second paragraph, line 3: *"However,* the lack of mutagenicity..."

Response: Reformatting has eliminated this text.

Comment #4-142: p. 4-8, second paragraph, line 2-3: Strike "relevance of". Add "...the animal findings *as irrelevant...".*

Response: Reformatting has eliminated this text.

Comment #4-143: p. 4-8, last sentence: The overall ranking is moderate. Why make the person flip back to look it up?

Response: Reformatting has eliminated this text.

Comment #4-144: p. 4-8, first paragraph, line 7: This latter *assessment* utilizes... .

Response: Reformatting has eliminated this text.

Comment #4-145: Section 4.2.1, p. 4-8, paragraph 2: Last sentence creates a dilemma -- why then model these data? (CTSA Review/Comments, page 9).

Response: Reformatting has eliminated this text.

Comment #4-146: p. 4-8, fifth paragraph: Why weren't the literature studies critically reviewed? If they aren't done here, where will they be reviewed?

Response: Reformatting has eliminated this text in this chapter. See Chapter 3 discussion which explains the type of review that was done.

Comment #4-147: p. 4-8, second paragraph: What is the importance of the fact that animal response cannot be confidently extrapolated to an estimated human response at low exposures. Why is this the case.

Response: Reformatting has eliminated this text from this chapter.

Comment #4-148: p. 4-8: The MOE approach for assessing cancer risks is based on the ED10 rather than the LED10. Yet, Appendix C discusses the use of both the ED10 and the LED10 and the US EPA 1996 proposed guidelines for carcinogen risk assessment recommends the use of the LED10. The use of the LED10 would be consistent with the proposed EPA guidelines.

Response: As the commenter has correctly noted, the Dose-Response Assessment appendix (now D) discusses both the ED_{10} and the LED_{10}. Since methods available for deriving these values for the CTSA entailed the same computer routine as that used for deriving unit risk, which is derived using the routine's upper bound (which is dominated by a linear term), presentation of an MOE based on the ED_{10} gives an alternative less tied to a linear derivation than would the LED_{10}, despite the latter's being discussed in the 1996 EPA proposal. The chapter has been revised; real values were used, see exhibit 3-2.

Comment #4-149: p. 4-8, third paragraph: The second to the last sentence justifying the use of an estimated value in place of real data is pretty difficult to follow.

Response: Reformatting has eliminated this text from this chapter. Chapter 3 now incorporates measured data and discusses the use of measured and modeled data in hazard assessment.

Comment #4-150: p. 4-8, first paragraph, line 4: "more informative..." *than what??*

Response: Reformatting has eliminated the text. It referred to the fact that dose-response assessments that follow data on mechanisms are more informative than models based solely on the numbers of a single dose-response study.

Comment #4-151: p. 4-8, first paragraph, line 3: "USEPA suggest *that...*

Response: This text has been eliminated.

Comment #4-152: p. 4-8, first paragraph, line 2: *or,* not *nor.*

Response: This text has been eliminated.

Comment #4-153: p. 4-8, second paragraph, third sentence: What is the support for the statement that PCE accelerates growth of cells in affected tumors? I don't think this has been demonstrated anywhere.

Response: This text has been eliminated.

Comment #4-154: p. 4-8, first paragraph, second sentence: The meaning is obscure to me.

Response: This text has been eliminated.

Comment #4-155: p. 4-9: In situations in which data are available, it would be most useful to indicate the range of values determined. For example, in the discussion of inhalation of PCE it is stated that it will be assumed that absorption will be 100 percent. Ranges of experimentally determined absorption rates should be reported as well.

Response: The discussion of inhalation absorption of PCE is presented in both Appendix C and Chapter 3. For this screening level assessment, EPA feels it is appropriate to assume 100% absorption.

Comment #4-156: p. 4-9, "Routes of Exposure, Inhalation": "For purposes of this risk assessment, inhalation and oral doses are assumed to be absorbed 100% into the body." I am not qualified to comment on this; however, I have published documentation to the contrary and have included "Patty's Industrial Hygiene and Toxicology" as Attachment 2 of this report.

[Patty's Industrial Hygiene and Toxicology, Clayton, G.D. and F.E. Clayton, eds., Fourth Ed., Vol. II, Part E, New York: John Wiley & Sons, Inc.]

Response: 100% absorption was utilized for oral and inhalation exposures as the default value for this screening level risk assessment. The reference cited does not provide a specific proportion absorbed by inhalation. The CTSA text, however, has been changed, now including the primary source for the Clayton and Clayton citation.

Comment #4-157: p. 4-9, paragraph 3: PCE is commonly detected in low concentrations in office indoor environments. How does this affect these calculations?

Response: A brief discussion of PCE concentrations in indoor office environments has been included in the general population section of the exposure chapter (now Chapter 4). PCE concentrations in office environments would not be expected to have much effect on overall exposures to the general population.

Comment #4-158: p. 4-9, third paragraph, last line: Why "may" be a major source of PCE indoor air levels. What are the other likely major sources? At least you could say "is likely to be a major source". Similar comment for p. 4-24, 1st par. under "uncertainties".

Response: The extensive revisions to the risk chapter have removed this sentence. The uncertainties in the various sources are discussed more extensively in the Exposure chapter.

Comment #4-159: p. 4-9, second paragraph, second line: Why are drycleaning workers and residents of apartments in the same building with PCE drycleaners only "potentially" exposed? We have quite a lot of measurements of that exposure, and it would be rather difficult to use all that solvent without some getting into the local air.

Response: Since EPA does not have information describing every situation involving co-located residences, the word "potential" is used in this case.

Comment #4-160: p. 4-9: The paragraph 2 summary should mention workers in adjacent businesses as potentially exposed.

Response: Extensive revisions in the risk chapter have removed the exposure summary section. The revised exposure chapter (now Chapter 4) presents data on PCE exposures to workers in adjacent businesses.

Comment #4-161: p. 4-9, Exhibit 4-27: the table requires that the reader refer back and forth to the previous exhibits and to the appendices.

Response: [It is assumed that the commenter is referring to Exhibit 4-2]. This table has been eliminated in the revised chapter (now chapter 5), and a self-contained table (Table 5-1) that does not require flipping pages has been substituted.

Comment #4-162: p. 4-9 to 4-29: These pages cover two sections of the PCE risk characterization. We found this section difficult to understand. Although the subject matter is complex, some of the difficulties could be eliminated by general revision to eliminate typographical errors and/or omission, and to make it shorter and more organized. Some of the problems are noted below.

Response: The chapter has been extensively revised in an attempt to make it more understandable.

Comment #4-163: p. 4-9 to 4-29: The use of five difference measures of exposures (EC, LADC, LADD, ADC, and ADD) makes it difficult to compare the risk of different exposure scenarios. This may be unavoidable given the necessity of assessing various route of exposures, but an effort should be made to reduce the number of exposure measures or the information should be provided in a more organized fashion, perhaps by the addition of a glossary.

Response: The revised exposure chapter (now Chapter 4) has been reorganized to provide a better description of exposure routes and pathways. This reorganization is reflected in the revised risk chapter (now chapter 5).

Comment #4-164: p. 4-9 and 4-17: The headings of Sections 4.2.4. (Human Risks) and 4.2.5. (Exposure Scenarios for Potential Risks) should be changed. The title of the second section is uninformative and confusing as exposure scenarios and risk estimates are presented in the first section. The rationale behind this separation is unclear since all the tables first presented in section 4.2.4 are also cited in section 4.2.5. These two sections should be combined into one section. In this combined section, each exposure scenario should be first discussed, followed by presentation of the risks associated with each exposure scenario, and then the risk characterization.

Response: The chapter has been revised extensively in an attempt to make it easier to read.

Comment #4-165: p. 4-9, first paragraph: Why are summaries of the exposure scenarios presented in section 4.2.4 and the summary of exposure characterization here?

Response: The chapter has been reformatted to make it more understandable.

Comment #4-166: p. 4-9, Exhibit 4-2: This is awkward but essential given the current organization of the CTSA. It would be better if the reader did not have to flip between chapters.

Response: As mentioned in Response to Comment #4-161, this table has been eliminated in the revised risk chapter (now Chapter 5), and a self-contained table (Table 5-1) which does not require flipping pages has been substituted.

Comment #4-167: p. 4-9: Note that the summary of the exposure characterization for PCE is not consistent with the Executive Summary which lists breast feeding infants of PCE exposed mothers as a high exposure group.

Response: The exposure characterization has been eliminated in the revised risk chapter (now chapter 5). Inconsistencies with the Executive Summary have been corrected.

Comment #4-168: p. 4-9, third paragraph: Are nursing, breathing infants (living above or near shops) not among those heavily exposed?

Response: The text has been eliminated. It was not meant to exclude infants as possible residents living above drycleaning shops.

Comment #4-169: p. 4-10, second paragraph (Dermal): The text says at several points that PCE is poorly absorbed through the skin. I am not aware of the basis for this statement, and considering the extensive dermal exposure of some workers, I am not sure I would dismiss this route of exposure as quickly as the text appears to do. I note that on p. 4-19 it is estimated that the potential dose rate through the skin might be as high as 18 gms/day. Since people have died after drinking less than 2 ml at a time, this doesn't seem like it is so small.

Response: The chapter has been revised to indicate the potential for dermal absorption of PCE, and risks to workers.

Comment #4-170: p. 4-10, Dermal: Again, there is no evidence presented here that PCE is poorly absorbed through the skin.

Response: Agree. See response to Comment #4-169.

Comment #4-171: p. 4-11, first paragraph: Where does this calculation come from. This paragraph is not understandable.

Response: This calculation is discussed in Appendix D (section, "Linear at Low Dose Approach"). It is used to estimate upper bounds on excess lifetime cancer risk for specific exposure scenarios. The text has been revised to read: "The calculated LADCs are multiplied by the unit risk per mg/m^3

(unit risk is defined in section 5.1.2) to give linearly-based upper bound lifetime excess risks, called linear risk indices' hereafter; or divided into the ED_{10} of 270 mg/m^3 to give MOE indices."

Comment #4-172: p. 4-11: In Exhibit 4-3, the category "manager" has a higher exposure than the category "cleaner," which does not seem logical. Consider combining the two categories under "machine operators." Also, the number of individuals in each job category should be included in the table.

Using the unit risk found in the text (0.00071), rather than the unit risk in the exhibit footnote (0.0071), the risk index for the "manager" category can be calculated as 0.0348, which is $> 3 \times 10^{-2}$, rather than the $> 1 \times 10^{-2}$ listed in the Exhibit.

Response: The OSHA data in Exhibit 4-3 (and Table 5-3 in the revised chapter) are associated with particular job descriptions, such as "manager". Without knowing whether the managers and cleaners performed similar tasks, it is not proper to combine data and job descriptions. It may well be that in some drycleaning establishments the "manager" may perform many of the same tasks that the machine operator/ cleaner performs. A second table (Table 5-4 in revised risk chapter) uses the job descriptions, "operators" and "non-operators". The total number of individuals under each of these job descriptions is not known, but the numbers of samples taken have been included in the revised tables.

The unit risk in the text is the correct one (0.00071 per mg/m^3). The footnote has been corrected in the revised table. The risk index in Exhibit 4-3 was listed as $>1 \times 10^{-2}$ because multiplication of a unit risk by an exposure does not apply at higher exposures where the curve is expected not to be linear; historically this approximation has been assumed not to hold above 1% excess response. Consequently, no exhibit showed a calculated estimate greater than 1%.

Comment #4-173: p. 4-11, 4-12, and 4-17: Exhibits 4-3 and 4-4 provide information on the inhalational exposure of dry-cleaning workers and the associated cancer risks, however, the same exposure data from these two exhibits is combined and presented in Exhibit 4-9, which provides information on the non-cancer risks. The same approach is used to combine data from Exhibit 4-5, 4-6, 4-7, and 4-8 into Exhibit 4-10. This makes comparison of the risks of cancer and non-cancers more difficult. We recommend using the one table, or at least the same format if two tables are used, to present the non-cancer and cancer risks of each exposure scenario.

Response: Cancer and non-cancer risk estimates are presented together in the revised risk chapter (Chapter 5).

Comment #4-174: p. 4-11 - 16: The Lifetime Average Daily Concentration (LADC) values found in Chapter 4 are biased. The assumption that most workers will be exposed for 8 hours per day, 250 days per year, for 40 years is unrealistic for drycleaning workers. Workers in this industry frequently change jobs and perform different jobs in the same place of employment. The primary source of worker exposure to perc in small shops comes from the drycleaning machine. Thus, when the drycleaning machine is not operating, exposures will be generally low. Often, owners of small drycleaning establishments will not operate their drycleaning machine for 8 hours per day [Earnest 1996; Earnest et al. 1997].

[Earnest GS [1996]: Evaluation and control of perchloroethylene exposures during drycleaning. Appl Occ Environ Hyg J 11(2):125-132.

Earnest GS, Spencer AB, Smith SS, Heitbrink WA, Mickelsen RL, McGlothlin JD, Ewers LM [1997]. Technical report: Control of health and safety hazards in commercial drycleaners: Chemical exposures, fire hazards, and ergonomics. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.]

Response: The commenter and the two Earnest references provide no evidence to claim bias in the LADCs. The only assumption which seems very uncertain is that of 40 years of exposure. However, this uncertainty has been stated. No data were found on years of exposure for workers in this industry. Workers performing different jobs within the same facility has also been stated as a potential exposure variable. The commenter seems to be assuming that the TWA exposure data have all been measured only while machines have been operating. However, there is no evidence that this assumption is correct. The uncertainties associated with the exposure data and assumptions used to calculate LADCs have been clearly stated.

Comment #4-175: p. 4-11 to 4-18: The table heading and subheadings of Exhibits 4-3 through 4-10 should be reviewed for grammar, consistency and accuracy. The title of Exhibits 4-3, 4-4, 4-5, 4-6, 4-7, and 4-8 differ more than they should since they all deal with cancer risk. We suggest the deletion of the first "PCE" in the title of Exhibit 4-8: (Potential Cancer Risks from PCE Associated with Oral Exposure to PCE). The titles of Exhibit 4-9 and 4-10 could also be improved.

Response: Agree; the revised risk chapter has improved the table titles.

Comment #4-176: p. 4-11, second paragraph: Risk numbers should be presented in terms of the chances of an individual contracting cancer over a lifetime of exposure or how many drycleaners will contract cancer over a lifetime of exposure (e.g., 1 in 100 drycleaners are estimated to get cancer over a lifetime of exposure). Just placing numbers here underestimates the importance of these very high risk levels and makes them harder to understand. If a drycleaner understands that he has a 1 in 100 chance of getting cancer, he will possibly be more prone to substitute for PCE.

Response: The revised chapter gives more text describing the content of the tables.

Comment #4-177: p. 4-11, Exhibit 4-3: Typographical error in note b for unit risk. Note discussion discouraging use of these data above. Also, population risks should be given here in addition to individual risks.

Response: The typographical error has been corrected. The presentation of risk assessment information is a very difficult one that involves not only presenting often highly technical data , but also supplying analysis and communicating the information in a useful form. EPA has not included population risks in the calculations presented in the revised risk chapter (now Chapter 5). However, it is intended that added discussion throughout the CTSA regarding the circumstances of exposure and the considerations in individuals weighing their own risks in comparison to those of others, as well as an enlarged range of exposure circumstances, will assist in enlightening the CTSA reader.

Comment #4-178: p. 4-11: The exposure and risk tables presented in this section do not adequately reflect the quality of the exposure data for the different occupational titles, etc. I do not believe that the exposure studies allow that type of extrapolation to the different categories. It would be more appropriate to refer to a generic drycleaning worker than extrapolate risk to different occupational groups based on weak exposure data. This is acknowledged at the bottom of page 4-17. At a minimum sample sizes should be referenced as was done in other tables in this section.

Response: See response to Comment #4-172. Also, the revised exposure chapter (now Chapter 4) states that, "However, typical activities and exposures may be difficult to characterize because workers may have rotating responsibilities and overlapping activities, that often vary from facility to facility."

Comment #4-179: p. 4-11: Exhibit 4-3, these are Occupational Cancer Risks, not potential risks. Same comment applies to Exhibits 4-4 and 4-5. Again, some description of what these risk numbers mean is necessary. It is important to note how high they are and the fact that in almost all of the scenarios they are above EPA action levels for unacceptable risk (1 in 1 million).

Response: The revised risk chapter has added more text to discuss the tables.

Comment #4-180: p. 4-12: Making the same calculation for the "transfer operator" category in Exhibit 4-4, the risk index is $> 5 \times 10^{-2}$. The appropriate footnotes from Exhibit 4-3 should be appended to this Exhibit also.

Response: No change has been made in the cell entries of this Exhibit. Multiplication of a unit risk by an exposure does not apply at higher exposures where the curve is expected not to be linear; historically this approximation has been assumed not to hold above 1% excess response. Consequently, no exhibit shows a calculated estimate greater than 1%. Footnotes have been added to what is now Exhibit 5-4.

Comment #4-181: p. 4-14 and 4-15: The tables on these pages also have too much detail. Why provide so many different exposure estimates and accompanying risk estimates? This implies much more confidence in the accuracy of these estimates that is warranted. Why model risk for ambient air in two locations (Exhibit 4-7)?

Response: The revised risk chapter (now Chapter 5) eliminates some of the exposure scenarios in the tables, and thus simplifies them.

Comment #4-182: p. 4-16, Exhibit 4-8: I have not checked all the numbers in the tables but I believe that the last row of this one has an error. Shouldn't 5×10^{-9} be 5×10^{-8}?

Response: This table has been eliminated in the revised risk chapter; however, the commenter is correct in pointing out the calculation error.

Comment #4-183: p. 4-16: The three paragraphs on non-cancer risk are barely intelligible to someone familiar with risk assessment literature. The many other technical people utilizing this document will not be familiar with risk assessment terminology. A more comprehensible explanation should be included.

Response: The text has been revised.

Comment #4-184: p. 4-16, first paragraph: Why is kidney toxicity used for the RfC? Is there evidence that it represents the most sensitive effect? I would think that neuropsych effects (e.g., disturbances of color vision or cognitive ability would be more sensitive). Some better justification for using this endpoint is needed.

Response: A discussion of this can now be found in the revised Dose/Response Appendix (now Appendix D)

Comment #4-185: p. 4-16: This reviewer has concerns about the calculation of lifetime cancer incidence from infant ingestion of breast milk. Explanation should be added to show the calculation. The assumption for the exposure time should be discussed. If a standard assumption for EPA screening-level risk assessment is being used, the report should say so and state the assumed duration of breast feeding. If an innovative approach is being used, then the approach should be motivated as reasonable and its elements explained.

Response: The revised risk chapter (now Chapter 5) does not calculate quantitative cancer risk for infants. A section, however, is devoted to a qualitative discussion of infant risks.

Comment #4-186: p. 4-16, first paragraph: Why are non-cancer risks (not potential, because they are real) to workers calculated using the LOAEL and not the RfC. This will obviously underestimate risk, unless all of the data obtained are from human studies. Safety factors should be included as the authors note throughout the document all of the uncertainties in the data.

Response: The revised risk chapter uses the hazard quotient approach (which is based on a RfC) for calculating risks to workers.

Comment #4-187: p. 4-16: Exhibit 4-8, what about infant risk including inhalation? This would increase risk substantially, perhaps as high as 1x10-2, if using inhalation risk for adults.

Response: The revised risk chapter (now Chapter 5) does not calculate quantitative cancer risk for infants. A section, however, is devoted to a qualitative discussion of infant risks.

Comment #4-188: p. 4-16, Exhibit 4-18: Exhibit 4-8 presents the lifetime risk for an infant ingesting breastmilk from PCE-exposed mothers, using modeling results from Schreiber (1992 and 1993), however, it was also indicated that the infant's inhalation exposure is substantially larger than breastmilk exposure. The lifetime risks of childhood exposures, including an infant's exposure via both inhalation and milk ingestion, should be incorporated into the CTSA. Also, a new work by

Schreiber (1997) contains additional information about infant exposure via breastmilk and via inhalation.

[Schreiber, J. 1997. Transport of Organic Chemicals to Breast Milk: Tetrachloroethylene Case Study. IN: Environmental Toxicology and Pharmacology of Human Development. Edited by Sam Kacew, Ph.D., George H. Lambert, M.D., Chapter 5, pages 95-143.]

Response: The revised exposure chapter (now Chapter 4) presents an expanded discussion of infant exposures, including reference to the Schreiber article.

Comment #4-189: p. 4-16, third paragraph: The hazard quotient is sort a reciprocal MOE. It is unnecessarily confusing to have one risk characterization index going up when another goes down. Why not divide the RfC by the LADC or ADC and just explain that these ratios will be a lot smaller than the corresponding MOEs because of the use of uncertainty or safety factors in deriving an RfC, but so long as these ratios are greater than unity, it's OK?

Response: The revised risk chapter has attempted to use a more uniform characterization.

Comment #4-190: p. 4-16: Explicitly cite the specific kidney effects that underline the RfC. If ADC's are averaged only over the duration of exposure, e.g., 8 hours, then they should be called something else, e.g., Average *Workday* Concentrations (WDC's) or *8-hour* Average Concentrations. To call them ADC's is misleading, and only breeds confusion.

Response: The revised dose/response Appendix (now Appendix D) discusses the principal studies used in deriving the RfC. The revised CTSA is no longer using ADC's.

Comment #4-191: p. 4-17, Exhibit 4-9: The MOE provided in Exhibit 4-9 for transfer machines and dry-to-dry machines appears to be incorrect.

Response: Exhibit 4-9 is no longer in the revised risk chapter.

Comment #4-192: p. 4-17 and 4-10: Exhibit 4-9 and 4-10 present information on the non-cancer risks of PCE exposure, but use different methods of assessing non-cancer risks for different populations. Exhibit 4-9 uses a MOE approach (LOAEL/Exposure) and Exhibit 4-10 uses a Hazard Quotient (Exposure/RfC). This makes comparison of the risk difficult, especially when the concern decreases as the MOE increases but increases as the hazard quotient increases. An alternative approach would be to develop a provisional RfC for occupational exposures, and compare occupational exposures to this value. Thus, both the occupational exposures and residential exposures would be compared to an RfC and all risk indices for non-cancer effects would be hazard quotients.

These changes would be relatively easy to conduct because the LOAEL in Exhibit 4-9 is the occupational LOAEL (adjusted to continuous exposure) used to derive the RfC in Exhibit 4-10. Thus, a provisional occupational RfC would become the occupational LOAEL (divided by 100, the same uncertainty factor applied to the adjusted LOEL) or 0.7 mg/m^3 (but see comment on pages C-5 through C-7). Using only hazard quotient to assess non-cancer effects would also more clearly

differentiate non-cancer and cancer assessments because only the cancer assessment would contain an MOE-based approach.

Response: The hazard quotient approach has been used for non-cancer risks in the revised risk chapter.

Comment #4-193: p. 4-17 to 4-29: These pages contain the risk characterization for seven different exposure scenarios. However, the presentation of information for each scenario does not follow the same pattern, which make it difficult to understand the technical information in each section. For example, the organization of the section on occupational exposures for dry-cleaning workers differs from all other sections by having a separate discussion for non-cancer and cancer effects and by not having a conclusion. Also, section heading should be consistent (Is it Other Important Information or Additional Information?). Seven scenarios have subheading Uncertainties and Strengths/Weaknesses: five have the uncertainty section before the strengths/weakness section and two have the reverse order.

Response: Agree; the risk chapter has been reformatted to make it easier to read.

Comment #4-194: p. 4-17, first paragraph: Cite the specific references for the data on exposure.

Response: The exposure data are cited in the revised risk chapter.

Comment #4-195: p. 4-17, first paragraph, line 1: ...common drycleaning...4-25 *Summary p. 3,* Good idea to use a range of exposure years (10, 30, 50). Should have used this practice more frequently, especially when many assumptions are made.

Response: The text has been corrected to add the word, "cleaning". More recent data (reported by Consumers Union) have replaced the study to which you refer. Responding to numerous comments on the unwieldy size of the exposure chapter, the revised exposure chapter (now chapter 4) has eliminated some of its quantitative estimates.

Comment #4-196: Sections 4-2.4 and 4.2.5 are somewhat confusing and not as concisely presented as they could be. In particular, they contain a lot of unnumbered subsections and sub subsections with similar titles and the distinction between them is murky. Reorganization of these sections to shorten them is warranted.

Response: The chapter has been extensively reorganized.

Comment #4-197: p. 4-17, first paragraph, second line: Why "maximum" exposure? In the 3rd line from the end, why "may" inhale PCE at the measured...time weighted average concentrations. The workers surely will inhale the PCE at those concentrations unless they are wearing gas masks to stop breathing.

Response: The language in this paragraph has been changed with the revision of the chapter.

Comment #4-198: p. 4-17, Exhibit 4-9: Identify the endpoints upon which the LOAEL was based.

Response: A discussion of the derivation of the provisional RfC, and the LOAEL is given in the revised Dose/Response Appendix (now Appendix D) and the revised Technical Human Health Hazard Appendix (now Appendix C)

Comment #4-199: p. 4-17, third paragraph: "Only if equipment is adequately maintained will the exposure be reduced (not limited)."

Response: Agree; the paragraph has been eliminated in the revision of the chapter.

Comment #4-200: p. 4-17, Section 4.2.5: I don't understand why the section is called exposure scenarios for potential risks (again these are risks not the conditional potential risks) and then the subsection is risk characterization.

Response: The chapter has been extensively revised in an attempt to eliminate this confusion.

Comment #4-201: p. 4-17, first paragraph: need references to the studies in the text.

Response: References for the occupational studies cited have been included.

Comment #4-202: p. 4-18, first paragraph: Again, the clear statement that the slope factors are conservative. They are only conservative with respect to the chosen model. The same issue appears on p. 4-19, 3rd paragraph

Response: As responded for Commend #4-84, EPA agrees that steeper-than-linear dose-response relationships, were they used, could produce higher estimates. Text has been added at the outset of the chapter to identify the origin of the upper bound nature of the estimates. In general, however, the concept of a slope factor is a conservative one by nature and in its general form (defined in the IRIS Appendix B as "the slope of the straight line from the upper bound risk at zero dose to the dose producing an upper bound risk of 1%") expected to be conservative by calculation. This is noted in the response to Comment #4-74.

Comment #4-203: p. 4-18, Exhibit 4-10: Most of the other exhibits in Chapter 4 are relatively consistent in their data presentation. The introduction of Hazard Quotient with no text explanation and little basis is not useful. If this is not an accepted and tested technique within the risk assessment field I would hesitate to introduce it in a document meant for the general public. Chapter 4 is already nearly impenetrable because of field specific jargon.

Response: The point is a valid one. This table has been eliminated in the revision of the chapter. The number of tables in the revised risk chapter (now Chapter 5) has been kept to a minimum and whenever possible, tables have been simplified. The concept of hazard quotient has been explained early in the chapter, and is used throughout the tables to avoid confusion. The hazard quotient has been used in EPA assessments for at least a decade.

Comment #4-204: p. 4-18, first paragraph: Are these really upper bound estimates, considering all of the weaknesses in the data presented and the underestimates of exposure commented upon in the previous chapter. The last sentence of 1x10-2 being indicative of concern for potential risk is ridiculous and completely undermines the importance of this data. This is indicative not of concern, but of a public health catastrophe that may have or could occur. Even OSHA protects workers at the 10-3 level so that these exposures would violate the Agency's General Duty Clause. EPA should spring into action in response to such enormously high risks.

Response: The assessment recognizes weaknesses in the hazard data, the dose-response modeling, and in the exposure measurements and modeling. It is not felt, however, that all weaknesses or uncertainties in the exposure assessment necessarily result in underestimating actual exposures and risks. The important feature of these figures is their magnitude relative to one another. The risk conclusions in the revised risk chapter (now Chapter 5) give a broader, clearer picture of the unit risk approach used in the cancer risk analysis.

The intent of the screening level analysis used in this CTSA is for informational purposes. The document is not designed to recommend or support specific regulatory action. However, EPA is planning to reevaluate its cancer assessment of PCE in the near future.

Comment #4-205: p. 4-19, fourth paragraph: The caveats on exposure should be reflected in the risk estimates. The OSHA data set is biased towards higher levels; this should be reflected in the range of risks presented in this report.

Response: EPA believes sufficient caveats have been used with the risk discussion.

Comment #4-206: p. 4-19, first paragraph: Again, there is no evidence presented that dermal absorption is low for PCE. Workers may have significant exposures via this route.

Response: Agree; the chapter has been revised to reflect evidence of dermal absorption of PCE.

Comment #4-207: p. 4-19, second paragraph: The sentence starting "Given the high occupational exposure...there is a reasonable basis to conclude that there is a potential cancer risk..." is poorly worded and again underestimates the importance of the data. There is more than sufficient basis to conclude that there is a cancer risk to workers from inhalation exposure to PCE.

Response: The text has been revised.

Comment #4-208: p. 4-19, third paragraph: These estimates are not likely bounding estimates, as they have failed to consider additive exposures of workers (who may live in co-located residences) and infants who will be exposed through breast milk and inhalation. There is absolutely no indication that the risk could be as low as zero given the data. Risks could possibly be even higher than those estimated, if additive exposures, chemical interactions, etc. are considered.

Response: The text of this chapter has been revised extensively, including separate sections for the several groups discussed in this comment.

Comment #4-209: p. 4-19, fourth paragraph: This paragraph again underestimates the power of the data. It is assumed here that uncertainties in exposure assessment tend to overestimate risk. This is completely untrue. First, as previously noted, just because exposure assessments were taken in response to compliance investigations, this actually may indicate workplaces with less exposure. In epidemiologic studies, uncertainties in exposure assessment tend to bias results towards the null. There is a tendency throughout the document to identify only those potential uncertainties which may overestimate risk, not those that may underestimate risk. This paragraph is not consistent with the Agency's mandate to protect human health and the environment.

Response: In addition to adding sections as identified for Comment #4-208, extensive revisions of the discussion of uncertainties has been added. It is true that, when data from the homogeneous setting of laboratory animals are applied to estimating excess risk in a work or general population setting where a variety of susceptibilities can be encountered, the result may underestimate the dose-response relationship. The relative contribution of these under- and overestimations is especially difficult to gauge, however, when the dose-response relationship itself may or may not be linear.

Comment #4-210: p. 4-19: Second paragraph, second sentence "there is a potential cancer risk." While this is accurate the following sentence indicating that this is supported by the risk assessment, etc. is not clear. Especially given the following sentence implying that there is no uncertainty about the occupational cancer risk because of the high occupational exposures. This overstates the level of evidence for occupational cancer risk given the epidemiological studies, etc.

Response: The particular paragraph has been eliminated in the revision of the chapter (now Chapter 5). The revised risk chapter indicates there are many uncertainties associated with the risk estimate; and, we have also expanded the discussion of the epidemiological data (in Appendix C).

Comment #4-211: Section 4.2.5, p. 4-19, second paragraph: Poor logic.

Response: The paragraph has been changed. It is agreed that the last sentence as stated was not logically sound.

Comment #4-212: p. 4-19, fifth paragraph: Here we find that we don't know the exposures by the dermal route. So why is it continually discounted?

Response: The chapter has been revised to include discussion of exposure by the dermal route.

Comment #4-213: p. 4-19, fourth paragraph: It is not obvious to me that the OSHA compliance checks are biased upwards for exposure. The truth is that we have no idea how valid the estimate is.

Response: The wording in the revised risk chapter's (now Chapter 5) section on occupational exposure uncertainties indicates that it is not known how representative the occupational exposure studies are of actual exposures.

Comment #4-214: p. 4-19, last paragraph: As mentioned above, the NOES data is biased toward larger drycleaning facilities. I question using this as the basis for estimating the work force.

Response: The revised exposure chapter (now Chapter 4) uses new data from American Business Information, 1994, to estimate the commercial drycleaning work force.

Comment #4-215: p. 4-19, last sentence of second paragraph: This sentence should be dropped. Occupational exposures are not as high as those for test animals and this is still an issue.

Response: The sentence has been eliminated.

Comment #4-216: Section 4.2.5, p. 4-19, third paragraph: Primary uncertainty is due to lacking or just bad data.

Response: The paragraph cited has been revised. It cites the lack of information on exposure data including lack of information on use and effectiveness of exposure controls.

Comment #4-217: p. 4-19, second paragraph, last sentence: Aw, come on! As the document notes elsewhere, the unit risk is an upper bound estimate of potency, and the risk model is linear. Furthermore, LADC's assume 40 years of work in the drycleaning industry, as well as a C x T preserving risk metric (i.e., risk from 200 ppm for 8 hours = risk from 67 ppm for 24 hours). And the upper bound risk estimates are still at most on the order of 1%, which is 10-fold below the detection limit of the animal studies. The issue of whether effects occur in human at low doses of PCE is very much a factor in the occupational scenario. I suggest striking the last sentence altogether.

Response: The sentence has been eliminated; the paragraph has been revised.

Comment #4-218: p. 4-20, sixth paragraph: Just because the ADC's are within the OSHA PEL does not mean that there will be no health impacts. The OSHA PEL was taken from the ACGIH TLV in 1970. Many TLVs have been shown to be unfounded in science and all are consensus standards.

Response: The language has been deleted in the revised chapter (now chapter 5). It was included originally for comparative purposes, and was not meant to indicate that there could be no health impacts below the PEL.

Comment #4-219: p. 4-20: For many of the reasons mentioned in the uncertainties, the weaknesses of these data should be acknowledged in this section.

Response: This section has been eliminated in the revised chapter.

Comment #4-220: Section 4.2.5, p. 4-20, first paragraph: Is there any relationship between exposure and actual dose?

Response: Exposure can be defined as the contact of a chemical with the skin, nose, or mouth of a person over a given period of time. The process of a chemical's entering the body entails contact (exposure) followed by entry into the body. The dose is the amount of the chemical that is available at human exchange boundaries (skin, lungs, gut) where absorption takes place during some specified time. There is a relationship between exposure and dose, and mathematical models have been developed to try to quantitatively describe various exposure scenarios. EPA's Exposure Factors Handbook (Aug.,1997) discusses some general factors about exposure and dose.

Comment #4-221: p. 4-20, fourth paragraph: This information is repeated from page 2-51, reinforcing the perception that much of the information presented is redundant.

Response: Agreed; this text has been removed to avoid redundancy.

Comment #4-222: Section 4.2.5, p. 4-20, fourth paragraph: On what basis was the PEL remanded?

Response: The rationale for remanding the OSHA PEL can be found in the court record for the ruling in the case of AFL-CIO vs. OSHA in the 11th Circuit Court of Appeals. It is not the place of the CTSA to interpret this legal finding.

Comment #4-223: p. 4-20: Paragraph 3 should read, "NIOSH is currently engaged in monitoring the effectiveness of various *retrofit* control devices . . . [Ewers 1997].

Response: This paragraph has been eliminated in the revised risk chapter.

Comment #4-224: p. 4-20, third paragraph: The text refers to a NIOSH monitoring program that will produce data on control device effectiveness yet the Ewers reference is dated 1977.

Response: The commenter caught a typographical error in the peer review draft CTSA. This paragraph has been eliminated in the revised risk chapter.

Comment #4-225: p. 4-20, fifth paragraph: Are the exposures in Exhibit 4-9 a range of means from different studies or a mean range over studies?

Response: The exposures in peer review draft Exhibit 4-9 were shown as ranges of two types of means from two different data sets. Therefore, both the Exhibit 4-9 title and geometric mean exposure range column headings were erroneous. This exhibit has been replaced by Exhibits 5-3 and 5-4 in the final CTSA. Exhibit 5-3 is based on the current Exhibit 4-4, which summarizes data from OSHA. Exhibit 5-4 is based on the current Exhibit 4-5, which shows information from several studies derived from Thompson and Evans (1993), a reference cited by the peer reviewers.

Comment #4-226: p. 4-20: Risk Characterization - Non-Cancer Risks, paragraph 1: Identify the endpoints from the Franchini et al. study.

Response: The particular text no longer exists, but the information is contained in Appendices C and D.

Comment #4-227: p. 4-20, first paragraph: Include the cites for the exposure data.

Response: Citations for the occupational exposure data have been included in the revised chapter.

Comment #4-228: p. 4-20, fourth paragraph: I had to read this paragraph four times to abstract the idea that the OSHA PEL was lowered to 25 ppm and then raised again by the Court.

Response: This paragraph has been eliminated.

Comment #4-229: p. 4-20, fifth paragraph and earlier: The difference between the geometric mean and expected value (or average) needs to be made clear to the reader. Why is the geometric mean best for describing the occupational data, but not the other data? As a decision analyst, I am more interested in the expected value.

Response: Where possible, the arithmetic mean has been provided. In most instances, where a geometric mean is given, that is all that the primary sources' authors provided. Discussion of the distinction can be found in the Exposure chapter.

Comment #4-230: p. 4-20, second paragraph under Other Important Information: This would also be a likely place to include information on the IDLH concentrations for PCE.

Response: This section has been eliminated in the revised chapter. IDLH information has been included with the occupational exposure sections in the updated Exposure Chapter.

Comment #4-231: p. 4-21, second full paragraph, line 3: "...human studies has *large* gaps."

Response: It was felt that the addition of the adjective, "large", was not needed.

Comment #4-232: p. 4-21, sixth paragraph: Co-located resident risk. This whole section could be condensed to one paragraph: Highly variable studies indicate exposures (caveats to the data have already been cited twice), exposures are high enough to indicate cancer risk to residents. There is not need to repeat the same warnings at each point where the same data set is referenced. The same applies for the ambient air, consumer, outdoor air, and oral ingestion sections that follow. A summary of the risk data could easily be given at the end of the earlier exposure or hazards sections with the methodology provided in an index. While the intent of the authors may be to be exhaustive in their coverage it is easily to obfuscate conclusions by overwhelming the reader with data.

Response: Agree; a concerted attempt has been made in the revised risk chapter to condense information, and avoid redundancies.

Comment #4-233: p. 4-21, fifth paragraph: Monitoring studies indicate that co-located residents are or can be (not potentially because it happens) exposed to elevated levels of PCE.

Response: "Potentially" is used to indicate that exposures "may or "can" occur to co-located residents. The monitoring information is not sufficient to say that exposure "always" happens, so the use of the word "potential" is appropriate.

Comment #4-234: p. 4-21, lines 5-6: As long as you're going to say "mild kidney..." identify the specific effects explicitly.

Response: This language has been eliminated in the revised risk chapter.

Comment #4-235: p. 4-21, first paragraph: Qualitative concern for developmental toxicity for (children of workers) - eliminate potential, it is a double conditional with concern for. In the next paragraph, workers are at risk (not just potentially) for non-cancer risks. Pregnant workers are at risk (could be potentially is a double conditional that downplays the risk) for developmental toxicity.

Response: The extensive revisions of the risk chapter have eliminated this particular paragraph, and the risk conclusions have been revised to be clearer and more concise. The term, "potential", as used in the text, has been examined and in some cases revised, however, it has not been completely eliminated from the text. Since the experience of the readers in the area of risk assessment is expected to vary, the use of the word "potential", in some cases, helps to underscore the screening nature of this assessment.

Comment #4-236: p. 4-21, third full paragraph, line 4: "toxicity, and *significant* uncertainties in the animal data...". Call the next very short section "*Exposure* Uncertainties".

Response: This language has been eliminated in the revised risk chapter.

Comment #4-237: p. 4-22, third paragraph: It is important to note that the few very high exposure levels from poorly maintained machines will have a very strong influence on estimates of the mean exposure level.

Response: The section on co-located residents has been extensively revised and shortened, and the uncertainty in the mean exposure value due to the wide range of exposures is expressed.

Comment #4-238: p. 4-22, Strengths/Weaknesses: This data set cannot be characterized as "strong." There were <u>only</u> 60 residences studied, and for the most part, the sampling in each residence covered a relatively short period of time. Given the geographical bias of these data and the lack of information on the distribution of machine type, drycleaning locations, etc., the

document needs to be much more cautious in attempting to extrapolate these data to characterize risk on a national basis.

Response: This section has been eliminated in the revised risk chapter.

Comment #4-239: p. 4-23, Other important information: The risk assessment appears to downplay the potential health risk for children. Children may be more susceptible to a number of health effects caused by PCE and could spend longer times in the residences. A more complete discussion of this issue should be included somewhere in the document.

Response: The revised exposure chapter (now Chapter 4) and risk chapter (now Chapter 5) have included sections on exposure and risk to children.

Comment #4-240: p. 4-23, first paragraph: Wasn't 8 years chosen for the LADC determination.

Response: This typographical error has been corrected.

Comment #4-241: p. 4-23, Other important information: This paragraph should be bolded. It is common sense that the risks due to PCE would be higher for children than adults.

Response: This particular paragraph has been eliminated in the revised risk chapter. The revised exposure chapter (now Chapter 4) and risk chapter (now Chapter 5) have included sections on exposure and risk to children.

Comment #4-242: p. 4-23, fifth paragraph: Risk indices for high-end exposures should be even higher if high end concentrations are used for the LADC calculation (see above for page 3-40 [Comment #3-276]).

Response: A discussion of the studies utilized in the exposure estimates is given in the revised exposure chapter (now Chapter 4). The exposure assessment involved extrapolations from short-term measured values to long-term estimates of exposure. Because of this, it is not appropriate to use upper end values in estimating high end exposures.

Comment #4-243: Response #4-217, p. 4-23, Conclusions: It should be mentioned that this is for non-cancer effects. "there is a concern for cancer risk (not potential)." It is not understood why "the only scenario of potential concern is that of residences located above drycleaning shops where poorly maintained machines are used." This is not consistent with the data at all. There is no indication that the elevated (above 1 in 1 million) risks for co-residents are in facilities with poorly maintained machines. As such this statement has no basis in the text so far and should be eliminated. Also, any scenario demonstrating elevated risk (even below 1 in 1 million) should be of concern. The last sentence about the RfC being an exposure estimate with uncertainty of about an order or magnitude. This uncertainty is part of the definition of an RfC and thus this statement downplays the data as all RfCs have high levels of uncertainty.

Response: The section on co-located residents has been extensively revised and shortened. The risk conclusions are consistent with the data indicated in the table 5-5 in the revised chapter, and the cancer and non-cancer risks are clearly indicated.

Comment #4-244: p. 4-23, Conclusions, paragraph 1, line 3: "The risk indices are *comparatively* high... ."

Response: The language has been changed in the revised risk chapter.

Comment #4-245: p. 4-24, first paragraph: How is personal activities a source of exposure to PCE in homes?? This is absurd.

Response: This language has been eliminated in the revised risk chapter.

Comment #4-246: p. 4-24, second paragraph under Uncertainties: Add to last sentence in parenthesis 'as well as continuous exposure'.

Response: This paragraph has been eliminated in the revised risk chapter.

Comment #4-247: p. 4-24, under "Additional Information": This paragraph as it stands is inadequate, and it needs revision. The results of recent TEAM studies should be used to clarify the extent and duration of PCE in indoor air from recently drycleaned clothes. Some discussion of this type is found on pages 4-26 and 6.

Response: This paragraph has been eliminated in the revised risk chapter (now Chapter 5). The revised exposure chapter (now Chapter 4) presents a discussion of studies relating to consumer exposure to drycleaned clothes.

Comment #4-248: p. 4-24, Uncertainties, paragraph 2, line 4: "e.g., the *estimated 18 year* duration of potential..."

Response: This paragraph has been eliminated in the revised risk chapter.

Comment #4-249: p. 4-24, last paragraph: good point

Response: Agree; however, this paragraph has been eliminated from the revised risk chapter since it deals with risk reduction measures rather than risk assessment.

Comment #4-250: p. 4-24, last line of second paragraph under "Uncertainties": It is beyond me why the duration of residence in one county is relevant to the assessment of community exposures. Drycleaning is done across the nation. The duration of exposure should be a full lifetime, assuming, for the sake of a simple analysis, that PCE use in drycleaning continues indefinitely into the future.

Response: Agree, the duration of exposure has been considered lifetime in the revised exposure chapter (now Chapter 4), and risk chapter (now Chapter 5).

Comment #4-251: p. 4-25, second paragraph: Note what this risk level means in terms of EPA action levels.

Response: Many commenters indicated that presenting risk estimates for a large number of exposure scenarios was confusing. In response, some exposure scenarios were eliminated, such as this one, in the revised risk chapter (now chapter 5). The revised exposure chapter (now Chapter 4) has been updated to include a summary of more recent studies on consumer exposures from wearing drycleaned clothes. The risk estimate would be similar using some of these data, however. Also, there are no unique EPA "action levels".

Comment #4-252: p. 4-25, first and third paragraph under "Summary": Again, it makes no sense to assume only a 30 year duration for consumer exposure. Further, although the individual risks may be relatively low, the population aggregate risk may be substantial enough to be worth some considerable trouble and expense to control. This is one reason why population aggregate exposures and risks should be calculated and presented in this document. This comment also applies to the conclusion of "low" risks from drycleaned clothes in the first new paragraph on p. 4-26.

Response: It is beyond the scope of the CTSA's screening level risk assessment to attempt to calculate population aggregate exposures and risks. The revised exposure chapter (now Chapter 4) has been updated to include a summary of more recent studies on consumer exposures, and uses a 40 year duration in an example exposure estimate.

Comment #4-253: 4-25, fourth paragraph: The presentation of ranges for important variables is to be commended. However, in this case duration of exposure is not the only (or even the major) source of uncertainty in estimates of risk. The presentation of ranges based on only one parameter may be misleading because readers may assume that all sources of uncertainty were treated as ranges when, in fact, most were point estimates.

Response: These data are no longer discussed in the revised risk chapter.

Comment #4-254: Section 4.2.5, p. 4-25, third paragraph: Again, are there no process determinants?

Response: These data are no longer discussed in the revised risk chapter.

Comment #4-255: p. 4-25, Summary, first paragraph, line 6: "quotient is *much* less than 1 for ...".

Response: The extensive revisions to what is now Chapter 5 have removed the particular scenario that generated this sentence. One cannot know that a hazard quotient is "much less" than 1 because we have no statistic to measure the disparity. The magnitudes of these calculations were such, however, that we had been relatively comfortable in saying they were "less."

Comment #4-256: p. 4-25: Data and a discussion on coin-operated drycleaning facilities should be added into the report. Many of these facilities are in laundromats, where customers spend a substantial period of time while washing and drying clothes. Indoor air exposure to PCE in these facilities could be moderately high, especially if there is leakage from the drycleaning equipment.

Response: A good idea; however, the scope of this CTSA did not allow for more than a screening level exposure and risk assessment, which cannot include all possible exposure scenarios.

Comment #4-257: p. 4-26, fourth paragraph: Models don't make assumptions, people do. There are inherent uncertainties in every modeled scenario.

Response: This language has been changed in the revised risk chapter.

Comment #4-258: p. 4-26, Risk Characterization Summary, lines 2-3: The risk indices are low except in close proximity to a drycleaning shop regardless of whether or not air is sampled!

Uncertainties: Such as ...

Response: Agree; this language has been eliminated in the revised risk chapter.

Comment #4-259: p. 4-27, third paragraph: Since in many cases PCE levels exceeded the MCL of 5ppb, and this 5ppm was the value used in the exposure assessment, actual exposure and thus risk could be much larger. As noted in the next paragraph, this is a LARGE uncertainty. In this case, no risk estimate should be made or no conclusions should be made based on that risk estimate.

Response: EPA disagrees that no conclusion should be made on the MCL. The revised risk chapter (now Chapter 5), however, provides the usage with caveats in both it's conclusion and uncertainties section.

Comment #4-260: p. 4-27, Summary, second paragraph, line 3: Strike "The source of".

Response: This language has been eliminated in the revised risk chapter.

Comment #4-261: p. 4-27, Uncertainties, lines 1 and 5: "major" and "large" are employed to characterize exposure uncertainty, but the basis for these adjectives is not obvious. Even if there is contamination above 5 ppb, does that automatically make the uncertainty major or large?

Response: The use of, "large" has been eliminated. Expanded discussions in the exposure chapter (now Chapter 4) make clearer the parts uncertainty and variability play in a CTSA reader's evaluations.

Comment #4-262: p. 4-27: There is a situation in California known to this reviewer where a drycleaning plant owner-operator complying with air quality rules flushed PCE-contaminated water from mandated control equipment down a sewer connecting to a POTW. But the sewer casing was cracked, the result was a PCE groundwater plume, and the owner-operator was held financially responsible for groundwater cleanup. A tie-in of the discussion in this section to the multimedia aspects of PCE and the control technologies described in chapter 1 should be made.

Response: The risk chapter attempted to deal with some of the multimedia aspects of risk, but at a screening level assessment it was not possible to cover all aspects.

Comment #4-263: p. 4-27, third paragraph: I don't see a good justification for using 5 ppb for the drinking water exposure. Surely there must be a database that gives better data. Did you try EPA's OSWER or ATSDR? PCE is one of the most prevalent groundwater contaminants and a major source of the loss of beneficial use of groundwater. This should be factored into the costs somehow. As to the low risk associated with drinking water contamination, see our study of PCE contaminated water on the Cape (Aschengrau, A., Ozonoff, D. Paulu, C., Coogan, P. Vezina, R., Heeren, T., Zhang, Y., "Cancer risk and tetrachloroethylene (PCE) contaminated drinking water in Massachusetts," *Archives of Environmental Health,* 48:284-292, 1993).

Response: Searches were conducted of ATSDR and other databases for PCE concentrations, and results of these searches are given in Appendix E. Since the searches were accompanied by minimal descriptive information it is not certain that the PCE contamination source is from drycleaners, and therefore, they were not used in the assessment. The CTSA assumes that residents would not be exposed to contamination for a lifetime. As mentioned in the response to Comment #4-3, the study cited has used many modeling assumptions to estimate exposure levels, and provides relative, not extra, risk. This means that we cannot use the study to get an estimate of absolute risk for a specific exposure level.

EPA has not factored the cost of groundwater contamination into its cost estimates.

Comment #4-264: p. 4-27, sixth paragraph: "the general population's exposures...are very low (the risks are low but not very low). Also, contamination of groundwater usually consists of more than one chemical. How does this assessment account for that?

Response: The specific language has been changed in the revised risk chapter. It is beyond the scope of this CTSA screening level risk assessment to deal with the multiple chemical composition of groundwater contamination.

Comment #4-265: p. 4-28, Uncertainties: To describe the uncertainty as *major* is not particularly helpful. How about including a coefficient of variation for exposure and carrying that through to a corresponding estimate of uncertainty in the estimates of risk for the various exposure scenarios?

Response: This was beyond the scope of the CTSA screening level exposure and risk assessments. Expanded discussions in the exposure chapter (now Chapter 4) make clearer the parts uncertainty and variability play in a CTSA reader's evaluations.

Comment #4-266: p. 4-28, first paragraph: It should be noted that, to the best of my knowledge, discharge water from a POTW does not go directly to the tap. The water source for a municipal water system is not the POTW.

Response: This paragraph has been eliminated in the revised risk chapter.

Comment #4-267: p. 4-29, Strengths/Weaknesses: The predicted estimate is about 1/4 of the measured mean value. I don't have any way to gauge whether this is good or bad agreement. For example, I suspect that four-fold discrepancies in project budgets would not be regarded as trivial, or as adding to the credibility of budget projections.

Response: This paragraph has been eliminated in the revised risk chapter.

Comment #4-268: 4-29, second paragraph: Values of metabolic parameters in PBPK models are another large source of uncertainty.

Response: Agree; the sections on exposure and risk to infants from breast feeding have been extensively revised.

Comment #4-269: p. 4-29, Conclusions: Is the RfD valid for infants?

Response: The RfD/RfC concept incorporates the idea that a 24-hour exposure over a lifetime at the designated level generally is not expected to be toxic to the general public, including sensitive sub-populations such as infants. Therefore, in the CTSA the measures of toxicity used for adults were also used for infants. Discussions in the revised chapter of risks to infants, however, are only qualitative.

Comment #4-270: p. 4-29: The conclusion of the section on Breastfeeding Infant Exposure Scenarios indicates that the non-cancer risk may be of lesser concern than cancer risks. However, the analysis fails to consider the larger issue, namely, what are the total risks to such infants from all routes of exposures.

Response: The section on infants has been revised, and the revised risk chapter now includes sections describing combined risks.

Comment #4-271: p. 4-29, third new paragraph: I hardly think that a datum that is four-fold larger than the predicted concentration of PCE in breast milk "adds credibility to the model."

Response: This paragraph has been eliminated.

Comment #4-272: p. 4-29, first sentence: What is this supposed to mean? All of these risk extrapolations are hypothetical.

Response: The section on infants has been extensively revised.

Comment #4-273: p. 4-29:, Conclusions: The relative benefits of breast feeding should at least be acknowledged as these probably outweigh the risks from PCE exposure. I believe that this was a major conclusion of the Schreiber paper.

Response: This has been included in the revised section on infants.

Comment #4-274: p. 4-29, third paragraph: There is no mention in the uncertainties that the risk estimate for infants is inherently underestimated because it does not consider inhalation exposure. This large omission should be considered in the conclusions, as well as the general greater susceptibility of children to toxic insults.

Response: The section on infants has been extensively revised. Combined risks are discussed in the revised risk chapter.

Comment #4-275: p. 4-29, lines 1-7: Again the uncertainties are not described in a useful manner. How far off might the PBPK model be? What are the impacts of the various sources of uncertainty? A formal uncertainty analysis not unlike that undertaken for particulate matter by Abt Associates on EPA's behalf would be a lot more helpful.

Response: The section on infants has been extensively revised. It is beyond the scope of this CTSA screening level risk assessment to undertake a formal uncertainty analysis.

Comment #4-276: p. 4-30, fifth paragraph: Just because the concern concentration is not exceeded does not mean that there is no concern for risk to aquatic species. Again, ecosystems are inherently complex so that any ecological risk assessment is fraught with large uncertainties and variability. This is a misguided statement.

Response: The concern concentration is a very conservative screening level, and if not exceeded, aquatic organisms will not be adversely affected. EPA agrees with the commenter that ecosystems are inherently complex, but EPA believes that it has made the best, most conservative choice.

Comment #4-277: p. 4-31: The test, line 4-5, is potentially misleading and should be replaced by two or more sentences, one about what is known in animals, and then a description of what is known and suspected in humans. PCE is known to cause cancer and other adverse health effects in animals such as rates and mice. The known human health effects occur at or above occupational levels. PCE is not known to cause cancer in humans, although some epidemiological studies suggest a possible effect at occupational exposure levels. Existing epidemiological studies are inadequate for establishing a causal relationship between PCE exposure and cancer in humans. (The last sentence is directly quoted from page A-1, end of 4th paragraph).

Response: This summary section has been extensively revised.

Comment #4-278: p. 4-31, second last sentence in paragraph: It is stated here that risks are higher from transfer machines, but this conclusion is tentative because of the small database. It

seems quite obvious to me that the exposures are higher for transfer machines and it is not necessary to be so circumspect. One could quite justifiably say, "Exposures from transfer machines are higher, as might be expected."

Response: This summary section has been extensively revised. The text now reads: "Exposures and, consequently risks, tend to be higher if transfer machines are used instead of dry-to-dry machines, but there are still health risks associated with PCE exposure levels from dry-to-dry machines."

Comment #4-279: p. 4-31, Exhibit 4-11: I really like this! It is very helpful in placing the various opportunities for exposure in proper perspective relative to one another. It might be additionally useful to also note on the diagram the levels at which toxicity of various kinds has been observed, both in humans and animals.

Response: EPA chose not to add a listing of specific experimentally observed values (which are subject to variabilities whose addition would make the now easily-read chart very busy) to keep the focus on the comparison of exposure ranges and generalized indicators.

Comment #4-280: p. 4-31: The chart and the conclusions on page 4-31 need to be highlighted. This is buried in the chapter. Clearly this indicates unacceptable risks to employees and to persons in co-located residences even with dry to dry machines without additional control technologies.

Response: Since the chapter does not focus only on PCE, this chart was kept with its section's overall summary. Extensive revisions to this chapter have made the conclusions easier to follow.

Comment #4-281: p. 4-31, Section 4.2.7: This summary was very useful relative to the rest of the chapter which was very difficult to understand and put in perspective.

Response: No action appeared to be required by this comment.

Comment #4-282: p. 4-31: it would be useful if the cancer risk estimates on Exhibit 4-11 were shown for 1 mg/m3, 10 mg/m3, and 100 mg/m3 as well as the low concentrations. Thresholds for non-cancer effects could be added as well.

Response: Any depictions based on the unit risk will be linearly related to one another, so we did not add these points because we were concerned not to make the chart too busy. The cancer risk index at 14 mg/m^3 is 1 in 100, hence that at 10 mg/m^3 would be so close to be indistinguishable and that at 100 mg/m^3 could not be properly placed on the chart, since there would be no proper estimate for it.

Comment #4-283: p. 4-31: Exhibit 4-11 is a nice way to present information. An improvement would be to use quantitative estimates of the uncertainty in health hazard information to make ranges on the left side of the figure too.

Response: As discussed in other responses, EPA has not added points or uncertainty brackets or similar modifications in order to avoid clutter in what seems to be a helpful chart. EPA does not have specific quantitative estimates of uncertainty for most of the hazard (or exposure) information; the general tendency is discussed in the text.

Comment #4-284: p. 4-31: Exhibit 4-11 is unclear. It seems to indicate that the OSHA PEL is 680 mg per meter cubed and the ACGIH TLV is 170. These values are not correct.

On the same page, the conclusion is again drawn that transfer machines pose a higher risk than dry-to-dry machines. The same comments apply as above.

Response: The OSHA PEL and ACGIH TLV values listed in the exhibit are correct. In 1989 OSHA adopted a 170 mg/m^3 time weighted average (TWA) permissible exposure limit (PEL) to replace the pre-1989 PEL. However, all new 1989 PELs were vacated via a court decision, and the pre-1989 PEL of 680 mg/m^3 is currently in effect. The current ACGIH TLV is 170mg/m^3.

Data indicate that transfer machines are associated with greater exposures (and hence, risks) to workers and co-located residents than dry-to-dry machines . This does not preclude high exposures associated with machines of any type that are in poor condition.

Comment #4-285: p. 4-31, Exhibit 4-11: Exhibit 4-11 presents an excellent summary of parts of a rather complicated chapter.

Response: No action appeared to be required by this comment.

Comment #4-286: p. 4-31: It is stated that "occupational PCE levels approach, and even exceed, PCE levels known to cause cancer." I suggest that the word "known" is too strong, and I am supported in this opinion by the IARC and EPA review committees. I suggest that the words "known to" be replaced by the words "that possibly".

Response: This summary section has been extensively revised, and the sentence eliminated.

Comment #4-287: p. 4-31, third sentence: "Known to cause cancer...in animals and humans." PCE is a probable carcinogen.

Response: This summary section has been extensively revised, and the sentence eliminated.

Comment #4-288: p. 4-31: Why are only two exposure scenarios standing out at "potential" candidates for risk reduction? Isn't the basis of pollution prevention that <u>all</u> exposures to potentially dangerous substances be minimized? According to the data presented, some of the exposure scenarios that do not fit into the definition of those that need to be reduced are indeed important (e.g., near by, non-co-located residents). All of the scenarios should be considered candidates for risk reduction, especially when it is clear that there are safer, cost effective alternatives to PCE technology. The comment (including children) should be especially children, given their greater susceptibility. Who defines mild kidney effects as presented in the next sentence.

Response: It is agreed that pollution prevention measures should be utilized wherever possible, and not just for the highest exposure scenarios. However, in this CTSA screening level assessment it was considered important to highlight the highest exposure scenarios. A discussion of mild kidney effects is presented in the revised Appendix C.

Comment #4-289: Exhibit 4-11: This is a great figure and should be put in the executive summary. This is what the report should strive for: put the exposure levels in the context of the risk associated with them. One figure like this could substitute for three chapters of caveat and explanation. The brief section summarizing risk from PCE should be in the executive summary.

Response: Agree; the revised executive summary contains a brief summary section.

Comment #4-290: p. 4-32, second paragraph: The first sentence needs to be revised. Keep in mind that using a linear model for PCE dose-response, any exposure via mother's milk can theoretically be enough to cause cancer effects (similar sentence should also be taken out of paragraph at the top of page 8-2). Again, it is important to note that these assessments reflect individual risk estimates, not population risk estimates, and that identification of significant risks and key remaining uncertainties might differ if population risks were the focus. For example, if focusing on population risks then the uncertainties related to the PBPK model for infants would probably not be on the list.

Response: The section on infants has been extensively revised, and this sentence eliminated. It was beyond the scope of this CTSA screening level risk assessment to attempt to calculate population risks. The general statements of concern for risks to workers and co-located residents however, remain pertinent.

Comment #4-291: p. 4-32, second bullet: You really want to know the relationship between exposures and levels in breast milk, not just the PBPK model.

Response: Agree; the section dealing with infant exposures via breast milk has been revised.

Comment #4-292: p. 4-32, first bullet: How would one ever answer the question whether PCE causes cancer in humans at low doses? This a straw man. This is not an empirically determinable question.

Response: It is true that the issue of whether PCE causes cancer in humans at low doses is unlikely to be empirically resolved through epidemiology.

Comment #4-293: p. 4-32, first paragraph, second sentence: Why does it state that the concentrations in residences are "below any known cancer...effect"? This is not keeping with the no-threshold regulatory concept, it is not an established fact, and it is certainly misleading. Reference to the 1993 paper by Aschengrau et al., cited above, would also tend to contradict this statement. It should be eliminated.

[Aschengrau, A., Ozonoff, D. Paulu, C., Coogan, P. Vezina, R., Heeren, T., Zhang, Y., "Cancer risk and tetrachloroethylene (PCE) contaminated drinking water in Massachusetts," *Archives of Environmental Health,* 48:284-292, 1993.]

Response: The statement has been eliminated in the revised risk chapter.

Comment #4-294: p. 4-32, first bullet: "Whether PCE causes cancer in humans at low doses..." Really, at any dose. The low dose mechanism is the subject of debate.

Response: Agreed, the low dose mechanism is the one subject to most debate.

Comment #4-295: p. 4-32, first paragraph: the statement that concentrations in affected residences are "below any known cancer or non-cancer effect level" has got to go. It inappropriately implies we should believe exposure levels below a known cancer effect level are of minimal concern.

Response: Agree, the language has been eliminated in the revised risk chapter.

Comment #4-296: p. 4-32, fourth paragraph: The unanswered key questions are only those that would lead the reader to believe that the risk has been overestimated. There are so many unanswered questions that if answered may even lead to greater risk estimates. The fact that we do not know the mechanism of action of PCE does not mean it doesn't pose a risk. These questions are clearly biased to underestimate PCE risk.

Response: Disagree. A screening level risk assessment, by its nature, leaves many unanswered questions. Although this particular listing will appear essentially unchanged, the chapter has been streamlined and reorganized better to identify throughout how uncertainties should be taken into consideration by the reader. The particular issues mentioned are seen as key ones, and were meant to give the reader a sense of the state of current knowledge in the area.

Comment #4-297: p. 4-32, first paragraph: The comment that these concentrations are below any known cancer or non-cancer effect level in humans or animals has two problems. First, we are assuming a no-threshold level for cancer so there is no level below which there is no risk. Second, the studies are limited so it is not clear whether these levels are actually below any know effect levels. High exposures could even possibly occur in well maintained dry-to-dry units, especially during maintenance, cleaning, and changing filters.

Response: The language has been eliminated in the revised risk chapter.

Comment #4-298: p. 4-32, second paragraph: What does the note that "PCE from drycleaned clothes and drinking water from ground water sources were estimated not to be of high enough concentration to warrant concern for cancer or non-cancer risks." What does this sentence mean? Does it mean there is no risk? Or does it mean that EPA does not know enough to determine the risk. Of course there is concern about risks any time a toxic substance is released into the environment. This sentence completely downplays hazard, especially given the fact that EPA did not consider any interactions of PCE with other substances, based its groundwater estimates on a

CA estimate that EPA has acknowledged underestimates exposure, and does not consider additive/cumulative exposures to PERC or other toxic substances.

Response: The language has been eliminated in the revised risk chapter.

Comment #4-299: p. 4-32, bullet 1: Strike the phrase "at low doses".

Response: Disagree. Low doses remain a key issue.

Comment #4-300: p. 4-33: The statement that the most significant hazard identified for PS is flammability seems to be unnecessarily strong given the lack of data for many toxicological endpoints.

Response: The language in the revised risk chapter (now Chapter 5) has been changed to, "A major hazard . . ." This reflects the commenter's concern while alerting the reader to the importance of the hazard.

Comment #4-301: p. 4-33: NPFA classifies, not grades, solvents based on their flash points. Stoddard solvents are not highly flammable. Their introduction during the 1920-1930 lowered the fire hazard in drycleaning plants significantly and made petroleum solvent cleaning much safer. See NFPA-32, Standard for Drycleaning Plants 1996 Edition for details.

Response: The language has been changed in the revised risk chapter.

Comment #4-302: p. 4-33, first sentence: There is a big judgment being made here about the toxicity of PS. In particular, the PS are presumed to be of zero or low toxicity because they have not been tested, not because they are truly of low toxicity.

Response: The language has been changed to avoid the misunderstanding indicated by the commenter.

Comment #4-303: p. 4-33, fourth bullet: "True range of exposure". That range is easy to determine with a relatively small random sample. You really want to know more about factors effecting exposures, etc.

Response: The CTSA screening level assessment could not conduct any random sampling in order to estimate the full range of exposures. The commenter is correct that we also want to know more about factors affecting exposures.

Comment #4-304: p. 4-33, paragraph 1: It would be helpful to provide the flashpoint of a common substance, such as gasoline for comparison purposes.

Response: It was not possible to incorporate all ideas into the revised chapter. The flammability of PCE, however, was compared with that of the hydrocarbon solvents.

Comment #4-305: p. 4-33, third paragraph, lines 1-2: Replace *neurotoxicity* with the specific endpoint(s) reported. Elaborate on the term *psychological measures.* Include some comment on the limited nature of the data as a result of there being only 8 subjects.

Response: This section has been eliminated since many commenters suggested eliminating duplicate summaries of hazard and exposure information found elsewhere in the CTSA. The Human Health Risk section in the revised risk chapter refers the reader to Appendix C for a discussion of the specific toxicity tests used.

Comment #4-306: p. 4-33, second paragraph, line 3: Strike *neurotoxicity* and the parentheses around dizziness.

Response: See response to Comment #4-305.

Comment #4-307: p. 4-33: In paragraph 1, explosivity should be discussed as a significant physical hazard along with flammability.

Response: It was felt that a discussion of explosivity would be speculative and out of the scope of the CTSA screening level assessment.

Comment #4-308: p. 4-34: To this reviewer's knowledge, no inhalation bioassay has been done on Stoddard solvent or its lower flammability variant. If true, this information should be included in the text. Given that fully vaporized gasoline produced kidney tumors in male rats and liver tumors in female mice it would not be surprising for PS to show strong evidence of carcinogenicity in high-dose animal tests, were such tests to be carried out. The negative result in the mouse skin-painting test is weak evidence that PS is not carcinogenic.

Response: The revised text indicates that there were no data suitable for drawing conclusions concerning carcinogenic potential of Stoddard solvent.

Comment #4-309: p. 4-34, first paragraph: All studies have severe limitations - why do the limitations in these preclude their use in assessment carcinogenic hazards. All epidemiologic studies have limitations. Does this mean that since the data is not available that there is no risk? Some type of limited assessment should be made.

Response: The screening level risk assessment used information on Stoddard solvent based on the ATSDR, 1995, document which indicates that the data are not sufficient for drawing conclusions concerning carcinogenicity. The fact that data are not sufficient to conclude risk does not mean that there is no risk. When conclusions cannot be drawn, an assessment, even of a limited nature, cannot be made.

Comment #4-310: p. 4-34: While there have not been studies of cancer occurrence in persons exposed only to petroleum solvents, some mention might be made of the study by Duh and Asal

(reference # 111). In that study, proportional mortality ratios for the various sites of cancer are presented for individuals employed in the drycleaning industry, and the authors indicate that in their population (residents of the state of Oklahoma) "greater than 50% of the total solvents used" were petroleum solvents.

Response: The revised Appendix C includes a section on information on carcinogenicity of the hydrocarbon solvents. According to EPA (1985), the Duh and Asal (1984) study was based on drycleaners and laundry workers in Oklahoma who died during the period of 1975-1981. The authors noted that petroleum solvents accounted for over 50% of the dry-cleaning solvents used in OK in 1983. This is in line with the commenter's statement. No text has been added, however. The study would have been no more useful for inferences about hydrocarbons than it was for PCE.

Comment #4-311: p. 4-34, hazard summary and characterization - cancer: It is stated that lung cancer, prostate cancer and Hodgkins lymphoma were observed in humans exposed to mineral spirits. Unfortunately, there is no scientific content to this sentence, since these common cancers also occur in humans who are unexposed to mineral spirits. What is needed is a basis of comparison, specifically the occurrence of these cancers in exposed individuals relative to that in unexposed individuals.

Response: The section to which this comment refers has been eliminated in the revised risk chapter (now chapter 5). We agree that comparisons cannot be made with the information provided. As identified in the hazard summaries appendix (now Appendix C), this was a case-control study in which only relative odds of exposure can be determined. The population base was a group of individuals diagnosed with a variety of cancers at a regional group of hospitals. The commenter's statement appears to agree with the CTSA's conclusion.

Comment #4-312: p. 4-34: The absence of a statement about the potential carcinogenic potential of PS is unacceptable. I realize the many problems with making provisional findings without agency approval, but not making a statement is the equivalent of declaring the material safe (for this hazard). This may be true, but if it is not then comparisons are significantly compromised. This is an opportunity for the use of QSAR and expert judgment to make the most scientifically plausible statement of hazard. Accurate comparisons also require scientifically plausible, not conservative, interpretation of the data.

Response: In the human health effects section, the decision was made to use reported data primarily because experimental data were, for the most part, available. In the ecological effects section, the decision was made to use SAR analysis because experimental data were, for the most part, not available. In retrospect, it could have been useful to combine the two methods in both sections, but it also would have been counter to the level of effort normally used in a CTSA screening level risk assessment.

Comment #4-313: p. 4-34, Exhibit 4-12: Replace *Toxicity Value* with *Exposure Level*. Be more specific than *Neurotoxicity*. Identify the endpoint(s) as was done with *Irritation, eye/throat*.

Response: Several measures are used to gauge the extent of effects that may be associated with exposure. These include Unit Risks (which are expressed per exposure unit) and Reference Doses/Concentrations (which are expressed in exposure units) and the text refers to them as

Toxicity Comparison Values. In the revised CTSA, Table 5-2 is the only one where these values are collectively displayed; unfortunately, although the title calls them 'toxicity comparison values,' the column headings have not been changed in the revision.

Comment #4-314: p. 4-34, Section 4.3.2 Ecotoxicity: This tiny section seems out of place here. Why not organize the document so Human Health followed by Human Exposure and Human Risk, then go on to Eco issues.

Response: EPA received many comments on reformatting. The risk chapter (now Chapter 5) has been reformatted, and should be easier to read.

Comment #4-315: p. 4-34, Uncertainties, line 2: *Greater uncertainty* is not a helpful term. How much greater? Try to quantify. If you can't quantify, then how can you be sure that it's greater?

Response: The wording of the uncertainties section has been revised for clarity. EPA does not have specific quantitative estimates of uncertainty for most of the hazard or exposure information; consequently, only the general tendency is discussed in the text.

Comment #4-316: p. 4-35, Conclusions: To say that "There is high concern" when the analysis is based on virtually no data is ludicrous!

Response: The revised hazard (now Chapter 3) and risk (now Chapter 5) chapters include some limited toxicity data on Stoddard solvent. EPA has, however, successfully used SAR in predicting toxicity to aquatic organisms for many years. References are presented in the revised Appendix B.

Comment #4-317: p. 4-35, Section 4.3.3, second paragraph: Oral exposure was not addressed because of a lack of data on this exposure route. There is information in the literature on ingestion of petroleum solvents as well as case reports.

Response: The oral exposure route was not considered a relevant exposure route for this CTSA.

Comment #4-318: p. 4-36, fourth paragraph: Change "could be gotten" to "were available."

Response: The section has been revised, the phrase is not used.

Comment #4-319: p. 4-37, fifth paragraph: The text indicates that no quantification for PS is available but some data and a discussion of flammability hazard is included on page 1-29.

Response: The text indicates that the risk of fire cannot be quantified. The discussion of the flammability hazard on page 1-29 (now discussed in chapter 3 of the revised CTSA) does not give sufficient data to quantify the risk of fire due to flammability.

Comment #4-320: p. 4-37, fifth paragraph: As noted several times, OSHA data gathered during compliance inspections may actually provide underestimates of the real situation.

Response: It is agreed that the OSHA data may underestimate the real situation, because complaint inspections are often initiated because there is an air contaminant problem that may not represent the average situation. This has been noted in the revisions. Although OSHA data may underestimate the real situation, there are other uncertainties. These data are also supplemented by other sources in the CTSA.

Comment #4-321: p. 4-37, fifth paragraph: The fire risks should be characterized.

Response: Characterization of risks due to fire was beyond the scope of this CTSA

Comment #4-322: p. 4-37: Some attempt must be made to estimate (with attendant uncertainty) the risk of fire from drycleaning with PS. The data from Japan, mentioned elsewhere in the report (p. 8-24), could be used to make an estimate. In making comparisons of alternative technologies, all relevant risks must be identified and quantified to the extent possible.

Response: Characterization of risks due to fire was beyond the scope of this CTSA

Comment #4-323: Exhibit 4-14: This is the key table where QSAR/expert judgment-based "Relevant Toxicity Comparison Levels" must be developed.

Response: This table has been extensively revised. Table 5-9 of the revised risk chapter lists only reported hazards. See response to Comment #4-312.

Comment #4-324: p. 4-38: The conclusions drawn from Exhibit 4-38 illustrate perfectly the problem of using the MOE approach and comparing to the RfD-based HQ (see comment on page 4-4, paragraph 4, above) [Comment #4-98]. If the NOAELs used to calculate the MOE had the usual 100 fold adjustments of the RfD, some of MOEs (or more precisely, the quasi-HQs) would be near 1.

Response: It is agreed, as stated in Comment #4-98 and referred to here, that the use of the MOE is not equivalent to the HQ which is based on the RfD. The risk chapter has been extensively revised, and the HQ approach is used in the revised tables.

Comment #4-325: Exhibit 4-14: As usually defined, hazard information is irrespective of use, dose, or exposure levels. This means that the statement "No major health effects expected under proposed use concentrations/conditions" does not satisfy the needs of hazard identification. Use concentrations/conditions are not factored into judgments of the hazard of other compounds like PCE or PS.

Response: The commenter is correct. Exhibit 4-14 has been extensively revised, and this language has been eliminated.

Comment #4-326: p. 4-38, Conclusions, line 2: Since when are MOE's below 100 indicative of potential risk for neurotoxicity? What evidence is this interference based upon?

Response: The particular line cited has been changed. Often the uncertainty factors used for developing an RfD/RfC are used in comparisons (see Barnes & Dourson, Regulatory Toxicology and Pharmacology, 1988). As mentioned in responses to other comments, the revised chapter uses Hazard Quotients (where larger values are associated with greater hazard potential) to give the reader a handle on the potential differences in toxicity other than cancer for different exposures. These are based on the RfD/RfC itself, and are compared to unity.

Comment #4-327: p. 4-38: Exhibit 4-13 should include sample sizes.

Response: Agree; however, this table has been eliminated in the revised chapter. Whenever possible tables include sample sizes.

Comment #4-328: p. 4-39, General Population Risks: As with the section on PCE, this section seems to downplay the risks for children. Petroleum solvents are known neurotoxins, and there is good reason to believe that children would be more susceptible. The lack of data on Petroleum Solvents is a major concern and should not be ignored simply because the usual risk assessment extrapolations cannot be performed.

Response: The risk chapter has been revised to include sections dealing specifically with sensitive subpopulations, such as children. The hazard data used were for hydrocarbon solvents that are currently used in drycleaning.

Comment #4-329: Section 4.3.5, p. 4-39, fifth paragraph: Understated.

Response: Agreed; the language has been changed in the revised risk chapter.

Comment #4-330: p. 4-40, second paragraph: The release data for PS listed here should be placed back in section 3.1.2 where no single value was presented. However, this number is questionable. On page 1-30, paragraph 2 it was reported that the industry consumed 109 million gal of PS in 1991. This suggests that the majority of all PS purchased is released to the environment. Earlier references suggested ½ of all perc is released. What would account for this difference?

Response: This section has been eliminated in the revised risk chapter.

Comment #4-331: p. 4-40, Overall Summary, line 5: Be more specific than *neurotoxicity*.

Response: This section has been eliminated. The risk chapter has been revised, so that discussion of the specific hazard end points are found in Chapter 3 or Appendix C.

Comment #4-332: p. 4-40, Overall Summary, first paragraph, line 3: Replace *Both have not* with *Neither has*.

Response: This section has been eliminated in the revised risk chapter.

Comment #4-333: p. 4-40, Overall Summary, second paragraph, line 1: Strike *due*.

Response: This section has been eliminated in the revised risk chapter.

Comment #4-334: p. 4-40, sixth paragraph, line 1: remove (due) ...risks (due) to...

Response: This section has been eliminated in the revised risk chapter.

Comment #4-335: p. 4-40: Risk to aquatic organisms. What about accidental releases of petroleum solvents to surface water?

Response: Risks due to accidental exposures are beyond the scope of the CTSA risk assessment.

Comment #4-336: p. 4-40, second paragraph: A weakness of hazard information used in isolation is that the likelihood of the hazard occurring is ignored. In this case, the fact that PS are flammable is relevant only at concentrations at which flammability can be manifest. At ppb concentrations in the environment, flammability is unlikely to be a relevant hazard.

Response: This section has been eliminated in the revised risk chapter.

Comment #4-337: p. 4-40, second paragraph: None of the Petroleum Solvents, old, new, are Flammable. Flammable means (OSHA Definition) the individual flash point is below 100°F. Petroleum Drycleaning Solvents are various levels of Combustible.

Response: The paragraph in question has been eliminated in the revised risk chapter. The commenter is correct. EPA had tried to correct this definitional error before the final text had gone to print. EPA has used (and has indicated so) the definition for flammability of the National Fire Protection Association. By this definition, the hydrocarbons are given a ranking of "2", indicating that they must be moderately heated before ignition.

Comment #4-338: p. 4-41, third paragraph, line 1-2: Strike *neurotoxicity* and the parentheses around *dizziness*.

Response: This section has been eliminated in the revised risk chapter.

Comment #4-339: p. 4-41, third paragraph, line 5: Replace *neurotoxicity* with *dizziness*.

Response: This section has been eliminated in the revised risk chapter.

Comment #4-340: p. 4-41, Section 4.5: Are MSDS's a potential source of at least some hazard information?

Response: Yes, MSDS's are generally a source of some hazard information; however, they were not provided for the example detergents described in the CTSA.

Comment #4-341: p. 4-41, line 2: Are the potential contributions to smog and global warming discussed in more detail elsewhere? If so, direct the reader to that section of the document. If not, add additional explanation here.

Response: There is a brief discussion of environmental fate with some references in the revised Appendix A.

Comment #4-342: p. 4-41: Include Controlled PS with PS category

Response: Controlled PS is no longer considered a separate category in the revised CTSA.

Comment #4-343: p. 4-41: The CTSA indicates that the primary concern over the use of petroleum solvents is their flammability. As I stated earlier, conventional petroleum solvents have aromatic fractions which include benzene. Benzene is an established human carcinogen. The new high flash point petroleum solvent, DF-2000, an Exxon product, has never been tested for chronic toxicity and might very well be an animal carcinogen. There is simply now way to know.

Exhibit 4-14 is called out under machine wetcleaning. It is not mentioned under petroleum solvent but it contains information on petroleum solvents. Throughout the text, the exhibits need to be cleaned up. Exhibits should be referred to before they are presented.

A statement is made that "all four formulations consist of 3 to 13 cleaning chemical components in aqueous solution." This information is never presented or discussed anywhere in the text. It is not clear where it came from. Again, MSDSs for the wetcleaning formulations should be presented and discussed early on in the document.

Response: As indicated in the CTSA, a variety of hydrocarbon solvents has been used as drycleaning agents. Toxicity data are presented for Stoddard solvent which is assumed to qualitatively represent the hazard of the other solvents. This was all that was possible within the scope of the CTSA screening level assessment. Since the hydrocarbon solvents are unique mixtures, it is recognized that they may differ somewhat in toxicity from each other, and it is also recognized that many mixtures have not been tested.

Exhibit 4-14 has been completely revised, and it is hoped this version will be clearer to the reader. The particular language referred to on page 4-41 has been revised. The composition of two example detergent cleaning formulations is presented in Chapter 2 of the revised CTSA.

Comment #4-344: p. 4-42, Exhibit 4-14: In the first row, replace *neurotoxicity* with the specific endpoint, probably *dizziness*.

Response: This section has been eliminated in the revised risk chapter.

Comment #4-345: Section 4.5.2, third paragraph: Assumed earlier that all chemical residues were removed...garment baggers would have no exposure, then.

Response: The revised risk chapter does not contain this language.

Comment #4-346: p. 4-47, first full paragraph, lines 5-6: Strike *Toxicity comparison values* (i.e., and end paren after *LOAEL's*.

Response: This section has been eliminated in the revised risk chapter.

Comment #4-347: p. 4-48, Uncertainties, line 2: "Uncertainty as to *the extent of* actual..."

Response: This paragraph has been eliminated in the revised risk chapter.

Comment #4-348: p. 4-48, sixth paragraph: Why aren't risks qualitatively assessed here?

Response: The revised risk chapter illustrates qualitative comparisons in Table 5-9.

Comment #4-349: p. 4-48, Uncertainties, line 3: "Uncertainty...*is*...a major problem." Is *problem* the right term?

Response: This paragraph has been eliminated in the revised risk chapter.

Comment #4-350: p. 4-49, Section 4.5.5: The PCE section noted POTWs and treatment in calculating risk, why is that not considered here?

Response: Treatment has been considered in the revised risk chapter.

Comment #4-351: p. 4-49, top: The risk of eye and skin irritation is quite low.

Response: The revised risk chapter indicates low concern for irritation.

Comment #4-352: p. 4-49, line 2: Strike *There is a high level of uncertainty as to* and replace with *There is virtually no data regarding...*

Response: This paragraph has been eliminated in the revised risk chapter.

Comment #4-353: Section 4.6: Should a non-existent technology be included, only to state that there are no data? Could be addressed (and then dismissed) in Chapter 1.

Response: The CTSA has been extensively revised, and this section has been eliminated from the revised risk chapter. This technology is now discussed in Chapter 11, devoted to emerging technologies. It was judged that there was not enough exposure and/or toxicity information for these emerging technologies to do risk assessments; but it was felt that readers should be aware of these new processes.

Comment #4-354: p. 4-50, Microwave Drying, first paragraph: Comment on the lack of relevance of the ocular effects of high-intensity exposure to the issue at hand. If you don't, the reader will be unnecessarily and unjustifiably alarmed.

Response: Microwave drying is not considered a separate cleaning technology in the revised CTSA, and there is no discussion of it.

Comment #4-355: p. 4-50, first paragraph: The lack of data on carbon dioxide in the dry-cleaning situation does not tell an adequate story on risks associated with CO_2. This is a technology developed to create a solvent-like process that specifically avoids environmental contamination, worker hazard, disposal costs, etc. There is extensive data on CO_2 from food processing applications (coffee decaffination, fragrance extraction, soda carbonation, etc.), precision parts cleaning, and dozens of industrial applications. CO_2 has no cancer causing properties, is not toxic in normal working concentrations, and poses little or no risk. Data from other applications are as applicable as the Cosmetics data is for the wetcleaning processes. The same is true for ultrasonics applications for cleaning applications other than clothing.

Response: The CTSA has been extensively revised, and this section has been eliminated from the revised risk chapter. This technology is now discussed in Chapter 11, devoted to emerging technologies. It was judged that there was not enough exposure and/or toxicity information for these emerging technologies to do risk assessments; but it was felt that readers should be aware of these new processes.

Chapter 5

Comment #5-1: 4. Chapter 5 is full of very interesting primary data. The only comment I'd make here is that it is difficult to gather an overall sense of what it all means from the many tables. I think maybe a little more analysis of the data - say, is the rate of X% size change for non-solvent methods statistically different from solvent-based ones? - roughly speaking might help. Or maybe just try drawing more and broader conclusions. Perhaps the problem is that the tables are full of entries and it takes the reader a long time to figure out what the entries mean. Might consider some more graphical ways to present these results?

This document pertains to chapter 5 in particular. I did not have this difficulty in the rest of the document.

Response: The intent of the performance summary chapter is to report the results of several performance studies. EPA has not analyzed the results in the studies or attempted to draw broad conclusions. EPA has modified the chapter by moving the summary section into the front of the text. The format of the chapter has remained the same; that is, only that pertain to specific studies conclusions are presented.

Comment #5-2: Q-1: The stated purpose of the chapter is to convey to the reader that for fabricare, "generalized scenarios" are not possible and that "data on performance are likely to represent case studies." The data collected in these studies support the position of experts that both aqueous and nonaqueous fabricare cleaning technologies are required to clean the wide range of today's textiles in the market place. It will indeed be difficult to come up with black and white answers about which new fabricare technology will be a complete alternative to the PCE technology. Further textile research and site demonstration studies with alternative technologies are required to generate useful and reliable guidelines about textile care to all members in the textile chain.

Response: The Agency is aware that data gaps exist with textile research and demonstration studies to date. EPA has attempted to use the available information base regarding textile research to provide the most comprehensive technology performance presentation possible.

Comment #5-3: Q-2: The text is understandable, but the discussion on performance evaluation of clothes cleaning is weak. It troubles me when so much credit is given to a non-technical group of graduate students who have written a term paper on a project they carried out for credit (Blackler et al.). The authors credibility, and this document's credibility, is shot when they are quoted as the source that AATCC "has developed historical criteria for "trouble shooting" drycleaning problems. This is simply incorrect. More importantly, they are given credit for "plagiarizing" my redefinition of fabricare at the Hamilton, Ontario conference, at the Vision 2000 conference and in several of my publications in the trade press. My redefinition states these basic generic requirements for all alternative clothes cleaning technologies and broke the paradigm that all drycleaning has to be done in PCE.

Clarity of the chapter could be enhanced by reorganizing the performance assessment into objective, subjective and survey responses to cleaned garments. Textile performance test methods and the methodologies used to assess shrinkage, colorfastness and appearance as well as cleaning

performance need to be given. Textile and Cleaning experts will ask for this information before they accept the reported results.

Response: The text authored by Blackler et al. is publication of the National Pollution Prevention Center for Higher Education (NPPC) based at the University of Michigan School of Natural Resources and Environment. This document was peer reviewed prior to publication by experts in fabricare industry, EPA, state regulators, and academicians. EPA has modified the citation to reflect the actual authors of the statements.

EPA has kept the organization of the chapter in the same format, upon further review of this and other suggestions by commenters. In general, studies followed standardized testing and performance evaluation standards, as noted for each test. This information is provided in each individual study, but will not be include in this chapter's summaries.

Comment #5-4: Q-3: Tables presented enhance the understanding. However, some tables could be put into the appendix (i.e., Exhibits 5-7a to 5-8b or 5-19) with only a verbal discussion given in the body of the text. The text and the tables on costs and consumption don't belong into this section. They should be moved into chapter 6.

Response: EPA has reviewed this suggestion, but will keep the tables in the text of the chapter, rather than moving them to an appendix. Information on costs and consumption remain in the performance data chapter because they are specific to the performance study described in the chapter.

Comment #5-5: Q-4: There are technical inaccuracies which need to be edited, overall there are no inconsistencies between text and tables.

Response: EPA has reviewed the document for technical inaccuracies and made corrections where they were identified.

Comment #5-6: Q-5: Some trade association in the USA (IFI, NCA-I) have published bulletins on this subject matter. The environmental groups may label these industry sources as biased. And the industry may look at the information coming from environmental sources as biased. Independent and unbiased institutions must be involved in the objective search for viable alternatives, and this is happening now. But in the final analysis, it is the professional cleaner who must be convinced to invest in an alternative technology.

DfE should make a concerted effort to analyze the many comprehensive reports on alternative cleaning technologies published by Hohenstein and Krefeld in Germany. Other European countries, such as England and the Netherlands are also engaged in alternative technology research. The movement towards alternatives started in Europe and has been successfully implemented in many commercial cleaning plants. We see predominantly European firms conquering the US market.

Response: EPA is funding several textile performance studies by academic organizations in an effort to promote this type of unbiased research in the United States. These studies include traditional PCE and PS (hydrocarbon) technologies, as well as the innovative methods being developed in the U.S. and Europe. The Agency has decided not to use the numerous European

studies on alternative clothes cleaning technology due to the recognized cultural differences (e.g., types of fabrics used in clothing, levels of soiling, number of wearings per cleaning) between the populations.

EPA agrees that the decision to invest in an alternative technology remains with the professional cleaner. To provide some general understanding of the results of performance demonstrations and studies, the CTSA covers the most relevant work done in the United States and Canada. EPA is funding several textile performance studies by academic organizations in an effort to promote this type of unbiased research in the United States. These studies include traditional PCE and PS (hydrocarbon) technologies, as well as the innovative methods being developed in the U.S. and Europe. The Agency has decided not to use the numerous European studies on alternative clothes cleaning technology due to the recognized cultural differences (e.g., types of fabrics used in clothing, levels of soiling acceptability, number of wearings per cleaning) between the populations.

Comment #5-7: Q-6: There are many research papers and books on textile and cleaning performance available. It appears that the experimental studies to date did not take full advantage of these information.

The most applicable "reference bible" is Technical Manual, published annually by the American Association of Textile Chemists and Colorists (AATCC). It contains consensus test procedures for textiles on their biological properties, colorfastness, dyeing properties, evaluation procedures, identification and analysis and physical properties. There are also many cross references to procedures and standards of the American Society for Testing and Materials (ASTM) and to the International Standards Organization (ISO) which develops international standards. Many experts in the textile chain are familiar with these publications and use them for the performance evaluations of their textile products.

Other valuable resources for this audience are the Proceedings of the International Symposium of the European Wet Cleaning Committee (EWCC), held on June 17, 1996 at the Hohenstein Institutes in Boennigheim, Germany. It summarizes the wetcleaning experiences in nine countries, including the USA and Canada.

Response: The goal of this chapter is to summarize the clothes cleaning performance tests completed to date in the U.S. and Canada. The Agency decided not to use the numerous European studies on alternative clothes cleaning technology due to the recognized cultural differences (e.g., types of fabrics used in clothing, levels of soiling acceptability, number of wearings per cleaning) between the populations.

Comment #5-8: Chapter 5 begins the sections of the report which are of interest to the industry. These are the chapters that can have greatest impact for control of emissions and exposures.

Response: EPA is aware of the importance of the information contained in this chapter. The Agency has refined the organization and content of the chapter in a manner that will maximizes its effectiveness in the document.

Comment #5-9: It is unclear why technical and economic performance are mixed in one chapter. Shouldn't economic performance of different demonstration projects be included in chapter 6.

Also, is the CTSA going to include information from the UCLA report which is soon to come out? This chapter should cover just cleaning performance and exclude both environmental and

Response: EPA has not included economic information from the performance studies directly into the cost estimates because the data reflects costs from varied machine types and operating conditions. The cost chapter attempts to standardize costs for a model facility across process types. The performance demonstration study costs were considered, however, when evaluating the reasonableness of the costs estimated for the cost chapter.

Comment #5-10: Many important aspects of wetcleaning technologies are excluded in this document. First, there is the control that the workers have over the cleaning process. They are no longer just placing garments in a vat of solvent. They have to make conscious cleaning decisions, as in any type of handicraft. Also, wetcleaning systems are extremely flexible. Utopia Cleaners in Arlington, MA has 4 Daiwoo machines to clean several types of clothes under different conditions at once.

Response: EPA reports the results of studies as they were conducted and described. The various aspects identified by the commenter that contribute to variations in results are part of the reason that EPA makes broad conclusions throughout the document and does not attempt to prescribe process selections for cleaners. EPA has reviewed this comment, but has made no modifications with regard to the commenter's suggestions.

Comment #5-11: It should be noted that some garments that typically require drycleaning can be wetcleaned under particular conditions. For example, wool needs agitation, heat, an water to shrink.

Response: EPA has reviewed this comment, but has made no specific modifications with regard to the commenter's suggestion. The CTSA does indicate that information suggests that most garments can be cleaned with wetcleaning processes.

Comment #5-12: The already comparable performance in many aspects of wet and drycleaning provides strong indication of the viability of this alternative technology. If EPA starts with the idea that wetcleaning is better from a health and environment standpoint, then improvements in wetcleaning technology will occur over time as individual drycleaners, producers of machines, and clothing manufacturers gain knowledge and experience.

Response: The intent of this chapter is not to make comparative assumptions about the health and environment impact of clothes cleaning technologies. The information in the CTSA is developed to form a basis from which cleaners can make their own determinations about the technology to choose. The Agency hopes that technologies that offer improvements in performance and reduce health and environmental impacts over current technologies will continue to develop. EPA has reviewed this comment, but made no modifications to the text of the chapter with regard to these suggestions.

Comment #5-13: Formatting indicating the different studies is confusing at times. Also, tables should be placed within the section in which they are referenced.]

Response: EPA has made modifications to the organization of chapter to limit confusion to the reader.

Comment #5-14: Conclusions about how to improve the performance of wetcleaning operations would be very helpful (as in the section on ways to reduce PCE exposure - Chapter 7).

Response: This chapter is not the proper section of the CTSA for conclusions on how to improve the performance of wetcleaning operations. These, in fact, are not part of the CTSA. Some in format on approach to reducing environmental and human exposure and machine wetcleaning processes in Chapter 9. EPA has not modified the chapter with regard to this comment.

Comment #5-15: Why is an analysis of PCE performance alone omitted in this chapter (though it was compared to some wetcleaning processes). Is PCE performance considered without problems? In the few comparisons provided in many aspects wetcleaning performed similarly to drycleaning and was cheaper.

Response: EPA recognizes that PCE performance is not without some problems, however, the Agency is under the impression that PCE cleaning is considered an industry "standard." Therefore, the Agency thought it was most appropriate to present comparative studies that describe the performance of PCE clothes cleaning in conjunction with various alternative technologies. In addition, there were no PCE performance studies identified by EPA.

It is not the intent of the chapter or the CTSA to recommend improvements to technologies. EPA has not modified the chapter with regard to this part of the comment.

Comment #5-16: p. 5-1, third paragraph: The performance data analysis indicates that no data were available for performance for liquid CO_2 systems. I have included a package of several references on the performance of CO_2 cleaning systems submitted as part of a Los Alamos R&D 100 award. Note that there is some proprietary data that should not be cited but also some cleaning performance figured. This data was derived using IFI standards in many cases and indicates a cleaning efficiency equivalent to PCE. In the interest of presenting a fair assessment of alternatives this data should be reviewed by the authors and the performance section appended. The references also contain relevant information on safety, worker hazards, energy consumption that is relevant to earlier chapters. There is a compromise to be achieved here. On the one hand it is important that the EPA get their results into the hands of the stakeholders in a timely manner. On the other hand, the response of dry-cleaners to the new liquid CO_2 machines at trade shows has been a stampede. The current CTSA draft could well lead a dry-cleaner considering purchasing a new machine to conclude that this new technology is too far into the future to be a viable alternative. A little extra time spent updating this draft could make a large environmental impact. University studies of materials compatibility in liquid CO_2 are also available and included. While these studies were generally conducted for the system developers the contracting Labs are independent technical organizations and the collective judgment is qualitatively the same across competing systems.

Some additional performance information of the liquid CO_2 machines is as follows. In water, PCE, and PS systems the drying cycle is about 140°F which causes stain setting, wrinkling, and shrinkage which increases the labor required to finish the garments. In a CO_2 system the liquid CO_2

is converted to a gas and evaporated at 54°F to 58°F. This lower temperature reduces stain setting, shrinkage and wrinkling. These tests further indicate that materials such as fur, leather, and decorative items such as sequins are cleaned without damage.

Response: EPA is appreciative of the information which this reviewer has provided for the Agency's consideration in the CTSA. EPA did not intend to leave out specific technologies, or mislead the public about the availability of specific technologies. Such information may not have necessarily been available to the Agency personnel and/or contractors during the development of this draft of the CTSA. The Agency has reviewed and included some of this information in a section of Chapter 11.

Comment #5-17: p. 5-1, fourth paragraph: The point about variations in technology and knowledge causing a range of results is critical and should be bolded. It should also be noted that there is a learning curve with any technology, where with time results will improve substantially. This is not highlighted here and was likely an issue with PCE at its beginning.

Response: EPA has modified the text of the chapter to reflect these suggestions.

Comment #5-18: p. 5-2: ASTM is the American Society for Testing and Materials (not Measurements).

Response: EPA has modified the chapter to properly reflect the name of ASTM.

Comment #5-19: p. 5-3, fifth paragraph: It is clear that wetcleaning requires more skill and experience because of the increased control over the cleaning process. So from a work organization/psychosocial conditions perspective, wetcleaning is superior.

Response: EPA has reviewed this comment and finds no basis for the commenter's conclusion. No modifications were made with regard to the reviewers suggestions.

Comment #5-20: Section, 5.2: Too much detail is provided on primary studies. Imbalanced with respect to other areas of review.

Response: The Agency wrote this chapter with the intention of striking a balance between presenting concise, yet comprehensive performance data. EPA has reviewed this suggestion, but not modified the chapter to reflect the reviewers comments.

Comment #5-21: p. 5-5, second paragraph: If 0.08% of garments were damaged (254/31,734) was there any consistent pattern to the damage or particular fiber type? This would be very useful.

Response: EPA has reviewed the study with regard to the damaged garments, but has determined that modifications of the text, based on the reviewers comment, are not feasible for this section of the chapter.

Comment #5-22: p. 5-5: It is important to note that claims were paid on very few wetcleaned garments, consistent with the dryclean industry. This should be bolded.

Response: It is not the intent of this chapter to provide analysis of the summarized studies. EPA has reviewed the study and finds that the development and presentation of this information is beyond the scope of this document.

Comment #5-23: p. 5-5, second paragraph: (the shop accepted virtually all garments). I read a report that said they did not accept garments they knew they could not clean.

Response: EPA has reviewed the study with regard to the discussion about accepted garments, but has determined that modifications of the text, based on the reviewers comment, are not feasible for this section of the chapter.

Comment #5-24: p. 5-9: Shrinkage was and is a major factor in wetcleaning, why doesn't the writer say that?

Response: EPA wrote this chapter on the basis of the text in these studies. The Agency does not deem it appropriate to draw separate conclusions based on the information presented by these studies. A statement to this effect is presented in the introduction to the chapter.

Comment #5-25: p. 5-10, last paragraph: Is this limitation of small sample size applicable to the side by side evaluation as well?

Response: EPA has reviewed the study with regard to the sample size of the side by side evaluation, but was unable to determine the applicability of the limitation to the side by side evaluation.

Comment #5-26: p. 5-10, Exhibit 5-6: Are these results comparable to drycleaning?

Response: The data presented in Exhibit 5-6 is drawn directly from the CNT study. EPA notes that this particular exhibit draws a comparison between a sample of 52 sets of clothing (3 identical pieces per set). The results include a comparison of clothing drycleaned and machine wetcleaned, as compared to the uncleaned *control* piece with each set.

EPA has reviewed the study with regard to the sample size of the side by side evaluation.

Comment #5-27: p. 5-13: The paragraph *Additional Comments* summarizes the findings of the EPA-sponsored study, Alternative Clothes Cleaning Demonstration Shop, performed by the Center for Neighborhood Technology (CNT). In this study, CNT concluded the that "wet cleaning, although not a complete replacement for drycleaning operations, is a viable substitute for a significant percentage of clothing labeled 'dry clean only.'" This conclusion is supported by the results of the University of Guelph study [Environment Canada 1995] reported in Exhibits 5-15 and 5-16. This study found significantly higher shrinkage in wool, rayon, and silk garments that were

wetcleaned rather than drycleaned. These results support the position that wetcleaning is a substitute for only a percentage of garments currently being drycleaned and not a complete replacement for drycleaning. This conclusion should be emphasized in the CTSA.

Response: EPA is merely reporting the conclusions of the various studies mentioned in this chapter. The Agency specifically did not draw its own conclusions about the performance of the various clothes cleaning technologies. This is stated in the introduction to the chapter.

Comment #5-28: p. 5-13, top: What do these bullet points have to do with cleaning performance.

Response: EPA has removed this information from the chapter.

Comment #5-29: p. 5-13: The water-based cleaning formulation used at the Greener cleaner in the CNT study contained ethylene glycol monobutyl ether which is a listed HAP and is very toxic. It is absorbed through the skin which could be a problem for the wetcleaning application.

Response: EPA has removed this information from the chapter.

Comment #5-30: p. 5-13, first paragraph: Why are financial data presented here. Shouldn't they be considered in the cost section.

Response: EPA has removed this information from the chapter.

Comment #5-31: p. 5-13, *Financial data:* What were the reasons for losing $44,000? Are there any estimates for the 2nd year?

Response: EPA has removed financial information from the chapter because it was not appropriate. While not used specifically in the cost chapter, financial data in the studies were considered in the development of the cost sections of the CTSA. The reasons for the $44,000 loss were not reported.

Comment #5-32: p. 5-13, last bullet: ...tested <u>except</u> for...

Response: EPA has removed this information from the chapter.

Comment #5-33: p. 5-14: Exhibit 5-9 should be in the cost benefit section. It is not cleaning performance data and is thus confusing. Same comment applies to Exhibit 5-10.

Response: EPA has removed this information from the chapter.

Comment #5-34: p. 5-19, bottom: "first six (not sixth) months..." The fact that only 14 claims were paid is outstanding and should be noted..

Response: The Agency has merely reported the information contained in the study, and did not make value judgements about the results. EPA did not modify the text of the chapter based on this comment.

Comment #5-35: p. 5-19: On Exhibit 5-14, why isn't drycleaning included?

Response: Drycleaning is included in Surveys II and III, as is noted at the bottom of the Exhibit 5-14.

Comment #5-36: p. 5-23, last paragraph: The following was used as justification for the data on Exhibit 5-22 showing water usage as being higher for Drycleaning versus Machine Wet Cleaning. "Recirculating water cooling systems are not necessarily feasible for use in colder climates, such as Canada, because the water may freeze in these systems and their cooling towers." This statement is inaccurate regarding the towers. In addition, other types of non-contact cooling systems are available on the market. Towers work better in colder climates and have automatic systems for preventing freezing. Showing this type of comparison, knowing full well that no business would run the water continuously and that alternatives exist, is inaccurate and should be changed to show the actual water usage of non-contact cooling water on Drycleaning machines.

Response: EPA has removed this information from the text of the chapter.

Comment #5-37: p. 5-23, bottom: Why is it not noted elsewhere that drycleaning uses 22% more water than wetcleaning per piece of clothing. This is critical for the cost comparison because the cost of water is not considered for drycleaning.

Response: EPA has removed this information from the text of the chapter.

Comment #5-38: Exhibits 5-21-22: For utility uses and costs and water consumption and costs the footnotes should include a precise indication of the time period. Is this for three months, the days of testing annual?

Response: EPA has removed this information from the text of the chapter.

Comment #5-39: p. 5-29, second paragraph: Jan. 31, 199<u>7</u>

Response: EPA has modified the text of the chapter to reflect the proper date.

Comment #5-40: p. 5-35: The discussion about ultrasound is not very accurate. It states that ultrasound technology reduces the need for mechanical agitation. Ultrasonics is a mechanical agitation method.

Response: EPA has revised its discussion of the ultrasonic technology to more accurately describe the process.

Comment #5-41: p. 5-36, 5.3: A summary of the major findings would be very helpful in giving an overall perspective of the case studies. Suggestions:

- Wetcleaning is effective at dissolving polar soils (i.e., salts, sugars...)
- Wetcleaning is effective at cleaning hydrophobic fibers, high twist yarns...
- Pressing is more difficult and takes 5-50%
- Capital and start-up costs are comparable to drycleaning
- Utilities are comparable to drycleaning
- Customer satisfaction is high (95%) and most will return
- Most of the customer complaints are the result of shrinkage and color changes
- Skill and experience of operators will have a decisive influence on success
- Wetcleaning can be used on many garments that specify drycleaning
- Stain and spot removal does not vary significantly
- Wetcleaning has lowest level of soil redeposition
- Labor costs between dry and wetcleaning show little difference

Response: EPA did not intend to make specific, industry-wide observations, based on the results of the studies summarized in this chapter. The Agency has included a brief summary of the studies presented in the chapter, but has not drawn separate conclusions based on this information.

Comment #5-42: p. 5-36, second paragraph: Summary - It appears that half of the studies included in Chapter 5 are not yet finished. As with the CO_2 results, the overall impact of this document may be significantly advanced by delaying publication in order to add the new results. Also, the chapter introduction indicates that it will recommend possible research directions based on the results. This is not done. A quick paragraph or two should be included to indicate where the authors believe the greatest gaps in the data are.

Response: EPA considers these observations valid, but has not rewritten the chapter to include a section on research needs and data gaps. Additional information regarding CO_2 technology was included in the chapter.

Comment #5-43: p. 5-36: The CTSA states that there is a continuing debate on the percentage of clothing that can be safely and effectively cleaned with wetcleaning techniques. In principle, probably nearly all garments can be wetcleaned. The issue is whether they can be economically wetcleaned. A cleaner must be able to clean about 1,500 pounds of clothes a week to have a viable business.

It is not necessarily true that the customer is the final arbiter for judging the cleaning and cost-effectiveness of wetcleaning. There is so much competition in the cleaning industry that cleaners cannot raise their prices above a certain level. If wetcleaning is not cost-effective given that level, then cleaners (not customers) will decide whether it is viable.

Response: EPA has reviewed these comments and made some modifications to the text to reflect the information presented by the commenter.

Comment #5-44: p.5-36, Summary of findings: This section would be strengthened with more quantitative performance data from the various studies. Also, EPA may want to consider its own

comparative study. The learning curve aspect of new technologies should be bolded here. "Most researchers agree that most or the majority (not many) dryclean only garments can be effectively wetcleaned." The fact is that wetcleaning is a acceptable substitute for most consumer garments. To state that it may be an acceptable substitute for some garments is to deny the results of the various projects and the fact that there are some 40 wetcleaning facilities in operation.

Response: EPA has included a brief discussion about learning curves in the text. The chapter summary specifically does not include quantitative performance data, given the stated design of the chapter.

Comment #5-45: p. 5-36: In the last paragraph, it should be noted that wetcleaning is feasible now as the existence of numerous financially sound wetcleaning establishments attests. This would indicate feasibility for widespread dissemination of these technologies.

Response: EPA has reviewed these observations, but has not modified the chapter to include this information directly.

Comment #5-46: p. 5-36, fourth paragraph: This claim is not true based on p. 5-10. This claim sounds like the authors are pre-judging their conclusions based on what they want the answer to be.

Response: The observation made in paragraph four on page 5-36 reflects customer claims only. Page 5-10 references results that were a part of a side-by-side garment test which was performed by trained evaluators, rather than actual customers. EPA has reviewed this comment, but has not modified the text based on the reviewer's suggestions.

Chapter 6

Comment #6-1: No comment.

Response: No response required.

Comment #6-2: I hate to say so, but I have a substantial amount to say about this. It is not so much that I disagree with what you've done, but rather that I think way too much has been sacrificed to achieve the appearance of specificity.

Response: The commenter did not specifically note what had been sacrificed. It is likely that the issues are addressed in other comments so no further action was taken.

Comment #6-3: First, the costs are estimated as, essentially, out-of-pocket costs. But the purely private perspective is more complex due to the tax law. Normally, when people do the private perspective, they depreciate equipment and all. Very messy. You are probably too far down this road already to change anything, but I would say that a much more robust argument for doing out-of-pocket and then filling in 5% sales taxes is in order. Otherwise, I would probably have left out the 5% sales tax adjustment to avoid arousing suspicions.

Response: Drycleaners are likely to depreciate their equipment. Sales tax was excluded from the calculations in this chapter because of its variability across states and the implication that the numbers are precise enough to warrant its inclusion.

Comment #6-4: Your stated objective is to provide information to the fabricare community on the costs and risks associated with alternative cleaning options. Yet, what you really present is much more on the order of an RIA - where it is normally necessary to arrive at "point" estimates, or to make other assumptions that drive toward a well-defined "answer".

But to inform the many individuals in quite diverse settings that are your actual target audience, flexibility and accommodating differences is the key. It seems to me that you should be allowing the users/readers to input their own values for many of the parameters, e.g., the borrowing rate, throughput, labor costs, etc. You will get considerable debate, I think, on the 7% real borrowing rate. These are small businesses, for the most part.

Thus, my general comment is that instead of presenting all of this information as "best estimates for the typical...", why not provide a spreadsheet or Web-based exercise that these people can tailor to their own circumstances? This goes for the risk side as well.

I understand that this is more work, but the document as it stands is designed for RIA readers, not the informed public seeking guidance on technology choices. It introduces homogeneity rather than facilitates analysis of differences.

Response: The purpose of the CTSA is to provide general information to illustrate the trade-offs related to making technology choices, particularly those that are environmental and health-related. The commenter's suggestions are outside of the scope of the CTSA. However, the DfE program uses the CTSA to develop information products that allow decision-making by individuals.

Comment #6-5: Doing cost estimates for 13 PCE scenarios is repetitive and tiring. The same information is repeated in some instances 13 time. This should be omitted or relegated to an appendix, as these are not cleaner technology substitutes. This information could be presented in table form producing a much more readable format.

Response: The EPA has reduced the number of PCE technology configurations to eight. However, the level of detail provided for each of the scenarios will be maintained in order to allow the reader to evaluate how the numbers were derived.

EPA believes that it has provided a reasonable illustrative of the costs of technologies relative to each other. It is clear that differences in facilities will contribute to different absolute results. For this reason, assumptions are well specified allowing readers to consider what effect changes in these assumptions might have. The document is designed to point out relevant considerations when making decisions. The document, however, is not intended to provide specific answers for individual cleaners and interactive spreadsheets for such decision-making are not appropriate.

Comment #6-6: Under the Massachusetts Toxics Use Reduction Act, companies are required to conduct a cost of toxics assessment, which is essentially a full costing of the toxic chemical, attributable to the process. The state provides guidance on the types of costs that should be included. A list of these costs, which should be included in this analysis are included as an appendix to this letter.

Response: An exhibit was added to the text to reflect the costs mentioned in the Massachusetts TURA toxics assessment. However, it was not feasible, given the current format, to incorporate all of these costs into this assessment into the revised version of this chapter.

Comment #6-7: The costs of wetcleaning are overestimated compared to drycleaning. First, full energy costs for wetcleaning are included while only control technology costs for drycleaning. Water costs are included for wetcleaning and not for drycleaning which the previous chapter notes uses 22% more water. These omissions are critical and do not even include the omission of externalities (e.g., environmental damage, health and safety impacts, subsidies to PCE producers, etc.) in this analysis. Also capital maintenance costs for PCE technologies are 1.64% per year while they are estimated as 2% with a major overhaul every 5 years. Is there any reason to believe that the maintenance costs for the technologies are different. It is more likely that maintenance for PCE is higher given all of the add on control technologies. Assumptions of this sort need to be explicit.

Response: The assumptions made in calculating costs for each of the technologies was explicit or the commenter could not have made the comparisons above. The costs for PCE and PS energy use were incorporated into the chapter for the dry to dry technologies. This information was not available for the older transfer technologies. Maintenance costs were recalculated using existing information in the CTSA, data from the Neighborhood Cleaners Association International, International Fabricare Association, and UCLA/Occidental PPERC.

Comment #6-8: In Chapter 6, although the summary cost/# comparison can be obtained from the tables, it would be nice if the chapter ended in a paragraph summarizing all of this for easy

comparison. This is given in Chapter 8 and could easily be reworked for this chapter, since the chapters appear to be stand-alone documents.

Response: This chapter has been modified to provide some conclusions and summarization, but the existing format was not changed.

Comment #6-9: The introduction to the chapter provides a clear overview of what is to come. However, more explicit mention of how costs come down as technology is used to a greater extent should be made. Ashford has noted that cost benefit analyses of technologies often overestimate costs as technological innovation and new better understanding of technologies leads to reductions in cost over time. However, this chapter will be difficult to understand by anyone who has not been trained in economics. More simplified conclusions are needed, as well as some description of the comparison tables contained within. Also, more explicit description of assumptions, uncertainties, and omissions is needed here.

[Ashford, N. and C. Caldart. 1991. Technology, Law, and the Working Environment. New York: Van Nostrand Reinhold.]

Response: The commenter would like both a more sophisticated analysis that includes information on how costs decrease when technology is used to a greater extent but also states that this chapter will be difficult to understand for anyone who has not been trained in economics. The Agency has maintained the technical tone of the chapter as more accessible documents will be derived from this report. The text of the chapter was modified to include information found in the reference provided by the commenter.

Comment #6-10: Conclusions: There aren't any. Most of the previous chapters make some comparison and conclusion concerning the compared technologies but data is only presented in Chapter 6. Conclusions concerning comparative costs are appropriate. Similar to my earlier comments, the summary tables of Chapter 6 should be put into the executive summary.

Finally, one complaint frequently heard from dry-cleaners is the cost of compliance (paperwork and other activities associated with regulatory compliance are not discussed). Are these costs assumed to be included in labor rates? This may be the case but if an alternative technology offers significant relief in this area vis-à-vis a different technology the costs to an operator could be significant.

Response: As mentioned in response to Comment 6-8, the Agency has attempted include some conclusions and summarization in this chapter. However, the original format of the chapter is unmodified as per the Agency's discretion. The cost of paperwork is included in the regulatory costs for the PCE options, based on estimates provided by the NCAI.

Comment #6-11: p. 6-1, end of first paragraph: "will experience greater changes in price.." is very vague. Are you trying to say that the costs of these newer technologies are likely to decline in the future? If so, I'd just say it.

Response: The Agency has clarified this statement based on Ashford and Caldart.

Comment #6-12: p. 6-1, first paragraph: The last sentence makes an extremely equivocal statement that as manufacturers gain expertise with their production, new technologies will experience greater changes in price than older ones. This should be clarified: I can't tell whether the writer thinks prices will be higher, lower, or fluctuate. My recent experience with developing technologies in this area suggests that (1) new technologies typically start higher and then move lower as volume increases, and (2) given the pressures on manufacturers, the developers of new processes are doing everything humanly possible to be price competitive with existing choices. This is particularly true in a somewhat traditional industry like dry-cleaning. New machines are attempting to match cost, performance and machine footprint with existing systems.

Response: EPA has included a clearer statement based on the reviewer's statement.

Comment #6-13: p. 6-1: The estimated health costs in Chapter 6 should include the costs of health effects (e.g., medical costs, worker's compensation).

Response: Costs of health insurance and worker's compensation would be considered a labor cost. Because of the difficulty in obtaining reasonable estimates of labor costs, EPA has not included quantitative estimates in the CTSA. EPA's research suggests that less than 10% of professional cleaning facilities in the U.S. offer a health care plan to their employees, so this cost may not be significant to the typical cleaner. Data regarding the medical costs from exposure to PCE are not included in this analysis.

Comment #6-14: p. 6-1, fourth paragraph: Do the hazardous waste disposal costs include labor involved in manifesting and insurance/liability for hazardous wastes?

Response: Hazardous wastes cost include only the cost of disposal. Regulatory compliance costs which include manifesting are included for PCE.

Comment #6-15: p. 6-2, second paragraph: Is labor really process dependent??

Response: Based on conversations with industry representatives it is clear that labor costs are entirely process dependent. There is not enough data to conclude whether the variability within processes is greater than the variability between processes. However, EPA quantitative labor costs have not been included due to the difficulty in obtaining reasonable estimates.

Comment #6-16: p. 6-2: The model plant cleans 39,465 pounds of clothes annually. This is not enough. The average cleaner cleans 1,500 pounds of clothes per week.

Response: The model plant size has been modified to one that cleans 53,333 pounds of clothes annually, based on calculations presented in the CTSA.

Comment #6-17: p. 6-3: The model plant is assumed to operate 312 days per year. This is inconsistent with the 250 day per year operation assumed earlier for PERC drycleaners.

The first paragraph on the page ends with 126 pounds. Of what?

Four loads per day is an underestimate of the number of loads cleaned by the average cleaner.

Response: The cost analysis was conducted with 312 days per year, which is consistent throughout the document. The Agency has modified the text to say 126 pounds of clothes. The Agency has reevaluated the number of loads for each process and presented the modified information in the chapter.

Comment #6-18: p. 6-4: The CTSA discusses energy consumption for facilities with a capacity of 105,240 pounds. Again, of what? I assume it is clothing. If this is the case, then the energy consumption would not be applicable to the model plant assumed here with about 40 percent of the clothing processed.

Response: This information has been modified to reflect a more accurate portrayal in the text. The wording of this statement will be changed to 105,240 pounds of clothes. The capacity adjustment was made for the cost model as shown on page 6-4.

Comment #6-19: p. 6-4, first paragrap1: Energy costs presented in this section are quite mixed. The only energy values presented for the PCE machines are on the controls while full data is presented on wetclean processes and the liquid CO_2 process. This leads to a somewhat skewed result in the comparison tables since annual cost per pound of clothing is calculated using figures based on different factors. This is of particular interest in the PCE case because of the drying cycle is intended to both dry the clothing and volatilize the perchloroethylene for filtration. The drying cycle in PCE and PS cleaning is the most energy intensive part of the cleaning cycle yet it is left out of the analysis. For example, in the last column of Exhibit 6-3 the energy cost of the control devices is minuscule. However, actual energy costs for the process, drying, and hazardous waste disposal are orders of magnitude higher. In Exhibit 6-6 the energy cost of multiprocess wetcleaning is $65 year compared to machine wetcleaning at $4712/year. I would bet that the first does not include drying while the second does. This underestimates the total cost for the multiprocess wetcleaning technique. If you substitute the $4712 annual energy cost of the machine wetclean process for the $65 of the multiprocess wetclean the total annual cost/pound of the two processes is exactly the same: $0.50. This is a serious methodology flaw in the cost estimation.

When compared to liquid CO_2 this is critical. At the temperatures and pressures used for the DryWash and MiCell systems the vapor pressure of CO_2 assures that when the door is opened to remove the clothing they will be dry and ready for finishing. Actually, a small degree of heating will be necessary to prevent the CO_2 from being a solid snow on the clothes. DOE estimates that full conversion from perchloroethylene to CO_2 cleaning would result in an energy savings of 4.17×10^{ft} BTU of energy/year in the U.S. alone. This energy savings is a major reason why DOE has supported R&D in the dry-cleaning industry but the impact of that energy savings is missed in the CTSA.

In the calculation of energy consumption it would be extremely useful to have a breakdown of the energy consumption by process for each alternative (i.e., washing, drying, emission control, etc.). This would give a relative comparison of costs between techniques.

Response: The text has been modified to include PCE and PS energy use estimates for dry to dry technology. The liquid CO_2 technology is still emerging. Information on it has been moved to a separate chapter. Cost estimates, however, are not included.

Comment #6-20: p. 6-4, Section 6.2.4: The fact that energy costs for PCE are based only on control technology is misleading and disingenuous. Just because there is no data on PCE energy costs does not mean they exist. So what the authors have done is increased the cost of machine wetcleaning relative to that of PCE. If we base machine wetcleaning energy costs on the same level as those for PCE, the cost of wetcleaning is reduced to less than $.40/lb! This is a serious problem and should be remedied.

Response: The energy costs for hydrocarbon and PCE dry to dry equipment are included.

Comment #6-21: p. 6-5: The current disposal cost is not $6.96 per gallon. It is more like $5.00 per gallon. Contact Safety-Kleen, the major waste hauler for the industry.

Response: EPA has contacted Safety-Kleen and updated the cost estimates for PCE and hydrocarbon waste disposal.

Comment #6-22: p. 6-5: Footnote current PCE costs and hazardous waste disposal costs.

Response: Text was added to elaborate on PCE costs. The hazardous waste costs are already footnoted and have been modified appropriately.

Comment #6-23: p. 6-5, last paragraph: The hazardous waste disposal cost of $6.96 per gallon is likely much greater now given the increases in price noted in footnote 5 and the 2.5 years that have transpired since this estimate (as much as $8/gallon).

Response: EPA has contacted Safety-Kleen and updated the PCE waste disposal price.

Comment #6-24: p. 6-5, 6.2.6 solvent material cost and sec. 6.2.8 hazardous waste disposal costs: the 6/94 technical paper enclosed as a suggested reference has typical solvent and hazardous waste disposal costs for the case of 2nd, 3rd, and 4th generation PCE machines.

Response: EPA has reviewed the paper submitted and updated the text based on information provided by Safety-Kleen and PCE suppliers.

Comment #6-25: p. 6-5, first paragraph: Tax is not included on solvents but is included on all other costs. It probably doesn't change the bottom line significantly but some processes have much higher solvent costs than others.

Response: See response to #6-3.

Comment #6-26: p. 6-6, Section 6.2.9: It is doubtful that benefits are paid to employees, other than vacations, in this industry. This is noted later in the chapter.

Response: No response necessary.

Comment #6-27: p. 6-6: Where does the figure of 537 gallons of hazardous waste come from? It is unclear where the other estimates of hazardous waste generation come from an these differ from earlier chapters.

Response: The hazardous waste generated for PCE processes are based on EPA engineering estimates and have been modified to maintain consistency.

Comment #6-28: p. 6-7: It is not clear why you would cost out a transfer machine since they are no longer available. It is not reasonable to cost out this option.

Under solvent waste, the document assumes a value of 512 gallons per year. This figure is far too high. This is where the values of Exhibit 3-3 get you in trouble. The values in the waste category in the exhibit include air releases. Furthermore, no drycleaner that generated that amount of waste would ever ship separator water off-site as hazardous waste. They would purchase an evaporator which they could amortize in a few months.

Check with Safety-Kleen on the average cost to drycleaners of waste disposal. It is more in the range of $1,000 to $1,500 per year. Assuming a price of $5.00 per gallon, this implies a waste generation of about 200 to 300 gallons annually.

Response: The cost of transfer machines is included as a baseline estimate. Solvent waste disposal estimates are based on EPA engineering estimates. EPA has checked with Safety-Kleen and updated its waste disposal cost prices.

Comment #6-29: Is 6.3.1 - 6.3.13 necessary since all this information is already in the chart in Exhibits 6-2 and 6-3.

Response: The explicit calculations remain in the text because of controversy over assumptions and the importance of full disclosure in this report.

Comment #6-30: p. 6-8, Exhibit 6-2: Does the cost of hazardous waste disposal include manifesting and other labor?

Response: The cost of waste disposal does not include manifesting or other labor, because these costs are built into the regulatory compliance costs for PCE.

Comment #6-31: p. 6-8, Exhibit 6-2: It would be helpful to have solvent mileage noted here.

Response: Text was modified where appropriate.

Comment #6-32: p. 6-8: Again there is no such thing as a machine with vented secondary control. If you mean fugitive control, then the price should be closer to $40,000. A closed loop machine with secondary controls is probably no more than $42,000 to $45,000.

Response: The technology descriptions for PCE machines have been modified.

Comment #6-33: p. 6-8, Exhibit 6-2: This is a very difficult display to create. Recommendations are as follows:

Annual cost of Hazardous Waste - Do not calculate separator water as a part of Hazardous Waste. The EPA has provided rulings that this water is process waste water and the cleaner can purchase cheap devices to legally dispose of this water. In addition, PCE-M and L machines offer "Spin" filters which significantly reduce the level of Hazardous Waste as well as cost of filters. Your overall base cost for a Transfer machine is too high. A small plant like the model (40k Lbs/Yr.) should be averaging approximately 220 Lb/month for a total of 2640 Lbs. Consideration should be given to the costs of solid waste and liquid waste to make the totals. Based on my visits to the cleaners, the monthly average for such a small plant should be approximately $120-160 for annual amounts of approximately $2k for a PCE-A and $1200 for PCE-M.

Mileage is not easily understood. When I perform my equipment and performance inspection, I always calculate the mileage. To supplement the EPA estimates that are used, I offer the following:

TYPE OF MACHINE:	CTSA EST:	RECOMMENDED:
PCE-A	85	50
PCE-B	104	200
PCE-C	113	100
PCE-D	109	85
PCE-E	115	85
PCE-F	95	100
PCE-G	176	240
PCE-H	150	170
PCE-I	141	130
PCE-J	154	130
PCE-K	225	700
PCE-L	299	750
PCE-M	304	1000
PS-A	11	9
PS-B	15	9
PS-C	15	27
PS-D	45	600

* - If RC is external. If RC is internal; same as PCE-K.

Response: EPA has modified the hazardous waste and solvent mileage amounts based on updated EPA engineering estimates.

Comment #6-34: p. 6-9, Exhibit 6-3: The annual energy costs for the control devices sound very low. Where are these figures from?

Response: The energy cost sources were documented in the CTSA.

Comment #6-35: p. 6-10: The figures for annual hazardous waste disposal cost are too high by 2.5 times. Again, drycleaners will not ship huge quantities of water off-site. It would not be cost-effective.

Response: The hazardous waste disposal costs were modified based on new estimates from Safety-Kleen.

Comment #6-36: p. 6-11, first paragraph: The record keeping costs for leak detection and repair of $341 per year seems extremely low. This would be only 34 hours per year for one person. I seriously doubt that this cost is correct given the large amounts of record keeping needed for PCE users. This number should be recalculated and include all costs associated with hazardous waste generation (see above). Where did the figures of how long each load takes come from? There is no explanation. Why aren't FTE's used in the calculation?

Response: The cost model for PCE was modified to include regulatory compliance costs independent of hazardous waste disposal costs.

Comment #6-37: p. 6-11: PCE Transfer Machines are obsolete and will soon have to be replaced by the requirements of federal and state environmental regulations. Shouldn't this be noted, and only refer to upgrading 2nd and 3rd generation dry to dry machines? We would want to discourage any further use of transfer machines, and showing the costs of retrofitting these old, polluting, machines implies that this is a viable option.

Response: The processes chosen to be included in the CTSA have been updated.

Comment #6-38: p. 6-11: Where did the solvent use of 378 gallons come from for the transfer machine with refrigerated condenser? It would probably be closer to 700 gallons.

Response: The solvent mileages for all PCE processes were modified and updated in the CTSA text.

Comment #6-39: p. 6-12, second paragraph: Hazardous waste costs should also include any liability insurance of potential liability associated with the use. Filter costs need to include the cost of labor to install and dispose of them.

Response: EPA has modified the cost model to include regulatory compliance costs. The model will not include the labor costs associated with installing filters. Filter disposal costs are a part of total hazardous waste disposal costs.

Comment #6-40: p. 6-13: Again, where did the estimate of 348 gallons for a transfer machine with a carbon adsorber come from. A better figure would again be 700 gallons.

Why is an azeotropic vent controlled unit included if they are no longer sold. Virtually no machines with azeotropic systems are used anymore.

A transfer machine with azeotropic controls would be equivalent to an uncontrolled transfer machine and it would have a solvent use of about 1,000 gallons a year.

Response: All estimates are derived from EPA engineering calculations. Azeotropic vent controlled unites are not included in this new cost model.

Comment #6-41: p. 6-14: There is some misunderstanding regarding the use of a carbon adsorber with a Solvation unit. The second generation of the Solvation units came equipped with a small carbon device that was used as a door fan. Although some of the fugitive emissions during unloading were reduced on some installations, it was 1/20 the size of a real CA and contributed only a small amount to the machine mileage.

Response: EPA has attempted to clarify this information in the text.

Comment #6-42: p. 6-14: You need a higher PERC use value (700 gallons per year) for the transfer machine with azeotropic and carbon adsorption controls.

Response: EPA has modified the PCE solvent mileages based on EPA engineering calculations.

Comment #6-43: p. 6-15: Uncontrolled machines are still in use in Coin Laundries.

Response: These machines are not included as a part of this analysis.

Comment #6-44: p. 6-15: Why evaluate the dry-to-dry vented system if they are no longer sold?

Response: EPA has decided to not modify the cost model or text based on this comment.

Comment #6-45: p. 6-16: The figure of 224 gallons per year is too high for the closed loop converted system. It might be 150 gallons per year.

Response: EPA has modified this information using engineering calculations.

Comment #6-46: p. 6-17: A dry-to-dry machine with a carbon adsorber is not a closed loop machine.

Response: The text was modified appropriately.

Comment #6-47: p. 6-18: Why are you evaluating an azeotropic solvent recovery system if they are no longer sold?

Response: This technology is no longer included in the CTSA.

Comment #6-48: p. 6-19: The hazardous waste of 1,998 gallons per year is ridiculously high. Likewise the cost, at $13,96. Again, the cost of disposal for a drycleaner is $1,500 per year.

Response: Hazardous waste disposal costs were modified based on information from Safety-Kleen and updated engineering estimates from EPA.

Comment #6-49: p. 6-20: A dry-to-dry closed loop machine has an annual PERC usage of about 100 gallons, not 155 gallons. Again the waste disposal cost is about $1,500 per year.

Response: Hazardous waste disposal costs were modified based on information from Safety-Kleen and updated engineering estimates from EPA.

Comment #6-50: p. 6-21: Again, there is no such thing as a vented machine with secondary controls. A spill guard is an option for any machine, not just a machine with secondary control.

Retrofitting a dry-to-dry closed loop machine with secondary control ranges in cost from about $3,000 to $8,000. The cost given here is too high.

The solvent use for a dry-to-dry closed loop unit with controlled emissions is about 80 gallons per year.

Response: EPA has dropped this technology option from the CTSA.

Comment #6-51: p. 6-21: Confusion. The PCE-M is the "Fourth Generation" machine. When a vented control device is connected to a RC machine, that is all that it is since it is still venting. What does a spill basin have to do with the CTSA? The computer which uses a PID detector is only provided on a machine with an integral carbon adsorber, not on a vented machine. A "Drying Sensor" which is supplied on either a PCE-K, L or M is a float device that extends the drying cycle if liquid is still returning from the reclaimer and has nothing to do with the level in the wheel.

Response: EPA has dropped this technology option from the CTSA.

Comment #6-52: p. 6-21, third paragraph: How was solvent use of 132 gallons estimated?

Response: All mileage estimates were based on EPA engineering calculations.

Comment #6-53: p. 6-22, Section 6.3.13, second paragraph: The mileage is 340 pounds per gallon. Michigan's studies clearly show 1,000 plus pounds clothes cleaned per one gallon of solvent used.

Response: EPA has modified the engineering estimates for solvent mileage.

Comment #6-54: p. 6-22, Section 6.3.13. Solvent use: The mileage for a typical 4th generation machine of 304 pounds of clothes per gallon of PCE appears to be in error. This would be equivalent to 16,720 pounds of clothes per 55 gallon drum of solvent, typical of 2nd generation dry-to-dry equipment. 4th generation machines have solvent mileage values of greater than 40,000 as documented in our 6/94 paper. Many newer 4th generation machines have DCE solvent mileage greater than 50,000 pounds per drum of PCE.

Response: EPA has modified the engineering estimates for solvent mileage.

Comment #6-55: p. 6-22: The PERC use in a dry-to-dry closed loop with secondary control is about 50 gallons per year, not 130. In all cases, the waste disposal cost is much too high.

Response: EPA has modified the engineering estimates for solvent mileage and hazardous waste production/disposal costs based on EPA calculations and information from Safety-Kleen.

Comment #6-56: p. 6-24, Exhibit 6-4: The total operating costs do not include full energy costs or water costs an are thus an underestimate.

Response: EPA has included energy costs for PCE and hydrocarbon dry to dry machines. Water cost data is included for wetcleaning machines in terms of solvent cost.

Comment #6-57: p. 6-27, fifth paragraph: How can the authors assume that energy costs for petroleum are 10% higher than for PCE if they do not know what it is for PCE. Also, is Hill's assertion costs for control equipment or for all equipment as a whole. Maybe PS control equipment uses the same amount of energy. This should be referenced as before: energy costs not applicable or not available.

Response: Energy costs have been modified for hydrocarbons to include machines and control technology, based on information provided by manufacturers.

Comment #6-58: p. 6-29: This section fails to consider the important health and safety benefits of wetcleaning over the traditional methods, which are difficult to quantify.

Response: This is the cost analysis section. The health and safety evaluations of the alternatives are covered in other sections.

Comment #6-59: p. 6-29: Why are capital maintenance costs of wetcleaning considered to be so much higher?

Response: The maintenance costs of wetcleaning machines were based on the data available.

Comment #6-60: p. 6-29, Section 6.5.1: Why are other wetcleaning machines not considered. The Daiwoo machines which cost about $1000 and are quite energy efficient are being used in several establishments. What is meant when the authors state that "machine capacity is 55 percent of the nominal value (of what?)?"

Response: Information about the Daiwoo machines has been included. Nominal values are the actual drum capacities versus the operating capacity, which is the capacity at which the machine operates most efficiently.

Comment #6-61: p. 6-29, third paragraph: The water needed/LB of garments cleaned conflicts with the data provided for the Canadian test site (p. 5-27, Exhibit 5-22).

Response: The Agency reviewed the information in the Canadian study which was based on extrapolation from a single machine. The estimated water use, 0.929 gallons per pound, is lower than that estimated in the CTSA. 3.5 gallons per pound. The Agency continued to use its 3.5 gallon per pound estimate because it was supplied by the model machine's manufacturer. The Canadian data since it was based on extrapolation from a single machine was not compelling.

Comment #6-62: p. 6-29: Why are both water and full energy costs considered for wetcleaning and not for PCE or PS? This will tend to overestimate the costs of wetcleaning unduly. If you do not have cost figures for the water or energy of the PCE and PS technologies than these should not be considered for wetcleaning to ensure an even playing field.

Response: EPA has included energy costs for both hydrocarbon and PCE dry to dry machines. Water use costs for wetcleaning are included because it is the "solvent". They are not included for the hydrocarbon and PCE because the majority of use is focused on pressing which is not considered for any technology.

Comment #6-63: p. 6-31: Discharge fees are not included in the costs of wetcleaning.

Response: The water cost includes sewerage as well as the cost of fresh water.

Comment #6-64: p. 6-33, Section 6.5.3: Cost estimates for alternative PS technologies should be included in the PS section.

Response: This comment is unclear at this point.

Comment #6-65: p. 6-34, First Paragraph: What is the electricity consumption for a closed loop with vented secondary controls PCE machine - this is not given (only for control technologies).

Response: EPA has included energy costs for the dry to dry PCE machines.

Comment #6-66: p. 6-35: The discussion on carbon dioxide is entirely speculative. The vendors do not know the cost of a machine because none is yet available. The estimate of $54,000 to $58,000 is wishful thinking.

The CTSA states that the MiCare system has a target cost of $0.10 per pound of clothes cleaned. This is simply vendor marketing information and has no basis in fact.

Response: EPA has removed cost estimates for the emerging technologies. The data are expected to be too speculative.

Comment #6-67: p. 6-35, Section 6.5.5: It should be noted that the cost of a CO2 machine will likely come down as the technology gains market share. Full energy costs for this technology are also provided which will bias the cost of garment cleaning upwards relative to PS and PCE technologies.

Response: EPA has removed cost estimates for the emerging technologies. The data are expected to be too speculative. EPA has included full energy costs for the dry to dry options of the hydrocarbon and PCE technologies.

Comment #6-68: p. 6-36: The carbon dioxide process might generate hazardous waste if spotting compounds which contain listed hazardous wastes are used.

Response: The carbon dioxide process might generate hazardous waste if spotting compounds which contain listed hazardous wastes are used.

Chapter 7

Comment #7-1: The purpose of this chapter and its contents are not consistent with its title. While the title mentions p2, the chapter as a whole does not cover many p2 options. One would expect here an analysis of pollution prevention opportunities in the industry as a whole, not technology by technology. For example, the reader would expect to know whether wetcleaning or CO^2 cleaning provides pollution prevention benefits compared to PCE. This technology by technology assessment of control options does not seem to be the purpose of the CTSA. The CTSA was designed to look at cleaner technology substitutes not pollution control options. This chapter would fit better in a document entitled, "Exposure reduction opportunities in the solvent dry cleaning industry". The pollution prevention benefits that result from changing workplace practices are described, but a large percentage are not pollution prevention. As written, this document provides little additional assistance to drycleaners in making decisions about various technologies. It serves little purpose in a Cleaner Technologies Substitutes Assessment. This is definitely not a pollution prevention chapter in the strict sense of the word and should either be shortened; contain a comparison of the various technologies in terms of their pollution reduction potential; or be eliminated completely. It must be noted that none of these process modifications, maintenance, etc. will prevent exposure, they will only reduce it. The only way to prevent exposure is to eliminate PCE.

Response: The title of this chapter has been changed to more accurately reflect the contents. The chapter is intended to provide information on ways to reduce emissions to cleaning solvents and detergents from particular processes. The chapter does not suggest that the practices discussed will prevent all exposure to PCE.

Comment #7-2: Chapter 7's BMP is good, but could maybe be better arranged - possibly a checklist broken down by equipment, maintenance, employee suggestions/recommendations.

Response: The chapter has been reorganized and streamlined.

Comment #7-3: Much of the data presented in this chapter are indoor air levels of PCE measured in residential apartments by NYSDOH and others. The levels are substantially elevated compared to indoor air levels of PCE measured in residential areas away from operating drycleaning facilities. A comparison of average levels at 'study' and 'control' locations indicate that these residents are exposed to highly elevated levels. However, the CTSA does not give any guidance regarding a comparison to 'acceptable' levels of PCE in air. The EPA RfC and/or the Agency for Toxic Substances and Disease Registry (ATSDR) Minimal Risk Level (MRL) could be used to provide a comparison. The EPA RfC of 0.17 mg/m^3 and the ATSDR chronic MRL of 0.270 mg/m^3 are exceeded in the majority of residences where PCE levels have been measured. A comparison of air levels to the RfC and MRL would provide useful information to assess the degree of risk encountered in co-located residences and other locations.

Response: This chapter is not the appropriate location for a comparison of PCE levels to MRLs and RfCs. Comparisons of air concentration to such measures has been included in Chapter 5.

Comment #7-4: This chapter does not adequately inform the reader that following best management practices (as discussed in section 7.1.1) does not ensure that airborne emissions from

PCE drycleaning facilities may still result in substantial airborne contamination in the drycleaning facility and in neighboring areas. The cleaner may be led to the erroneous conclusion that following manufacturers' instructions will allow operation of the drycleaning equipment without fugitive emissions or cause for concern.

Response: The chapter gives no allusion that following best management practices or taking the measures discussed will eliminate emissions or problems caused by emissions.

Comment #7-5: The format of this chapter is often hard to follow. Numbers for each sub-section would be useful.

Response: The chapter has been reorganized to make the presentation clearer.

Comment #7-6: Are the individual owners expected to do all of these maintenance items? Are they capable of doing all of these maintenance items or do they have to hire additional personnel or outside contractors to do these? In the labor cost estimates, the costs of conducting these maintenance items should be outlined and compared to the costs of not doing these items.

Response: The CTSA does not require the practices in the CTSA, they are suggestions for operating facilities. Estimates of labor costs have been eliminated from the CTSA because of the difficulty in obtaining reliable information to support them.

Comment #7-7: The wide variation in operating conditions, training, work practices, and processes makes generalized maintenance recommendations less applicable to the industry as a whole.

Response: The chapter has been updated to better caveats its limitations.

Comment #7-8: Q-1: This chapter adheres in the early sections to its title. By the way, what are P2 opportunities mentioned in the title? Explain! The content drifts away from the title and repeats many release and exposure numbers in co-residential facilities described earlier. What's the purpose of putting them into this chapter? All of them should be combined with the data in Chapter 3, except Exhibit 7-7 and 7-8.

It is desirable to document how maintenance procedures and control options reduce fugitive emissions. The data presented here are more anecdotal and not really cause and effect-type actions. If there is an educational objective associated with this chapter, it needs major revisions. Why is there no reference to pollution prevention programs and efforts of the drycleaning industry?

Response: The title of this chapter has been changed to more accurately represent its contents. However, some of the measures described in the chapter will reduce PCE emissions and releases, which means some pollution is prevented. Although this documenting procedures and controls is desirable, it would be extremely difficult and is beyond the scope of this CTSA. Reference to industry programs for pollution prevention have been included.

Data on co-located residences is presented to demonstrate the effect of remedial actions on reducing PCE emissions.

Comment #7-9: Q-2: This chapter is poorly written. There are lengthy discussions on maintenance of outdated technologies (i.e., constant pressure and regenerative filters) which few, if any, drycleaners still use. The best management practices section reads like an unorganized laundry list. Its content needs to be restructured to reflect specific equipment maintenance requirements in a logical sequence. For example, list each functional part of the machine and follow with sequenced maintenance steps. State the benefits associated with the performed task.

Response: This chapter has been rewritten, reorganized, consolidated, and updated to the extent possible. The list and benefits issues were, however, beyond the scope of this chapter.

Comment #7-10: Q-3: If the Exhibits 7-7 and 7-8 retain in this chapter, they are adequately discussed in the text and enhance the purpose of the chapter.

Response: No response needed.

Comment #7-11: Q-4: There are no inconsistencies between table and the text. The question is whether they add to the purpose of this chapter.

Response: No response needed.

Comment #7-12: Q-5: Trade associations such as IFI (i.e., Industry Focus: Pollution Prevention in the Drycleaning Industry, No. 5, 1993) and NCA-I (i.e., Keep it Clean: Guidelines to reduce or eliminate PCE Releases to Air, Soil and Water) have prepared a series of excellent and very useful maintenance guidelines. Also, CEC's safe handling booklet referred to earlier contains useful tips on prevention and control of potential hazards for PCE drycleaners.

NIOSH has done a study on the effectiveness of pollution prevention measures and technologies which should be mentioned here (Earnest et al.). Earnest and Spencer have also prepared a report for the World Health Organization (WHO) on the effectiveness of pollution prevention technology practiced in Europe. These information should be discussed and referenced as well.

There are two Hohenstein research reports (in Germany) relevant to this chapter:

1. "Moeglichkeiten zur Reduzierung der Loesemittel Belastung in der Umgebung von Chemischreinigungsanlagen." (Feasibility of Lowering Solvent Vapor Load in the Vicinity of Drycleaning Machines). Research sponsored by the German Environmental Protection Agency. Final Report, 256 Pages. Hohenstein Institutes, Boennigheim, Germany (September, 1991).

2. "Reduzierung der Loesemittelkonzentration in der Nachbarschaft von Textilereinigungen." (Reduction of Solvent Vapor Concentrations in the Vicinity of Drycleaning Plants). Research sponsored by six German State Agencies. Final Report, 46 Pages. Hohenstein Institutes, Boennigheim, Germany (November 1994).

These two reports provide detailed and quantitative information about fugitive emission control technologies, analytical measurements and the effectiveness of diffusional barriers in 114 German drycleaning plants.

Response: NIOSH and IFI documents were used extensively to update this chapter. NCA has yet to provide the documents requested by EPA. The Hohenstein reports were available in English only as report summaries, and the summaries did not appear promising toward improving the contents of this chapter.

Comment #7-13: Q-6: The references are not comprehensive and really not related to the main thrust of this chapter. This chapter projects the impression that government supported studies are the only sources for best management practices and control options. There is one reference to industry pollution prevention programs of which they are plenty. Trade associations publish regularly bulletins about it for their members. They organize courses and environmental certification programs on a regular basis. These voluntary programs reach many drycleaners. Their inclusion in this chapter would add to this document.

Response: NIOSH and IFI documents were used extensively to update this chapter. NCA has yet to provide the documents requested by EPA. The Hohenstein reports were available in English only as report summaries, and the summaries did not appear promising toward improving the contents of this chapter. Industry trade association efforts have also been included.

Comment #7-14: In chapter 7, an additional operation and maintenance practice should be the maintenance of a log of these activities.

Response: This item has been added.

Comment #7-15: p. 7-1, first set of bullet points: For transfer operations it may be more risky and not best management practice (BMP) to locate the PS washer and dryer in close proximity. The BMP for PCE and PS should be separated.

Response: This issue has been included.

Comment #7-16: p. 7-1: For transfer operations the best management practice is to replace such obsolete equipment with a state-of-the-art 4th generation machine, or another alternative type of drycleaning system.

Response: The best management practices in this section are intended for managing current equipment. The purpose of this section is not to recommend particular machine types or technologies.

Comment #7-17: p. 7-1: The list of best management practices should be better organized at least with subheadings and some indication of relative importance of these practices regarding environmental releases.

Response: This chapter has been rewritten, reorganized, consolidated, and updated to the extent possible. The improved list is not intended to be fully comprehensive, and relative importance of practices were beyond the scope of this chapter.

Comment #7-18: p. 7-2, bullet 1: Unclear: through doors?

Response: This wording has been clarified in the updated, rewritten chapter.

Comment #7-19: pp. 7-2 to 7-3: provide ridiculous examples of best management practices, such as "train employees to avoid leaning into washer to remove clothes." While some of these are useful for drycleaners these are not relevant to this document and should be incorporated into a document on best management practices for PCE drycleaners.

Response: While the commenter may not find each example valuable, others may. Therefore, they have been kept in the document.

Comment #7-20: p. 7-2, third bullet: Add as a clarifier the following after "... peripheral plant areas": (i.e., keep the drycleaning and pressing rooms under a negative pressure).

Response: This wording has been clarified.

Comment #7-21: p. 7-2, 7-3: Other suggested P2 practices:
- Do not open the door (if the machine can be opened) before the end of the drying cycle.
- Vent dryer air streams to a carbon bed when the machine door is open.
- Determine and maintain the maximum or ideal ratio of clothes cleaned per activated carbon used.
- Carbon beds should maintain the ideal solvent to carbon ratio to ensure that the stripping is done at proper intervals according to manufacturers instructions
- Determine and maintain the ideal rated air flow capacity through the carbon
- Determine and maintain ideal stream pressure passed through the bed to strip solvents from carbon beds
- Clean the lint screens as often as necessary to avoid clogging the fans and condensers.
- Avoid underloading or overloading machine
- Place saturated lint from lint baskets in sealed waste containers
- Inspect chemical and waste storage containers for leaks
- Regularly remove the residues in distillation units. Excessive build-up of contaminants can reduce the efficiency of the still
- Drain filter cartridges in a closed container
- Consider drying filters in housings vented to carbon adsorbers
- Determine and maintain the ideal amount of clothes cleaned for each filter cartridge before stripping
- Determine the ideal steam pressure for stripping
- Request that your supplier provide solvents in returnable containers
- Use spigots, funnels, and pumps when dispensing materials and funnels
- Do not store chemicals in extreme heat or cold where shelf-life may be diminished or become unusable

- Keep chemical containers tightly sealed
- Provide secondary containment in storage areas
- Do not allow hazardous material to become mixed with non-hazardous material
- Recycle plastics, cardboard and paper
- Encourage customers to use re-usable garment bags.

Response: As appropriate, these and other additional practices found from other sources have been added.

Comment #7-22: p. 7-3, bullet 7: enclosure should be closure.

Response: This word was changed.

Comment #7-23: p. 7-3: Note those items that are required by the NESHAP.

Response: Although this point has merit, an incomplete list of NESHAP requirements may cause confusion.

Comment #7-24: p. 7-4 to 7-13: We will not provide specific comments on the various drycleaning machine components or ancillary equipment.

Response: No action required.

Comment #7-25: p. 7-4, second paragraph: The CFR section referenced here is different than those referred to in the regulatory section 2.4. Are there other sections of the NESHAP that are relevant? If this is a different requirement it should also be summarized in section 2.4.

Generally Section 7 is extremely useful to the operator and should be placed at an earlier point in the document to capture their attention.

Response: Discrepancies in the CFR references have been corrected. The document is not meant as a manual for operators, therefore, there is no compelling reason to move this text.

Comment #7-26: p. 7-5: An important maintenance procedure for carbon adsorbers is the maintenance of a proper air filter type. Many older "lint filters" are improper, e.g., furnace filters, that allow fine particles to slowly clog the pores of the activated carbon bed. It is important that only manufacturers' specified filter materials be used for carbon adsorbers.

Response: This issue has been included.

Comment #7-27: p. 7-7: Fans. PCE drycleaning machine local exhaust fans should be capable of maintaining a 100 fpm inward air velocity as per NFPA PCE guidance and NYS DEC regulatory requirements to properly control fugitive PCE emissions.

Response: This issue has been included.

Comment #7-28: p. 7-8: Aren't many of these suggestions already published as part of Clean Air Act guidance documents?

Response: Yes, but the CTSA includes some additional information.

Comment #7-29: p. 7-8: Are cartridge changes an auxiliary equipment? It is an action.

Response: This wording has been corrected.

Comment #7-30: p. 7-11, second paragraph: The statement of disposal of hazardous waste is usually best accomplished through the use of an EPA licenses hauler is obvious and unnecessary. Isn't it required for all those covered under RCRA?

Response: Many drycleaners are "small quantity generators" per RCRA and are not required to use licenced hazardous waste haulers.

Comment #7-31: p. 7-11, Water Separator: Double activated carbon treatment of separator water and evaporation should be mentioned as the best way to control PCE from separator water; with the spent carbon cartridges being sent to a licensed hazardous waste hauler.

Response: Although the modifier "best" used by the commenter cannot be verified, this issue has been included.

Comment #7-32: p. 7-11: The distillation unit is not necessarily the primary source of separator water. Refer to the document enclosed.

[Water Environment Federation. 1995. Controlling Dry Cleaner Discharges in Wastewater: How to Develop and Administer a Source Control Program.]

Response: The CTSA is not stating or implying a comprehensive or prioritized listing here.

Comment #7-33: p. 7-12, bullet 3: How is an owner/operator supposed to determine if the carbon bed is contaminated and determine when it is sufficiently uncontaminated? This needs to be carefully described.

Response: This issue has been given more thorough coverage, although this discussion is not intended to be fully comprehensive.

Comment #7-34: p. 7-12, last paragraph: How does an owner/operator know if the carbon needs to be replaced more often than every 5 years? This needs to be carefully described.

Response: This issue has been given more thorough coverage, although this discussion is not intended to be fully comprehensive.

Comment #7-35: On page 7-13, last paragraph, the report seems to implicitly endorse PCE in noting that it is important for drycleaner owners to understand the benefits of remedial actions and obtaining state of the art equipment. This type of statement is not appropriate in an alternative technologies assessment. It seems to indicate that if the drycleaner invests in these technologies pollution problems will be resolved. Investment in state-of-the-art PCE equipment will discourage investment in wetcleaning technologies, especially for small cleaners with few resources. Similar statements supporting wetcleaning technologies are not made.

Response:

Comment #7-36: p. 7-13 to 7-15: Co-located residences are impacted by operations of drycleaning facilities in the building, as stated in this section. The points that are made on page 7-14 are generally correct, although we do not believe there is enough data to say with certainty that vapor barriers and room enclosures are of limited use unless they enclose the pressing area. There is very little data on the effectiveness of these measures, and additional analysis of existing data and new information should be conducted by EPA and others.

Response: The language has been revised to read as follows: "Vapor barriers and room enclosures are marginally effective in reducing PCE concentrations in co-located residences and their effectiveness increases when they enclose both the drycleaning and pressing areas."

Comment #7-37: p. 7-13, Section 7.1.3: Does this section belong here or in the exposure section? It wouldn't appear to go along with a description of best management and control options. However, it is critical information that could possibly be included in chapter 2, 3 or in an appendix and just referenced here.

Response: This section is still in the chapter; however, the detailed information in the exhibits has been deleted. Conclusions from the study, which could affect best management practices, have been retained in this section.

Comment #7-38: p. 7-13: Chapter 7 could also include a discussion of the impact of facility conditions and remedial actions on perc concentrations within the facility.

Response: The chapter contains information on proper maintenance and operation of drycleaning machine components, as well as operation of control devices. If these practices are followed, emissions within the facility will be reduced. EPA is not aware of data that would show the quantitative effect of such activities on facility concentrations.

Comment #7-39: p. 7-14: The CTSA states that vapor barriers and room enclosures are of limited use unless they enclose the pressing area. I don't think this has been demonstrated.

Response: See answer to Comment #7-41.

Comment #7-40: p. 7-14, first full paragraph: Note that PCE can be stored in building materials such that these materials will off-gas PCE even after the source ceases to emit. This chapter is very lop-sided in that it is primarily discussing PCE. Again, the BMP for PCE and PS should be separated.

Response: The point about off-gassing was made in the exposure section. The chapter presents more information on PCE than other technologies because that is what was most available.

Comment #7-41: p. 7-14, second bullet: I would rephrase this sentence to something like the following: Vapor barriers and room enclosures are marginally effective in reducing PCE concentrations in co-located residences and their effectiveness increases when they enclose both the drycleaning and pressing areas.

Response: The language has been revised as suggested.

Comment #7-42: p. 7-15: High ventilation rates (10,000 CFM) appear to be an optimal solution in the BAAQMD for preventing exposure of PCE. However, the Hamburg Germany facility is controlling PCE by only exhausting about 1200 cm per hour, or about 700 CFM for the double positive air pressure ceiling control system. In this case, apartments above the drycleaner used to have PCE levels greater than 4000 ug/cm, but are now controlled to less than 100 ug/cm PCE with this new type of vapor barrier control system. (Personal observations on 4/97 trip to Hamburg Germany and reported by Mr. R. Golgert, Environmental Engineer of the Berzirksamt Wandsbek Abteilung Fur Umweltschutz, Hamburg Germany.

Response: The BAAMQD's recommendation was based on the types of equipment they had. Lower ventilation rates may be effective for reducing solvent concentrations in residences co-located with facilities having newer machines or having machines with better controls.

Comment #7-43: p. 7-16 to 7-21: We did not have the time to check the figures contained in Exhibits 7-2, 7-3, 7-4, 7-5, 7-6, 7-9 and 7-10, which contain information on the results of investigations conducted in New York State.

Response: These exhibits have been removed. Conclusions from the New York Department of Health study are summarized in the CTSA, and readers can request a copy of the study to obtain more information.

Comment #7-44: p. 7-16, Exhibit 7-2, 7-3, and some others that follow: I seriously doubt that the PCE concentrations are known to 5 significant figures. I suggest rounding off to, at most, 3 significant figures even if the original source did not.

Response: These exhibits have been removed.

Comment #7-45: p. 7-17: Again, the conclusion that dry-to-dry machines are less emissive than transfer machines is a foregone conclusion. This analysis did not need to be performed to demonstrate that fact.

Response: All things being equal, this is true, but machine condition can vary widely from one drycleaner to another.

Comment #7-46: The description of section 7.2 in the introduction is not consistent with he section in the report which is alternative technologies.

Response: The inconsistency has been corrected.

Comment #7-47: Section 7.2: There is so little information here that it would make more sense to drop it. It takes a page and a half to say there is no information.

Response: While this information is very sparse, it may be helpful to some, and it provides consistency of coverage across technologies.

Chapter 8

Comment #8-1: Chapter 8's discussion of Cost-Benefit analysis is OK, but appears to be unnecessary. The large table (8-7) is totally unnecessary. You do almost nothing with all of this (e.g., costs are private - but more on that later), so why bother to put it in? In fact, the information presented is either extraneous, or repeats early results and data. And there appears to be more reason for the little example of WTP for avoiding eye irritation.

I would vote for making this entire discussion a one or two paragraph intro to what actually does get done in this chapter - cost-effectiveness sorts of things and qualitative comparisons.

Response: Information in the final chapter is meant to summarize all material in the CTSA in a single place in order to assist in comparing trade-offs among processes. Therefore, some data is repeated from previous chapters. EPA has kept the chapter, but has modified it, including removal of the example on willingness-to-pay.

Comment #8-2: General - The early part seems to restate conclusions that have been made several time already. This is okay if the intention is to have each chapter stand alone. Otherwise it just make the document long and cumbersome to read. I would take pages 8-1 to 12 and make them part of the Executive Summary.

Response: EPA has reviewed the comment and maintained the summary of previous chapters. Information from this summary has been included in the Executive Summary.

Comment #8-3: Chapter 8 is great - lots of info in easy to follow formats. (Exhibit 8-6 is very good, Exhibit 8-1 should be located in Chapter 1, which would allow you to edit down that chapter dramatically.) I'd use this chapter as a model for the rest of the document.

Response: Much of the summary information has been included in the Executive Summary.

Comment #8-4: This trade off analysis should include some information on limitations of conclusions made.

Response: The chapter has been modified to include some of the limitations of conclusions.

Comment #8-5: Q-1: This chapter is obviously intended to convince drycleaners to make environmentally responsible investment decisions. Initially, the chapter provides some guiding summaries on potential risk. The statements concerning cancer risks for PCE appear affirmative: "these effects include cancer" or "...PCE through mother's milk to cause cancer." These statements will damage the industry since environmentalists are likely to use them out of context for irresponsible risk communication to the public. For this reason, the wording about cancer needs to be revised.

The cost section repeats earlier detailed technology options (i.e., Exhibit 8-1) which are repetitive and distract the reader. Other factors, such as cleaning performance, potential liability are added

without definite conclusions. All these inputs for making informed responsible decisions need to be expressed in a more precise and condensed way without repetitive details.

What should be really stressed in this chapter is the process of making informed and objective decisions. A brief listing of the advantages and disadvantages of the existing and future technologies are important inputs. They must include summaries on costs, performance, environmental concerns etc. Converting these information into cost/benefits is the challenge, especially if the costs are to include the social costs. Drycleaners must be convinced that the social costs are also of benefit to them. I don't think that overwhelming them with negatives (cancer thread, environmental extremism) will help. There is, however, a recognition that pollution prevention is essential.

Response: For completeness, EPA has maintained summary information for each of the chapters. Language has been carefully reviewed and changes have been made, where necessary, to accurately reflect the conclusions made in previous chapters. EPA has designed this chapter to provide many of the advantages and disadvantages of the technologies and explained how they fit into a cost-benefit decision making framework.

Comment #8-6: Q-2: The objective of this chapter - to summarize information for decision making can be substantially improved if concise decision making methodology is included. The book on "Understanding Risk - Informing Decisions in a Democratic Society" referenced in Chapter 4 has a schematic representation of the risk decision making process (Fig. 1-2, p. 28). This flow diagram could be modified to illustrate specific inputs for decision making here. EPA has the expertise in-house. Ray Kent, a co-author of the CTSA document, served as one of several EPA advisors to the NRC Committee which published the book.

Response: EPA introduces the decision making methodologies of cost-benefit and cost-effectiveness analysis.

Comment #8-7: Q-3: Deleting repetitive machine configuration tables (i.e., Exhibit 8-1 and 8-3) and summarizing the configuration tables identifying the best performer within each cleaning technology would enhance understanding and help in the decision making process.

Response: EPA has modified the processes chosen to be included in the CTSA and revised the presentation to enhance clarity.

Comment #8-8: Q-4: There are no apparent inconsistencies in the chapter, but references to outdated technology (azeotropic PCE recovery) or to carbon dioxide (anecdotal cost figures without field demonstrations) should be dropped or qualified.

Response: EPA has modified the processes chosen to be included in the CTSA and revised the presentation to enhance clarity. Cost for the carbon dioxide technology have been removed.

Comment #8-9: Q-5: [Are you aware of any specific sources where information is more current or different from that quoted in any chapter?] Identified in earlier chapters (technology related) or stated above (risk).

Response: No response.

Comment #8-10: Q-6: [Are relevant references provided for the information contained in each of these chapters?] Relevant references in earlier chapters (technology) or stated above (risk)

Response: No response.

Comment #8-11: This chapter could serve as part of the executive summary. However, little attempt is made to make conclusions about the assessment as a whole (e.g., is one technology environmentally preferable to another?)

Response: Information has been taken from this chapter and included in the Executive Summary. Conclusions are not made about which technology may be the best for individual cleaners.

Comment #8-12: Analysis of trade-offs - Because of the uncertainly of the current data, this section winds up being a tutorial on cost/benefit analysis (which I found relatively interesting) but which does not contribute anything more to the discussion than was accomplished by the first 12 pages of this chapter. This appears to be another say of stating what has been stated several times already. The summary Exhibits are good and could be incorporated back into pages 1-12.

Response: The intent of this chapter is to summarize trade-off factors and to provide approaches that the cleaner may use to compare these factors when selecting a technology.

Comment #8-13: p. 8-1, first paragraph: The CTSA does a good job of comparing facilities with the same cleaning output. I suggest that for each criteria the chapter needs a table comparing the different technologies, particularly for the risks. On the basis of cost alone, PS appears to be dominated by PCE with all values in Exhibit 8-4 exceeding the ones in Exhibit 8-2. In Exhibit 8-5, multiprocess wetcleaning appears to have the lowest costs, but it is not considered commercially viable. This needs to be explained. Overall, several PCE options and machine wetcleaning give similar costs (in the $0.50 per lb range). Since the cost of labor represents a substantial portion of the costs, this may mean that if labor rates change, there may be more of a difference between the costs associated with the two technologies. Some sensitivity analysis (along the lines of Blackler et al., 1995) might be helpful here for showing how labor rates and/or the cost of waste disposal change the relative favorability of the different strategies.

Response: A table that compares the trade-off factors associated with the various technologies has been provided in Chapter 10. Labor costs have been included qualitatively because of the difficulty in getting reliable estimates of their value.

Comment #8-14: p. 8-2, last paragraph, Env. Risks: should discuss the risks of going to a POTW.

Response: The CTSA has evaluated risks of wetcleaning chemicals under the assumption that they are sent to a POTW.

Comment #8-15: p. 8-2: As a parent, I care very much about possible risks to children, including my own. However, the statement about risk to children (nursing infants, whose mothers inhale PCE may absorb enough PCE through mothers milk to cause cancer effects) is technically misleading and seems gratuitous. First, cancer risks are treated as stochastic, not deterministic, so increasing dose increases risk (the probability of cancer) but does reach some deterministic level at which it can be stated to "cause cancer effects." Second, modeled risks to children, even those whose mothers are exposed at the TLV, are lower than the estimated risks to other populations including those who over a drycleaning establishment. I would expect that if a population were to be singled out, it would be a population at very high risk.

Response: The risks to children are not clear, however, as a general rule, exposure scenarios where health risk are a concern for adults, they should be considered a concern for sub-populations, such as children, similarly exposed. EPA has identified several models that estimate the amount of PCE to which an infant may be exposed through ingestion of breast milk. The CTSA has been modified to report these studies and does not quantify risks using the study results.

Comment #8-16: p. 8-2, first paragraph: "Nursing mothers...to cause cancer effects." Another misleading statement.

Response: EPA has revised language concerning nursing mothers and risks to infants.

Comment #8-17: p. 8-2, second paragraph: While it is important to note that the type of PCE technology can significantly affect exposure, it is also important to note that these technologies will only reduce exposures, not eliminate them. The only way to eliminate exposures to PCE is to substitute for the solvent.

Response: EPA acknowledges in its review of PCE machine configurations that control technologies may only reduce exposures to PCE and does not claim that exposures will be eliminated.

Comment #8-18: p. 8-2, first paragraph: Individuals exposed to PCE are at risk to suffer from various effects (not potentially).

Response: EPA has reviewed the language and believes that it has appropriately summarized the information on risk.

Comment #8-19: p. 8-2: The hazardous waste disposal costs in Exhibit 8-2 are far too high as discussed earlier.

Response: EPA has modified the hazardous waste disposal costs based on new estimates from Safety-Kleen.

Comment #8-20: p. 8-3, fourth paragraph, Env. Risks: should discuss the risks if going to POTW.

Response: The CTSA has evaluated risks of wetcleaning chemicals under the assumption that they are sent to a POTW.

Comment #8-21: p. 8-3: This is where the secondary risks from wetcleaning could be discussed. The increased energy demand and subsequent air emissions due to increased use of hot water deserve mention in the spirit of evaluating risks to neighbors and the community.

Response: EPA has included estimates of energy costs in its assessment. Air emissions resulting from increased hot water usage is part of a life cycle assessment which is outside of the scope of this document.

Comment #8-22: p. 8-3, sixth paragraph: Ultrasound and CO_2 risks - This conclusions amounts to damning by faint evidence. There is little information to suggest any risk associated with either of these technologies. Both have been used in other industrial applications with no worker safety problems. In fact, many of the industrial applications that these technologies were developed for were to mitigate a hazard caused by an earlier technology. Phrasing makes a big difference here.

Response: EPA has summarized the available information on these technologies in a separate chapter so that these technologies are not compared to existing technologies.

Comment #8-23: p. 8-3, third paragraph: The problems of risks from detergents could be resolved by using bio-based, degradable ones.

Response: EPA includes information that indicates that attributes, such biodegradability, are preferred for machine wetcleaning detergents.

Comment #8-24: p. 8-4: Cost estimates for PCE process options. See comments in Ch. 6 about lack of inclusion of regulatory compliance, manifesting, and other costs associated with the use of PCE technologies. These would tend to raise the cost/lb of clothes washed.

Response: See chapter 6 responses. EPA has made some revisions to cost estimates to incorporate some of the concerns of the commenter.

Comment #8-25: p. 8-4: The CTSA states that two machine types are "available for use." I would change that to "used." Transfer machines are no longer sold.

Azeotropic systems do not alone constitute a control system.

It is not reasonable to discuss the capital cost of a transfer machine since none are offered for sale.

Again a system with an azeotropic system and carbon adsorber is not a closed loop system regardless of the vendor claim. The only closed loop system is a dry-to-dry machine with an integral secondary control.

Response: The technology descriptions for PCE and hydrocarbon machines have been modified. The cost of transfer machines is included as a baseline estimate.

Comment #8-26: p. 8-5, Exhibit 8-1: Inaccurate information in description of PCE-E and PCE-J (See previous comments).

Response: The technology descriptions for PCE machines have been modified.

Comment #8-27: p. 8-5: Exhibit 8-1 and 8-3 are repetitive with table in Ch. 4.

Response: For completeness, this chapter has included materials from others to summarize. These particular exhibits have been removed.

Comment #8-28: p. 8-8, third paragraph: The statement that multiprocess wetcleaning should be revised considering that energy costs associated with drying do not appear to have been factored. With drying costs included costs are right in the middle of the PCE cleaning cost range.

Response: EPA has considered the energy costs associated with drying for the wetcleaning technology. The multiprocess wetcleaning technology has been removed from the CTSA.

Comment #8-29: p. 8-8: The CTSA concludes that the lowest cost option is multi process wetcleaning. I do not believe this. The only reason it looks attractive is because there is no equipment investment. The pounds of clothing cleaned for the model case are far too low. As you increase the poundage cleaning requirements, multi process wetcleaning looks worse and worse because it involves significantly increased labor costs. The only reason it looks good here is because the pounds of clothing cleaned is so low.

Response: The multiprocess wetcleaning has been removed as a technology alternative.

Comment #8-30: p. 8-8, third paragraph: This paragraph should note that the costs of CO2 and wetcleaning are likely overestimated relative to PCE and PS because the latter don't include water or full energy costs. Even so, the costs per pound of the alternative technologies are similar.

Response: The costs of CO_2 technologies have not been included in the CTSA. The energy costs for dry-to-dry PCE and hydrocarbon technologies have been modified.

Comment #8-31: p. 8-8, second paragraph: Included controlled PS technologies with PS technologies.

Response: The CTSA no longer characterizes controlled hydrocarbon technology as distinct from hydrocarbon processes.

Comment #8-32: p. 8-11, fifth paragraph: No conclusions can be made about the relative performance of the cleaning technologies. It could appear that some could be. Cost effectiveness was not considered in chapter 6, as noted in this paragraph.

Response: EPA provides information on the performance of cleaning technologies in a previous chapter but does not make conclusions regarding the studies reviewed. Statements regarding consideration of cost-effectiveness have been corrected.

Comment #8-33: p. 8-12, Section 8.1.5, first sentence: Take out "are likely to".

Response: This language has been modified and the comment is no longer relevant.

Comment #8-34: p. 8-12, third paragraph: It should be added that environmental concerns are beginning to affect the ability of operators to retain leases on existing sites and limits their ability to establish or relocate to new sites. Further, environmental compliance costs have increased steadily and there is no reason to expect this trend to change.

Response: EPA has included some measure of costs associated with regulatory requirements. In addition, the EPA ahs included information describing federal regulatory requirements which can affect cleaners using the various processes.

Comment #8-35: Exhibit 8-6: The CO_2 column should be updated: Risk: no evidence of risk based on other industrial applications, State-of-Technology; technology licensed to five manufacturers - commercial availability early 1998, Clothing applicability: all, Odor: No, Cleaning Performance: wide range of clothes.

Response: Comparative information on the CO_2 technology has not been included in this chapter due to its status as an emerging technology.

Comment #8-36: p. 8-13, Exhibit 8-6: Other PCE liability costs include spills, production hazards, and liability for harm to residents. For PS explosions are another liability.

Response: Many of these are mentioned in this chapter.

Comment #8-37: p. 8-13, Exhibit 8-6, "CO2 Risk": Not a lot is known of the CO2 systems. One fact is clear. The Drycleaner will be operating a high pressure machine with pressures exceeding that of utility boilers that require difficult, "Black Seal" licenses to operate. There will be inherent risks of injury or death because of mechanical failure and the kinetic energy stored in the Drycleaning Machine because of the compressed gas. As we can see from the review of the many DOH testing in plants that were not well maintained, the Drycleaner is, in many cases, unable to maintain a leak tight seal on machines that run at less than 1 psi. To propose that these same workers and owners can run a critical pressure vessel is a reach. Not only is this impractical, but it is likely that licensing and insurance costs will escalate.

Response: The commenter is speculating on the operation and costs of the CO_2 technology. Because most of the information on this technology is speculative, EPA has not included it in its comparative assessment of technologies.

Comment #8-38: p. 8-13, Exhibit 8-6: Exhibit 8-6, PCE column, Potential liability costs row: Add co-located resident illnesses and co-located fetus illnesses to this cell and possibly to the PS column as well. Recent court decisions in California have found that if a pregnant mother delivers a mal-formed fetus and she was exposed to pollutants that most people are not exposed to, then there is liability on the polluters side. A direct cause and effect was not needed.

Response: A general mention of possible liability costs has been included.

Comment #8-39: p. 8-14, fifth paragraph: Why isn't even a basic social benefit/cost analysis not possible here. These are critical costs that should think about. The statement on page 8-17 about encouraging environmental considerations into decision-making is laudable, but naive. Companies are unlikely to incorporate external costs of their production in their decision-making unless required to do so.

Response: The data developed in the CTSA does not allow development of a quantitative or monetized social benefit/cost analysis. Information is presented qualitatively so that social costs may be considered when considering trade-offs among technologies.

Comment #8-40: p. 8-14, fifth full paragraph: Why is a complete social benefit/cost analysis "obviously not feasible?" Why not attempt to quantify the benefits?

Response: The data developed in the CTSA does not allow development of a quantitative or monetized social benefit/cost analysis. Information is presented qualitatively so that social costs may be considered when considering trade-offs among technologies.

Comment #8-41: p. 8-14, fourth paragraph: Other societal costs may include the unquantifiable psychological and social costs of disease.

Response: EPA acknowledges that health effects contribute to social costs. The costs mentioned by the commenter would be considered a part of these costs.

Comment #8-42: p. 8-15, Exhibit 8-7: I was confused by the inclusion of some terms such as "willingness-to-pay" in the exhibit, when they were not a significant part of the cost benefit analysis included in the chapter.

Response: Language on willingness-to-pay has been removed.

Comment #8-43: p. 8-15, Exhibit 8-7: "such costs may, for example, result from (not form)". Human health benefits - why is switching from PCE to wetcleaning not considered an example of a human health benefit. It is unlikely that there will be a move from PCE to other solvents (except PS).

Response: The typographical error has been corrected. This Exhibit does not identify benefits of specific technologies, it is a glossary of terms. Exhibit 10-8 does illustrate benefits and costs of alternative technologies, however, does not present them as incremental (e.g. benefits of switching from one technology to another).

Comment #8-44: p. 8-15, Exhibit 8-7: Note what DDT stands for and what it is.

Response: This language has been eliminated from the CTSA.

Comment #8-45: p. 8-17: There is no explanation as to why the particular representative technologies were chosen for analysis. What if others had been chosen?

Response: Technologies were chosen to be representative based on the likely level of occurrence in the industry. The results presented in the benefit-cost discussion would not change, however, if different representative machine configurations were chosen because the results that are presented are very general, with the exception of cost data. Selecting an alternative machine configuration to represent technologies might affect the absolute value of the cost numbers, but those numbers would not be expected to be significantly different.

Comment #8-46: p. 8-17: The "willingness-to-pay" example used has very little relevance to the analysis. Only minor health effects are included. Either a complete analysis including cancer should be included and justified or this section deleted. If the analysis is included or expanded, then some discussion of approaches other than "willingness-to-pay" should be added, given the controversy over that approach.

Response: The discussion on willingness-to-pay has been removed.

Comment #8-47: p. 8-17 to 8-21: The concept of "Willingness to pay" seems to me to be an example of "misplaced concreteness" and unnecessary to the conclusions made.

Response: The discussion on willingness-to-pay has been removed.

Comment #8-48: p. 8-17, third paragraph: Reducing unlike or difficult to quantify costs to a single monetary value as is done in cost-benefit analysis has been criticized by numerous economists. See Stallworth, 1995 and Ashford, 1991.

[Ashford, N. and C. Caldart. 1991. Technology, Law, and the Working Environment. New York: Van Nostrand Reinhold.

Stallworth, H. 1995. The cost-benefit paradigm for environmental protection: An economist's perspective on the methodological, theoretical, and ethical problems. New Solutions. Fall.]

Response: The discussion on willingness-to-pay has been removed.

Comment #8-49: p. 8-17, fourth paragraph: Why is willingness to pay to avoid eye irritation, a potential effect identified for wetcleaning technologies used as an example here? This choice, while easiest for an example places importance on a relatively insignificant health endpoint of wetcleaning. It would be much more instructive and realistic to demonstrate the difficulties in trying to calculate a willingness to pay to avoid cancer from PCE exposure.

Response: The discussion on willingness-to-pay has been removed.

Comment #8-50: p. 8-18, Exhibit 8-8: Willingness to pay has been criticized by numerous economists, including those within the agency for providing a biased estimate of costs. WTP in no means encompasses the full value of avoiding an adverse health effect, as different individuals will pay differently depending on their social and economic circumstances. For a critique on Willingness to Pay and Cost/Benefit Analysis from agency perspective, see Stallworth, 1995.

[Stallworth, H. 1995. The cost-benefit paradigm for environmental protection: An economist's perspective on the methodological, theoretical, and ethical problems. New Solutions. Fall.]

Response: The discussion on willingness-to-pay has been removed.

Comment #8-51: p. 8-18/19: Exhibit 8-8 places all health-related expenses in external costs; however, owner-operators and their family members on the premises are also at risk of adverse health effects and will bear these costs directly.

Response: Costs of worker illnesses, which would include owner-operators and family members, are described as private costs.

Comment #8-52: p. 8-18, Exhibit 8-8: The last column is labeled "Known External Costs" includes mostly "potential" health effects.

Response: EPA has considered the comment and has not revised the description in the table.

Comment #8-53: p. 8-20, second paragraph: PCE risks are downplayed with the sentence, "there are potential health and environmental risks associated with the release of PCE during the drycleaning process". There are important risks, period! "changes to current PCE technologies that may serve to reduce (not prevent) pollution." These changes will not prevent pollution. None of the 13 options will completely eliminate worker and neighbor exposure to PCE.

Response: EPA has not claimed that the PCE machine configurations included in the CTSA will eliminate exposures to PCE. EPA has reviewed that its language on risk is appropriate.

Comment #8-54: p. 8-20: The economic comparisons, tables, etc. were very good.

Response: No response necessary.

Comment #8-55: p. 8-21, Cost Effectiveness: Why is the cost effectiveness analysis not completed for alternative technologies (e.g., wetcleaning). The desired goal is reduction in PCE emissions, but by how much?

Response: Cost-effectiveness analyses for PCE and hydrocarbon technologies were developed to illustrate costs of reducing exposure to drycleaning solvents. The CTSA attempts to set no target levels of reduction in PCE emissions.

Similar calculations were not developed for wetcleaning because the measure of effectiveness (e.g., amount of PCE or HC releases) is not appropriate for the wetcleaning technology.

Comment #8-56: p. 8-21, section on cost-effectiveness: Note that reduction in PCE emissions is not a good surrogate for reducing exposures and risk necessarily. In particular, if one is focused on the high occupational risks, then one is likely to make a big distinction between machine types, but unlikely to distinguish between different types of vent controls. In addition, these estimates of cost-effectiveness do not give any information about the cost per unit of risk avoided which would be much more meaningful. Note that recent advances in the field of medicine and health have attempted to standardize cost-effectiveness analysis (see Risk in Perspective by Professor Milt Weinstein enclosed for an overview and relevant citations.)

Response: EPA acknowledges that emissions may not be entirely reflective of reductions in exposure and risk, however, believes that, it represents a reasonable surrogate for exposure (See comment 8-57). Since population risks estimates were not developed in the CTSA, it is not possible to present costs per unit of risk avoided.

Comment #8-57: p. 8-21, third paragraph: PCE releases are almost always indicative of exposure.

Response: EPA has suggested the use of emission data as a surrogate for exposure in its cost-effectiveness analysis.

Comment #8-58: p. 8-22, Exhibit 8-10: Relative health risks, to what? To uncontrolled PCE technology? This is confusing for the reader.

Response: "Relative" refers to risks in comparison to the other technologies presented. To keep the table concise, no changes were made to this table entry.

Comment #8-59: p. 8-26, second paragraph: Steam injection is a fire and/or explosion suppressing safety device and it is not intended to be used other than in those situations. Injection of live steam into the reclaimer during the dry cycle would impede the reclamation and damage the garments. And, therefore, no wastewater would be produced.

Response: The function of steam in dry-to-dry PS (HC) process could not be ascertained due to conflicting information received, and this issue was not addressed in the CTSA.

Comment #8-60: p. 8-27, Exhibit 8-13: I disagree with using 1.64% of capital cost for labor. Labor should be constant for all machines of the same solvent for the same amount of garments. Finishing costs are significantly more than PCE with machine wetcleaning, and slightly less with PS.

Response: EPA has removed labor cost estimates from the CTSA.

Comment #A-1: I believe that a better attempt should be made to characterize the risks associated with PS. First, the fire hazards should be characterized, along with the damages associated with a typical fire. There was a fire recently (March 1995) at a German drycleaner that I believe was using a relatively new PS system. You should talk to Manfred Wentz of R.R. Street & Co. (cited for personal communications 417 and 418 in the reference list) about this. Second, it is inappropriate to believe the PS are non-toxic simply because they have not been subjected to an animal bioassay. I believe that this makes a shift to PS look appealing since it is unregulated, but that this is not a good term strategy. In particular, if the industry were to switch entirely from PCE to PS (a switch that is unlikely but possible), then it seems very reasonable to me that PS would be a good candidate for testing in an animal bioassay and more regulation. Finally, some PS may be regulated as VOCs that contribute to tropospheric ozone and this should be discussed.

Response: The updated CTSA refers to PS (petroleum solvents) as HCs (hydrocarbon solvents). The characterization of HCs has been revised to consider flammability and there is a more complete discussion of toxicity. This also includes a derivation of a NOAEL (see new Appendix D - Dose Response Assessment).

Comment #A-2: The information gathered seems to be quite comprehensive. I cannot evaluate it fully as I am not expert in the chemicals listed.

Response: No action appears necessary.

Comment #A-3: As for wetcleaning, my only concern is the lack of consideration of the potential effect that excess moisture might have for microbial growth and respiratory effects in the workplace. I am not familiar enough with wetcleaning to rule this out and it is not apparent to me from the draft that it has been considered. I also mention that low levels of phosphates were also not a problem in the environment, it was only in large quantities (i.e., when many household cleaners used them) that they became a major water problem. The CTSA should be looking for effects that could be important if the entire industry switches. Also, the CTSA needs to address the situation of increased water consumption in areas where water is relatively scarce or during droughts, and the sensitivity of the costs to prices for water and sewer disposal.

Response: 1. Although possible, the issue of microbial growth and associated respiratory problems in wetcleaning operation environments is unlikely. This is because clothes that are wetcleaned are likely to be dried quickly and efficiently in order to prevent mildew and odors associated with microbes.

2. EPA agrees that the phosphate detergent problem was due primarily to their ubiquitous use.

3. The issue of water consumption and associated cost is an important one, but not one to be addressed in the hazard portion of the CTSA.

Comment #A-4: The remaining analysis is biased against concluding human risk. If EPA is now discounting mouse liver tumors as evidence of human cancer risk, this document is not the place to take that position.

Response: It is not clear to what specific text the commenter refers. The revisions acknowledge the emerging evidence for alternative metabolic pathways. They also include language clarifying the contributions of both animal and human data to the weight of evidence considered by the EPA and IARC in their classifications of PCE.

Comment #A-5: I thought this section provided a very good summary of the health effects literature on these compounds. Although the data on reproductive and developmental effects were presented (when available), there was little discussion of potential effects on children. At least, the absence of such studies should be mentioned, given the importance of this exposure group.

Response: The revised CTSA discusses the potential effects of many of the clothes cleaning technologies on children and other susceptible populations. Because of the nature of the available data, these revisions were made primarily in Chapter 4 (Exposure) and Chapter 5 (Risk).

Comment #A-6: The sins of chapter 4 are rooted in Appendix A. The review consists of loose statements on metabolic pathways implying reduced risk to people without any clear logical structure connecting these hypothesis to the result.

Response: The extensive revisions in both (final) Appendix C and (final) Chapter 3 reflect better organization and analyses, including metabolism.

Comment #A-7: p. A-1, fifth paragraph: Something got garbled here. In any event, as noted elsewhere in the Appendix, IARC reclassified PCE to 2A.

Response: Agree, change made.

Comment #A-8: p. A-1, second paragraph: There are a number of reports in the older literature (when PCE was used as an antihelminthic in humans) of specially sensitive individuals who were affected or died after relatively small oral doses. For example, one of the authors of a report from 1925 took 1 cc of PCE after breakfast and experienced that night prompt relaxation of the muscles with a slight cerebral discomfort. He had an unusual dream involving levitation which he believed was due to the effect of the PCE (Hall MC, Shillinger JE. Tetrachlorethylene, new anthelmintic, *Am J Trop Med* 5:229-237, p. 233).

Kendrick (Kendrick JF. The treatment of hookworm diseases with tetrachloroethylene. *Am J Trop Med & Hyg* 9:43--434) treated over 100 prisoners in India with doses of 2 to 3 cc. He reported PCE was much more likely to cause vomiting, and the prisoners unanimously preferred carbon tetrachloride as a medication. Subsequent use on more than 1500 individuals showed PCE was well tolerated by most patients, but one individual showed signs of serious intoxication, lapsing into total unconsciousness within a few hours of receiving a dose of 3 cc PCE. After intensive treatment he was revived and appeared to suffer no persistent adverse effects. In 1934 Manson (Manson D. A comparative record of anthelmintic treatment with tetrachloethylene and oil of chemopodium. *Indian Med Gazette* 69:500-507, 1934) reported one case of jaundice after therapeutic doses, and Wright (Wright WH, Bozicevich J, Gordon LS. Studies on oxyuriasis, V. Therapy with single doses of tetrachloethylene. *JAMA* 109:570-573, 1934) described an 11 year old boy who lapsed into a coma after receiving 1.1 cc of PCE. Recovery was complete.

Chaudhuri (Chaudhuri RN. Death following administration of tetrachlorethylene. *Indian Med Gazette* 82:115-116, 1947) reported a fatal case in a 30 year old male given a 3 cc dose, after which the patient experienced severe abdominal pain and died the following morning. At autopsy the small intestine was deeply congested with a well-defined inflammatory process extending through the jejunum and the whole length of the ileum.

There are still other reports (which I have not cited) to indicate that for some people PCE can have potentially serious and/or lethal side effects at comparatively small oral doses (a few cc).

Response: Hall and Shillinger (1925), Kendrick (1929), Wright et al. (1934), and Chaudhuri and Mukerji (1947) were all reviewed in response to this comment. These largely represent case reports and do not provide the same basis for inference as epidemiology can. Collectively, these data do show some serious consequences in certain individuals exposed to very low doses of PCE, however, the circumstances in most cases show other factors at play. Therefore, this old use of PCE and the associated human data, was not incorporated into the CTSA.

1. Hall and Shillinger (1925). It is simply not good science to accept a statement - made in passing at the end of the article - that an unusual dream experienced by one of the authors could be attributed to a self-administered dose of 1 ml PCE. There could have been a variety of reasons for "the dream" including anxiety associated with self-experimentation.

2. Kendrick (1929). A 0.06% incidence (1/1500) of an adverse effect is not very high. Only one patient of 1500 treated with PCE as an antihelmenthic experienced CNS effects. Importantly, the PCE was administered in magnesium sulfate (see below).

3. Wright et al. (1934). Fifty boys (7-16 years old) were treated for worms with PCE. Data were presented on 47 of them; 25 were treated with PCE in magnesium sulfate and 22 were treated with PCE in magnesium citrate. Those treated with the sulfate version experienced more CNS side effects (15 or 16/25) versus those treated with the citrate version (4/22). The authors concluded, citing an article in which similar symptoms were observed in people given magnesium sulfate alone, that the sulfate may have been the culprit. (NOTE: Of course, the difference could be due to bioavailability, but that is another story....).

4. Chaudhuri and Mukerji (1947). This case report is the only documented death associated with the use of PCE as an antihelmenthic agent. However, the patient was a street beggar with severe malnutrition and thus medically compromised. Although the PCE may have contributed to the death, the authors concluded that it would be unwise to treat hookworm with PCE if there is obvious evidence of malnutrition.

Comment #A-9: p. A-1, first paragraph, first sentence: It is certainly more accurate to write, "may cause cancer in liver, kidney and other organs."

Response: Agree, change made.

Comment #A-10: p. A-1 last paragraph, line 7: IARC has classified PCE as a Group 2A carcinogen (probably carcinogenic to humans). The next line should be deleted. It states the same thing.

Response: Agree, change made.

Comment #A-11: p. A-1, last paragraph: I believe the position of the IARC on PCE carcinogenicity was not clearly stated. While a classification of "probably carcinogenic to humans" is the one that

was designated by the IARC Working Group, I believe the category that goes with that language is B-1, rather than "A", "group carcinogen", or "B-2".

Response: Disagree. As noted in the preamble to all IARC Monographs, Group 2A is defined as "probably carcinogenic to humans" and is based on limited evidence in humans and sufficient evidence in animals. You may have confused the IARC classification system with the EPA classification system.

Comment #A-12: p. A-1, fifth paragraph: Mid-paragraph: redundant sentence.

Response: Agree, change made.

Comment #A-13: p. A-1, last paragraph and reference section: An explicit reference to the August 16, 1991 SAB report should be added to Appendix A. See general comments above. [Comment #4-138]

Response: Agree, change made.

Comment #A-14: The last paragraph of the first page of Appendix A has some confusion about what the IARC classification of PCE is. As noted in the August 6 "Clarification," (and by Dr. Ozonoff), it is 2A. The Science Advisory Board statements about where it might fall on the continuum or their concern for high PCE exposures are outdated, tendentious and irrelevant to this section and should be deleted from the paragraph.

Response: The change has been made to identify the correct IARC classification for PCE. The SAB statements were made in 1991 and the Agency will be reassessing the toxicity of PCE, including carcinogenicity, in the future.

Comment #A-15: p. A-1, last paragraph, line 7-8: Remove duplicated text.

Response: Agree, change made.

Comment #A-16: p. A-1 (and A-5, A-12, A-13): These sections, which discuss the likelihood that human metabolism could generate mutagenic metabolites via glutathione conjugation, are out-of-date. The preliminary data of Green et al. (1990), cited to indicate that humans do not have the ability to produce mutagenic metabolites via glutathione conjugation, are clearly superseded by the data of Birner et al. (1996, 1997) which clearly show that urinary metabolites are formed by glutathione conjugation after inhalation exposures. These studies are extremely important to the eventual understanding the human carcinogenic potential of PCE.

[Birner, G., W. Dekant and J. C. Parker. 1997. Biotransformation of perchloroethylene in humans: quantitation of urinary metabolites formed by glutathione conjugation after inhalation exposure. Department of Toxicology, University of Wurzburg, Wurzburg, Germany; US EPA, NCEA, Washington, DC. The Toxicologist 36: 314.

Birner, G., A. Rutkowska, and W. Dekant. 1996. N-acetyl-S-(1,2,2-trichlorovinyl)-L-cysteine and 2,2,2-trichloroethanol: two novel metabolites of tetrachloroethylene in humans after occupational exposure. Drug Metab Dispos 1996 Jan; 24 (1): 41-8.]

Response: The Birner et al. 1996 article has been reviewed and included in the current draft. The 1997 publication is only an abstract, and as such has not been subjected to peer review.

Comment #A-17: p. A-1 to A-13: The human health hazard data on PCE should be update to include key human studies should be updated based on the results of recent studies of liver toxicity (Altmann et al., 1990, 1992; 1995; Birner et al., 1996, 1997; Blair et al., 1993; Brodkin et al., 1995; Cavalleri et al., 1994; Ferroni et al., 1992; Gennari et al., 1992; Mutti et al., 1992; Ruder et al., 1994; Sallmen et al., 1995). They articles provide key data on the human health effects of PCE. We have enclosed copies of each article, and summaries of each article can be found in the NYSDOH Criteria Document).

[Altmann, L., H. Florian Neuhann, Ursula Kramer, Jutta Witten, and Erich Jermann. 1995. Neurobehavioral and neurophysiological outcome of chronic low-level tetrachloroethylene exposure measured in neighborhoods of drycleaning shops. Environmental Research : 69: 83-89.

Altmann, L., H. Wiegand, A.Bottger, F. Elstemeier and G. Winneke. 1992. Neurobehavioral and neurophysiological outcomes of acute repeated perchloroethylene exposure. Appl. Psych. 41: 269-279.

Altmann, L., A. Bottger and H. Wiegand. 1990. Neurophysiological and psychophysical measurements reveal effects of acute low-level organic solvent exposure in humans. Int. Arch Occup. Environ. Health. 3: 493-499.

Birner, G., W. Dekant and J. C. Parker. 1997. Biotransformation of perchloroethylene in humans: quantitation of urinary metabolites formed by glutathione conjugation after inhalation exposure. Department of Toxicology, University of Wurzburg, Wurzburg, Germany; US EPA, NCEA, Washington, DC. The Toxicologist 36: 314.

Birner, G., A. Rutkowska, and W. Dekant. 1996. N-acetyl-S-(1,2,2-trichlorovinyl)-L-cysteine and 2,2,2-trichloroethanol: two novel metabolites of tetrachloroethylene in humans after occupational exposure. Drug Metab Dispos 1996 Jan; 24 (1): 41-8.

Blair, A., P. A. Stewart, P.E. Tolbert, D. Grauman, F. X. Moran, J. Vaught and J. Rayner. 1990. Cancer and other causes of death among a cohort of drycleaners. Brit J. Ind. Med 47: 162-168.

Brodkin, C.A., W. Daniell, H. Checkoway, D. Echeverria, J. Johnson, K. Wang, R. Sohaey, D. Green, C. Redlich, D. Gretch and L. Rosenstock. 1995. Hepatic ultrasonic changes in workers exposed to perchloroethylene. Occup. Environ. Med. 52: 679-685.

Cavalleri, A., F. Gobba, M. Paltrinieri, G. Fantuzzi, E. Righi and G. Aggazzotti. 1994. Perchloroethylene exposure can induce colour vision loss. Neurosci. Lett. 179: 162-166.

Ferroni, C., L. Selis, A. Mutti, D. Folli, E. Bergamaschi and I. Franchini. 1992. Neurobehavioral and neuroendocrine effects of occupational exposure to perchloroethylene. Neurotoxicology. 13: 243-248.

Gennari, P., M. Naldi and R. Motta. 1992. Gamma-glutamyltransferase isoenzyme pattern in workers exposed to tetrachloroethylene. Am. J. Ind. Med. 21: 661-671.

Mutti, A., R. Alinovi, E. Bergamaschi, C. Biagini, S. Cavazzini, I. Franchini, R.R. Lauwerys, A. M. Bernard, H. Roels, E. Gelpi, J. Rosello, I. Ramis, R. G. Price, S. A. Taylor, M. DeBroe, G. D. Nuyts, H. Stolte, L. M. Fels and C. Herbort. 1992. Nephropathies and exposure to perchloroethylene in dry-cleaners. Lancet 340: 189-193.

Ruder, A.M., E.M. Ward and D.P. Brown. 1994. Cancer mortality in female and male dry-cleaning workers. J. Occup. Med. 36: 867-874.

Sallmen, M., M.L. Lindbohm, P.Kyyronen, E. Nykyri, A. Antilla, H. Taskinen, K. Hemminki. 1995. Reduced fertility among women exposed to organic solvents. Am. J. Ind. Med. 27: 699-713.

NYSDOH (New York State Department of Health) 1997. Preprint Draft. Tetrachloroethylene Ambient Air Criteria Document. February 1997. Bureau of Toxic Substance Assessment. Albany, N.Y.]

Response: Several studies mentioned by the commenter had already been included explicitly or by reference to IARC or ATSDR. The following were specifically reviewed and included in the CTSA: Brodkin et al. (1995); Gennari et al. (1992); Mutti et al. (1992); Ruder et al. (1994); and Sallmen et al. (1995).

Comment #A-18: p. A1, fourth paragraph: The last paragraph should be revised to read more positively that the epidemiological data are at least suggestive of a causal relationship between PCE exposure and excess cancer risk.

Response: A change has been made to reflect IARC's conclusion that human data show "limited evidence" of a causal relationship between PCE exposure and cancer.

Comment #A-19: p. A-2, Absorption: Was ingestion via food considered? PCE is absorbed readily in fatty food (hamburgers, pizzas) and these are frequently taken in the workplace very near the machines (it has been described to me).

Response: Although exposure to PCE via ingestion pathway is possible, the likelihood of its contributing significantly to workplace exposures is low. PCE is extremely volatile and thus would be present as a vapor/gas in workplace air. Estimating the amount of PCE that may settle out onto food that might be present in the workplace would entail a level of effort outside the scope of the screening type of analysis performed in a CTSA.

Comment #A-20: p. A-2: The CTSA cites ATSDR (1993), which is a toxicological profile for PCE. However, ATSDR has published an updated toxicity profile for PCE (ATSDR, 1995) that contains data and information not found in the earlier draft. It should be used, along with key primary references, to update Appendix A.

Response: In response to numerous comments (see Comments A-16 and A-17, for example), several recent articles that would probably cover all the important and pertinent information reported between the 1993 and 1995 ATSDR versions have been reviewed and incorporated.

Comment #A-21: p. A-2, paragraph 2: Data "in" mice?

Response: Agree, change made.

Comment #A-22: p. A-3, Lethality: Cf. Above referenced cites on lethal outcomes with small oral exposures.

[Chaudhuri RN. Death following administration of tetrachloroethylene. *Indian Med Gazette* 82:115-116, 1947) reported a fatal case in a 30 year old male given a 3 cc dose, after which the patient experienced severe abdominal pain and died the following morning. At autopsy the small intestine was deeply congested with a well-defined inflammatory process extending through the jejunum and the whole length of the ileum.]

Response: See response to Comment #A-8.

Comment #A-23: p. A-3: The products of glutathione conjugation have been observed in humans exposed to perc [Birner et al. 1996]. Paragraphs 2 and 3 should reflect this new information.

[Birner G, Rutkowska A, Dekant W [1996]. N-acetyl-*S*-(1,2,2-trichlorovinyl)-L-cysteine and 2,2,2-trichloroethanol. Drug Metab Dispos 24(1):41-48.]

Response: See response to #A-16 above.

Comment #A-24: p. A-3, second paragraph: I believe work from Henschler's group shows that this conjugation goes on in humans as well (Henschler D, Vamvakas S, Lammert M, Dekant W, Kraus B, Thomas B, Ulm K, "Increased incidence of renal cell tumors in a cohort of cardboard workers exposed to trichloroethylene," *Arch Toxicol* 70:131-133, 1995). Moreover, they have found kidney cancer in TCE exposed workers. Since the alleged mechanism holds also for TCE, this is relevant.

Response: The work of Birner et al (cited in Comments #A-16 and #A-23) on glutathione conjugation pertains to PCE, and thus is relevant to the CTSA and has been added to the current draft. Corroborating information with TCE, although nice, is not necessary to make the point in the CTSA and so will not be included.

Comment #A-25: p. A-4: The summary of information on the non-cancer kidney toxicity in humans should be updated to include the results of Mutti et al. (1992).

[Mutti, A., R. Alinovi, E. Bergamaschi, C. Biagini, S. Cavazzini, I. Franchini, R.R. Lauwerys, A. M. Bernard, H. Roels, E. Gelpi, J. Rosello, I. Ramis, R. G. Price, S. A. Taylor, M. DeBroe, G. D. Nuyts, H. Stolte, L. M. Fels and C. Herbort. 1992. Nephropathies and exposure to perchloroethylene in dry-cleaners. Lancet 340: 189-193.]

Response: The article has been reviewed and added to the current draft.

Comment #A-26: p. A-5, fifth paragraph: Cf. cite to paper by Manson, above; and also the report of Meckler and Phelps (Meckler LC, Phelps DK. Liver disease secondary to tetrachloroethylene exposure--a case report. *JAMA* 197:144-145, 1966) who report a case of acute hepatitis after inhalation of PCE fumes in a dry-cleaning establishment. Saland (Saland G. Accidental exposure to perchloroethylene. *New York State J Med* September, 1967, pp. 2359-3261) also reported abnormal liver function tests in eight of nine firefighters exposed for only three minutes at a dry-cleaning plant spill.

[Manson, D.A. 1934. Comparative record of anthelmintic treatment with tetrachloroethylene and oil of chemopodium. Indian med Gazette. 69:500-507.]

Response: EPA did not receive a copy of the Manson article, and was unable to locate it and retrieve it. Thus, it was not reviewed. However, see the response to Comment #A-8 on the issues of PCE use as an antihelmenthic and use of case reports.

EPA reviewed Meckler and Phelps (1966) and Saland (1967), and concluded that the Saland article was worthy of inclusion but the Meckler and Phelps article was not. This was based on the Saland article's reporting reversible liver effects in nine firemen after a fire at a dry-cleaning facility. The Meckler and Phelps article, on the other hand, was a single case report of a woman experiencing acute hepatitis after working in a dry-cleaning establishment for 2½ months. Symptoms went away two months later. There were no PCE measurements or estimates of exposure. It was felt that the Meckler and Phelps article did not add anything new or necessary to the discussion.

Comment #A-27: p. A-5, last sentence on page: The use of the term "confounding factors" for case reports is confusing. This is an epidemiological term and doesn't have a strict meaning in this context. Perhaps what is meant is "alternative explanations"?

Response: The sentence was changed to read "alternative explanations" instead of "confounding factors".

Comment #A-28: p. A-5: The section on liver toxicity should probably reference the evidence showing liver changes in workers chronically exposed to perchloroethylene >15 ppm demonstrated on ultrasound (Brodkin CA, et al. Hepatic ultrasonic changes in workers exposed to Perchloroethylene. Occ Env Med 1995;52:679-685).

Response: The Brodkin et al. article was reviewed and included in the CTSA.

Comment #A-29: p. A-5 and A-6: The summary of information on non-cancer liver toxicity in humans should be updated to include the results of Gennari et al. (1992) and Brodkin et al. (1995).

[Brodkin, C.A., W. Daniell, H. Checkoway, D. Echeverria, J. Johnson, K. Wang, R. Sohaey, D. Green, C. Redlich, D. Gretch and L. Rosenstock. 1995. Hepatic ultrasonic changes in workers exposed to perchloroethylene. Occup. Environ. Med. 52: 679-685.

Gennari, P., M. Naldi and R. Motta. 1992. Gamma-glutamyltransferase isoenzyme pattern in workers exposed to tetrachloroethylene. Am. J. Ind. Med. 21: 661-671.]

Response: Both references were reviewed and included in the CTSA.

Comment #A-30: p. A-6: Cf. Also references cited above.

Response: See responses to #A-28 and A-29.

Comment #A-31: p. A-6 (and other places): The correct spelling of Cheverria is Echeverria.

Response: Agree, change made.

Comment #A-32: p. A-6: Summary statements about the results of Dmitrieva and colleagues should be deleted from the CTSA. Although the results are discussed in US EPA (1985), the US EPA also stated "...that the credibility of the reports must be questioned until independently

replicated." Inclusion of these results, but the exclusion of recent, highly relevant studies on the neurological effects of PCE in humans is questionable.

Response: Agree, change made.

Comment #A-33: p. A-6, second new paragraph, third line from bottom: I suspect that the appropriate citation is to Echeverria (1995). This should be changed here and in the reference list.

Response: Agree, change made.

Comment #A-34: p. A-6: The summary of information on neurotoxicity in humans should be updated to include the results of recent studies by Altmann et al. (1990, 1992, 1995), Cavalleri et al. (1994), Ferroni et al. (1992) and Seeber (1989). The scientific reasoning that lead to including a summary on the recent results of Echeverria et al. (1995), but not a discussion of these equally important papers, is unclear.

[Altmann, L., H. Florian Neuhann, Ursula Kramer, Jutta Witten, and Erich Jermann. 1995. Neurobehavioral and neurophysiological outcome of chronic low-level tetrachloroethylene exposure measured in neighborhoods of drycleaning shops. Environmental Research : 69: 83-89.

Altmann, L., H. Wiegand, A. Bottger, F. Elstemeier and G. Winneke. 1992. Neurobehavioral and neurophysiological outcomes of acute repeated perchloroethylene exposure. Appl. Psych. 41: 269-279.

Altmann, L., A. Bottger and H. Wiegand. 1990. Neurophysiological and psychophysical measurements reveal effects of acute low-level organic solvent exposure in humans. Int. Arch Occup. Environ. Health. 3: 493-499.

Cavalleri, A., F. Gobba, M. Paltrinieri, G. Fantuzzi, E. Righi and G. Aggazzotti. 1994. Perchloroethylene exposure can induce colour vision loss. Neurosci. Lett. 179: 162-166.

Echeverria, D., R. F. White and C. Sampaio. 1995. A behavioral evaluation of PCE exposure in patients and drycleaners: A possible relationship between clinical and pre-clinical effects. JOEM. 37: 667-680.

Ferroni, C., L. Selis, A. Mutti, D. Folli, E. Bergamaschi and I. Franchini. 1992. Neurobehavioral and neuroendocrine effects of occupational exposure to perchloroethylene. Neurotoxicology. 13: 243-248.

Seeber, A. 1989. Neurobehavioral toxicity of long-term exposure to tetrachloroethylene. Neurotoxicol. Teratol. 11: 579-583.]

Response: The CTSA was not supposed to be a *de novo* assessment of risk, nor an exhaustive discussion of the literature. A number of these studies had been reviewed prior to the peer-reviewed draft, and EPA looked at this entire list prior to making revisions to the CTSA. Some changes have been made to augment the discussion of these endpoints.

Comment #A-35: p. A-6, third paragraph: The Cheverria et al. (1995) study referenced here seems to be the most sensitive endpoint for calculating and RfD. Why was it not used?

Response: This study had not been examined in the development of the provisional RfC we used that, while not a consensus document, had received some limited review by another office. The time frame of revisions after the Peer Review did not permit a complete assessment of all possible additional papers into a new provisional RfC; we expect the upcoming Agency assessment of PCE will pull the entire literature together. The study was included in the review of possible health

effects. Lacking an unexposed control group, the authors relied on demonstrating a dose-response gradient (by a comparison of low and high exposure groups) to establish a relationship between PCE and effects. Then-current levels of exposure for wet-transfer workers in the "low" group (for which lack of a control prevents establishing an effect) were 0.6 ppm ("expected in air" 11.2 ppm) and in the high group were 41.8 ppm ("expected in air" 40.8 ppm). No single overall measure of exposure across types of shop was provided, but the dry-to-dry high group was measured at 11.4 ppm in air ("expected" 11.1 ppm). All these effect levels are higher than the 10 ppm taken as the starting point for provisional RfC derivation from the Franchini et al. (1983) study.

Comment #A-36: p. A-7: The discussion of the Eskanazi paper should note that they found a 2 times increased time to pregnancy among the wives of drycleaners, compared with the wives of laundry workers.

Response: Agree, change made.

Comment #A-37: p. A-7: This reviewer recalls that the authors in Eshkenazi (1991a) concluded there was some adverse effect on reproductive health among wives of PCE exposed workers, perhaps longer time to pregnancy. The summary should be checked against the original reference.

The exposure response study showing adverse effects on semen quality is very strong evidence, although it needs to be confirmed.

Response: Agree, change made (on Eskenazi 1991a).

Comment #A-38: p. A-7: The citation ATSDR (1995) should probably be ATSDR (1993) because the 1995 Toxicity Profile for Tetrachloroethylene (which would be cited as ATSDR, 1995) is not in the reference list. The 1995 ATSDR toxicity profile cited in the reference list is for Stoddard Solvent.

Response: Agree, change made.

Comment #A-39: p. A-7, Human Data: In the recital of "limitations" of the existing studies, it seems that many of the limitations apply more to the negative studies than the positive ones. There is no apparent attempt to evaluate the significance of the limitations for the conclusions of the studies.

Response: An attempt was made to make the discussion more balanced.

Comment #A-40: p. A-7 and A-8: Although no definite conclusions can be drawn from the human data on the developmental/ reproductive toxicity of PCE, the CTSA does not provide a balanced discussion of the epidemiological data on developmental/reproductive toxicity. The CTSA emphasizes the negative characteristics of human studies without discussing their strengths. In addition, a recent paper by Sallmen et al. (1995) that found reduced fertility among women exposed to organic solvents, including PCE, was not cited. We have discussed both the strengths and weakness of the human data in the NYSDOH Criteria Document (pages 40-42).

[NYSDOH (New York State Department of Health) 1997. Preprint Draft. Tetrachloroethylene Ambient Air Criteria Document. February 1997. Bureau of Toxic Substance Assessment. Albany, N.Y.

Sallmen, M., M.L. Lindbohm, P. Kyyronen, E. Nykyri, A. Antilla, H. Taskinen, K. Hemminki. 1995. Reduced fertility among women exposed to organic solvents. Am. J. Ind. Med. 27: 699-713.]

Response: See response to #A-39. Also, the Sallmen et al. study was reviewed and included in the current CTSA.

Comment #A-41: p. A-9 and A-10: Based on our analysis of the HSIA-sponsored multigeneration reproductive study of rats exposed to 0, 100, 300, or 1,000 ppm of PCE (found on pages 43 - 45 and Tables 5 - 7 of the NYSDOH Criteria Document), we believe that the lowest dose in the study (100 ppm) is not a clear-cut NOEL as implied in the CTSA. We recommend additional discussion of the results of the study indicating some of the uncertainties in the study results.

[NYSDOH (New York State Department of Health) 1997. Preprint Draft. Tetrachloroethylene Ambient Air Criteria Document. February 1997. Bureau of Toxic Substance Assessment. Albany, N.Y.]

Response: EPA recognizes there is more than one way to interpret a study. Our conclusions are based on our analysis and EPA believes that 100 ppm is the appropriate NOAEL.

Comment #A-42: p. A-10: The mutagenicity discussion should be updated to include the results of Birner et al. [1996].

[Birner G, Rutkowska A, Dekant W [1996]. N-acetyl-*S*-(1,2,2-trichlorovinyl)-L-cysteine and 2,2,2-trichloroethanol. Drug Metab Dispos 24(1):41-48.]

Response: Agree, change made (see response to Comment #A-16).

Comment #A-43: p. A-10 and A-11: The discussion of the epidemiological data on cancer is not balanced. The CTSA emphasizes the negative characteristics of the studies without discussing their strengths. A key paper by Blair et al. (1993) is not cited but several weak, early studies on dry-cleaning and laundry workers are cited. The strengths and weakness of the human carcinogenicity data are discussed in the NYSDOH Criteria Document (pages 58-62), IARC (1995) and Weiss (1995).

[NYSDOH (New York State Department of Health) 1997. Preprint Draft. Tetrachloroethylene Ambient Air Criteria Document. February 1997. Bureau of Toxic Substance Assessment. Albany, N.Y.

Weiss, N. 1995. Cancer in relation to occupational exposure to perchloroethylene. Cancer Causes and Control, Vol. 6: 257-266.]

Response: This section has been modified and is believed to represent a more balanced discussion.

Comment #A-44: p. A-10: The critical review of epidemiology in drycleaning would be the IARC review. This reviewer believes that the Duh 1984 study cited was of drycleaners in Oklahoma exposed only to Stoddard solvent. Results of this study should be checked and if this is so, cited under petroleum solvents.

Response: The IARC (1995) review has been added to this section of the CTSA. According to EPA (1985), the Duh and Asal (1984) study was based on drycleaners and laundry workers in Oklahoma who died during the period 1975-1981. The authors noted that petroleum solvents accounted for over 50% of the drycleaning solvents used in OK in 1983.

Comment #A-45: p. A-10: The critical review of epidemiology in drycleaning would be the IARC review. This reviewer believes that the Duh 1984 study cited was of drycleaners in Oklahoma exposed only to Stoddard solvent. Results of this study should be checked and if this is so, cited under petroleum solvents.

Response: Repeat of Comment #A-44.

Comment #A-46: p. A-10, final paragraph: The study by Duh and Asal (reference #111) is included in the carcinogenicity data pertaining to PCE. As indicated above, I believe the results of this study are probably more relevant to the potential carcinogenicity of petroleum solvents.

Response: See Comment #A-43 and #A-44.

Comment #A-47: p. A-11: A more recent review of the carcinogenicity of perchloroethylene has been published and might well be referenced here: Weiss NS. Cancer in relation to occupational exposure to perchloroethylene. Cancer Causes and Control. 1995;6:257-266. They review two large studies which you have also reviewed, and conclude that risk of esophageal and bladder carcinomas were elevated in exposed workers, particularly those exposed to prolonged employment, and long duration since first employment.

Response: Additional interpretation of studies we included can be helpful. EPA did not include Weiss (1995), however, because we already had the conclusions of IARC available to include in our discussion.

Comment #A-48: p. A-11: Ruder et al. (1994) found an association between PCE exposures and esophageal cancer. The summary discussion of this work in the CTSA states that the authors did not explore the possible influence of smoking and alcohol on the risk of esophageal cancer. However, the published article (Ruder et al., 1994) contains a discussion of the possible role of alcohol and smoking comes to the conclusion that "we (Ruder et al.) cannot assume that the excess esophageal cancer mortality is due either to drinking or smoking".

[Ruder, A.M., E.M. Ward and D.P. Brown. 1994. Cancer mortality in female and male dry-cleaning workers. J. Occup. Med. 36: 867-874.]

Response: This section of the CTSA has been reworded to show that Ruder et al. did not determine the smoking/alcohol intake status of their cohort. However, they indirectly inferred that these factors did not play a role due to the low lung cancer rates and liver cirrhosis rates observed in the cohort.

Comment #A-49: p. A-11, Residential Studies: The Aschengrau et al. (1993) study is incorrectly referred to as a Woburn study. It was actually a study on Cape Cod. Moreover, associations were also noted for bladder cancer, and kidney cancer could not be evaluated because latencies were too short. The exposure definition was quantitative and precise, based on a mathematical model that had laboratory validation. The limitations of small sample size are not unusual and dealt with by statistical tools. Causal interpretation was possible. The writers need not agree with it, but should not mistake the case.

Response: EPA takes exception to the statements that the exposure definition was "quantitative and precise". As EPA read the paper, the exposures were based on an engineering model of PCE leaching from the water distribution system in the region of interest to the investigators; thus, there were no actual PCE measurements taken. Furthermore, the only odds ratio in Table 4 for which the lower 95% CI is above 1 is for bladder cancers, under "high PCE exposure conditions", when latency is NOT considered. (NOTE: There were not enough data to do a similar analysis considering latency).

Comment #A-50: p. A-11: The first paragraph incorrectly reports that "Although smoking and alcohol are both risk factors for esophageal cancer, investigators failed to explore the possible influence of these confounding factors [Ruder et al. 1994]." This study did discuss the possible effect of smoking and drinking on esophageal cancer risk, and showed that risks of other diseases associated with high levels of smoking and drinking in a population (i.e., lung cancer and cirrhosis of the liver) were not significantly elevated in this cohort.

Response: See response to Comment #A-48.

Comment #A-51: p. A-12, Overall Evidence: Much of the peroxisome proliferation work cited is quite old. The field has moved quickly and what seemed like a nice story a few years back is now much less clear. The Peroxisome Proliferator Activated Receptor has been cloned and knockouts made. At this point any discussion of the role of PPAR in PCE metabolism would be speculation.

Response: The exact mechanism of action of peroxisome proliferators is still unclear.

Comment #A-52: p. A-12: The review of the NTP study should quote the NTP levels of evidence, which I recall were clear evidence for both the rat and mouse study. The exposure response relationship for leukemias in the rat are much more impressive if mortality adjusted rates -- the appropriate test for this lethal tumor -- are used.

Response: The CTSA reports the tumor incidence by tumor type for all the tumors of interest in both rats and mice. This is actually more informative than simply providing the NTP conclusions. For the record, NTP concluded there was clear evidence of carcinogenicity for male rats (leukemia and kidney cancer) and male and female mice (liver cancer), and some evidence of carcinogenicity for female rats (leukemia).

Comment #A-53: p. A-12: "Overall Evidence" More of this needs to be incorporated earlier in the main part of the document.

Response: No action appears necessary.

Comment #A-54: p. A-12, third paragraph, fifth line: The leukemia excess observed was highly significant, statistically in both male and female rats, if my recollection is correct. It should not be characterized as "marginally increased."

Response: As implied by the response to Comment #A-52, the incidence and severity of leukemias in male rats were higher than those in the female rats.

Comment #A-55: p. A-12 -13: The metabolism of perc via the glutathione pathway produces trichloro- compounds rather than dichloro- compounds as stated

Response: Agree, change made.

Comment #A-56: p. A-16, System Toxicity, first paragraph: "Aplastic anemia **and leukemia have** been causally linked to benzene-containing solvents".

Response: Agree, change made.

Comment #A-57: p. A-18, second paragraph: Under "Carcinogenicity": several errors in second sentence: lung cancer...prostate (not prostrate) cancer...

Response: Agree, changes made.

Comment #A-58: p. A-18, Carcinogenicity, first paragraph: "prostrate" should be "prostate."

Response: Agree, change made.

Comment #A-59: p. A-18, Carcinogenicity, second paragraph: "Case-referent" is a synonym for "case-control" design, not, as the parenthetical remark implies, a specific type of such design

Response: Agree, change made.

Comment #A-60: p. A-38: On p. A-38, three reasons for not discussing the health hazards of EMFs are given in the context of Microwave Drying. These reasons are inadequate. First, the magnitudes of EMFs from other technologies may well have been measured (by the EMF group at NIOSH), and it should be possible for some agency to get data from the microwave dryer manufacturers. Second, the fact that there is no consensus about "everyday exposures" to EMFs affecting human health does not apply here. This section is discussing industrial-level exposures from large dryers, which are not "everyday exposures." Finally, the personal reference to Dr. McGaughy, 1994) regarding the lack of qualitative difference in EMFs from microwave appliances and other appliances is not relevant here. There are several studies of cancer and other health

effects from workplace appliances which produce EMF exposure. I have enclosed one by Coogan, et al., 1996 that indicates increased risk of breast cancer in women with high potential for exposure to 60-Hz magnetic fields because of their occupations.

[Coogan, P.F., Clapp, R.W., Newcomb, P.A., Wenzl, T.B., Bogdon, G., MiHendorf, R., Baron, J.A., Longnecker, M.P. Occupational Exposure to 60-Hertz Magnetic Fields & Risk of Breast Cancer in Women. 1996. Epidemiology. 7:459-464.]

Response: Irrelevant because microwave drying has been removed from the CTSA.

Comment #A-61: p. A-43, second paragraph: Word missing.

Response: Agree, change made.

Comment #A-62: p. A-48, Subacute/Subchronic/Chronic Toxicity: Humans: The last line of the paragraph, the concentration number is grammatically incorrect. It should read 25 mg/kg/day.

Response: This sentence has been removed from the CTSA.

Appendix B

Comment #B-1: p. B-17, Exhibit B-11: Where is the study results from the apartment study that was in excess of 1,000 times the acceptable limits and the child care center on the second floor above the drycleaning establishment that was 680 times the acceptable limits, study results were printed in the Metro Voice newspaper, dated May 26, 1992.

Response : This newspaper article refers to PCE samples taken by the New York Department of Health. PCE samples collected by this organization have been discussed in the CTSA.

Comment #B-2: p. B-21, second paragraph: It would seem that the release rates in line 2 would be higher for the no control and lower for the best control per-site, but the converse appears to hold. Furthermore, the statement in bold text makes the assumption that release is constant 24 hours/day for 365 days/year. Shops do not clean continuously, and exposure would be at most for a 12 hour shift.

Response : These modeling results have been removed from the CTSA. Since monitoring data exist for PCE concentrations in air, it was decided that the locality modeling was not needed.

Comment #B-3: p. B-25, line 2: "EPA data shows" should be "EPA data show"

Response: The reviewer correctly identified a typographical error. The detailed information on this study has been removed from the CTSA. Readers can obtain this information from the original study.

Comment #B-4: p. B-25, fifth paragraph: "55% Polyester/55% wool" should be "55% Polyester/45% wool"

Response: The reviewer correctly identified a typographical error. The detailed information on this study has been removed from the CTSA. Readers can obtain this information from the original study.

Comment #B-5: p. B-28, Exhibit B-23: Michigan study results from commercial establishments revealed trace amounts (parts per billion) in garments after garments came from the finish department for bagging, however, high ppm concentrations of PCE were always found in garments from the coin-operated (small 8-15 pound) drycleaner units found mainly in the laundromat establishments.

Response to Comment #B-5": An analysis of coin-operated drycleaners is outside the scope of this assessment.

Comment #B-6: p. B-34, Exhibit B-28: There is a ? after tidal water body.

Response : This scenario has been revised. Instead of site-specific streamflow values, the revised estimates of surface water concentrations are based on streamflows from Standard Industrial Classification (SIC) codes. This exhibit is no longer in the CTSA.

Appendix C

Comment #C-1: Adequate discussion subject to the concerns raised above.

Response : No specific action appeared necessary. Owing to the reformatting of comments for our response, it's not clear which these concerns are; we hope, however, the various revisions to the text will make the CTSA generally more readable.

Comment #C-2: This section should be combined with the health effects summary in Appendix A. This would make it easier for the reader to refer back to the actual studies in evaluating this confusing matter.

Response : We did not make this change. While it is likely helpful for a reader to refer to discussion of particular studies while examining how they are or are not used in dose-response evaluations, combining this appendix's text into the health effects summary of what is now Appendix C was thought to be more cumbersome for the reader than a short expansion of the considerations in Appendix D itself.

Comment #C-3: Page C-1 raises the issue of whether the cancer dose-response relationship for perc is likely to be linear at low doses. One source of information which may be relevant to this issue is the shape of the dose-response curve in the animal studies. We suggest that Appendix C should include the model form and maximum likelihood estimates (MLE) of the best-fit model coefficients for those models used in the derivation of the unit risk, and discuss whether or not the best-fit models are in fact consistent with the assumption of low-dose linearity. A recent study by Bois et al. [1996] could be cited to argue that the uptake and metabolism of perc may be strikingly nonlinear, such that the low-dose uptake and metabolism from environmental exposures may be seriously underestimated by the use of high-dose experimental data. Bois FY, Gelman A, Jiang J, Maszle D.R., Zeise L, Alexeef G [1996]. Population toxicokinetics of tetrachloroethylene. Arch Toxicol 70:347-355.

Response : We have not included these discussions since the CTSA reports the results of already-available assessments, and the modeling is described in USEPA (1987). The statistic for goodness of fit only permits judgements regarding adequacy of fit. Among those models that are adequate, that statistic cannot serve to identify one as fitting best, although some different criterion can be added for selection among them. Confidence bands for those adequately-fitting models give guidance on whether they are consistent with low-dose linearity. Bois et al. (1996) discuss a scheme in which metabolism is linear below 1 ppm exposure. We understand the commenter's issue is that starting at a higher exposure to make the linearity assumption may result in missing the relationship (and underestimating) at the lower ones.

Comment #C-4: p. C-1, second paragraph, next to last line: The phrase "doses close to background" has no useful meaning. I believe what was intended was to indicate doses that might cause incremental effects that are smaller than or comparable to the background *response*.

Response : Actually what is meant here is "doses close to the amounts people showing background response receive." Reviewer comments will be taken into consideration in examining language to convey these distinctions.

Comment #C-5: p. C-1 to C-3: The dose-response for the carcinogenic effects is competently done using the standard US EPA methods.

Response : No action appears to be necessary.

Comment #C-6: p. C-1, fourth paragraph, last sentence and footnote: I strongly recommend redoing the equivalents based on 3/4 power scaling. The effect is NOT small, in my opinion. For 350 gram rats and 70 kg humans, the difference is nearly a factor of 2, which could be very important!

Response : No change was made in the calculation, since the CTSA is only reporting the results of already-available assessments. A comment on the magnitude of the impact of a change in scaling factor, however, has been included in the footnote.

Comment #C-7: p. C-1, third paragraph, first sentence: Very awkward construction. Confusing to read.

Response : The text has been changed to "A specific cancer dose-response assessment is developed under an assumption that the agent is a human carcinogen. It is intended quantitatively to define the relationship between the dose of the agent and the likelihood of a carcinogenic effect."

Comment #C-8: p. C-2, Nonprojection Approach, line 3: Just what is the limit of the range of observation? The sentence should read *The multistage model was use to estimate the ED10...*

Response : This language was simplified essentially as suggested by the commenter.

Comment #C-9: p. C-2, first paragraph, last line: *Nonoverlapping* did not convey to me what I believe was intended, namely, that double-counting of certain tumor types was avoided.

Response : We agree that this language is confusing and the sentence "Consequently, ...nonoverlapping data." has been deleted.

Comment #C-10: p. C-3 to C-6: The provisional RfC (0.17 mg/m^3) is derived in a competent manner using standard Agency methods. It is similar to the ambient air criterion (0.1 mg/m^3) derived by the NYS DOH (NYS DOH Criteria Document) and the chronic MRL (0.28 mg/m^3) derived by the ATSDR (1995). However, we disagree with the selection of Franchini et al. (1983) as the principal study. Other more recent studies, particularly studies by studies by Cavalleri et al., 1994; Ferroni et al., 1992; Mutti et al., 1992, may be better choices. Alternatively, the use of all available human data (e.g., Altmann et al., 1990, 1992, 1995; Cavalleri et al., 1994; Ferroni et al., 1992; Seeber, 1989; Mutti et al., 1992; Gennari et al., 1992; Brodkin et al., 1995) could be used in the derivation, similar to the approach NYS DOH used to develop an air criterion for non-cancer effects (NYS DOH Criteria Document). The use of all the data may not substantially change the

RfC, however, given the concern expressed in the CTSA over the use of the Franchini et al. (1983) to derive the RfC and the overall quality and consistency of the recent human studies on PCE, the use of the recent studies in the derivation can only increase confidence in the derived RfC.

[Altmann, L., H. Florian Neuhann, Ursula Kramer, Jutta Witten, and Erich Jermann. 1995. Neurobehavioral and naurophysiological outcome of chronic low-level tetrachloroethylene exposure measured in neighborhoods of dry cleaning shops. Environmental Research : 69: 83-89.

Altmann, L., H. Wiegand, A. Bottger, F. Elstemeier and G. Winneke. 1992. Neurobehavioral and neurophysiological outcomes of acute repeated perchloroethylene exposure. Appl. Psych. 41: 269-279.

Altmann, L., A. Bottger and H. Wiegand. 1990. Neurophysiological and psychophysical measurements reveal effects of acute low-level organic solvent exposure in humans. Int. Arch Occup. Environ. Health. 3: 493-499.

Brodkin, C.A., W. Daniell, H. Checkoway, D. Echeverria, J. Johnson, K. Wang, R. Sohaey, D. Green, C. Redlich, D. Gretch and L. Rosenstock. 1995. Hepatic ultrasonic changes in workers exposed to perchloroethylene. Occup. Environ. Med. 52: 679-685.

Cavalleri, A., F. Gobba, M. Paltrinieri, G. Fantuzzi, E. Righi and G. Aggazzotti. 1994. Perchloroethylene exposure can induce colour vision loss. Neurosci. Lett. 179: 162-166.

Ferroni, C., L. Selis, A. Mutti, D. Folli, E. Bergamaschi and I. Franchini. 1992. Neurobehavioral and neuroendocrine effects of occupational exposure to perchloroethylene. Neurotoxicology. 13: 243-248.

Gennari, P., M. Naldi and R. Motta. 1992. Gamma-glutamyltransferase isoenzyme pattern in workers exposed to tetrachloroethylene. Am. J. Ind. Med. 21: 661-671.

Mutti, A., R. Alinovi, E. Bergamaschi, C. Biagini, S. Cavazzini, I. Franchini, R.R. Lauwerys, A. M. Bernard, H. Roels, E. Gelpi, J. Rosello, I. Ramis, R. G. Price, S. A. Taylor, M. DeBroe, G. D. Nuyts, H. Stolte, L. M. Fels and C. Herbort. 1992. Nephropathies and exposure to perchloroethylene in dry-cleaners. Lancet 340: 189-193.

NYSDOH (New York State Department of Health) 1997. Preprint Draft. Tetrachloroethylene Ambient Air Criteria Document. February 1997. Bureau of Toxic Substance Assessment. Albany, N.Y.

Seeber, A. 1989. Neurobehavioral toxicity of long-term exposure to tetrachloroethylene. Neurotoxicol. Teratol. 11: 579-83.]

Response : This is a provisional assessment carried out solely for the CTSA. While it has been reviewed by ORD, it does not represent a full Agency position. A complete consensus assessment, including peer review, is scheduled to be undertaken soon. Rather than start de novo with a different study at this time, we included a comment on how other studies suggested by the reviewer compare to the CTSA's choice.

Comment #C-11: p. C-3 to C-6: Although we do not disagree with the application of a 100-fold uncertainty factor to the LOAEL identified in Franchini et al. (1993), we do have concerns over the choice of the individual uncertainty factors (10 for NOAEL to LOAEL and 10 for sensitive individuals). Recent discussion of empirically-based uncertainty factors (e.g., Dourson et al., 1996) suggest that using a 10-fold uncertainty factor to estimate a NOAEL from the LOAEL may be too large. On the other hand, the choice of not using an uncertainty factor to account for a less-than-lifetime exposures because "...14 years seems a substantial length of time" is not adequately defended.

Response : More discussion has been included on the choice of uncertainty factors.

Comment #C-12: p. C-3, third paragraph: This paragraph discusses the similarity of the NOEL for mice and rats with respect to PCE. However, critical information is not presented concerning the tested dose and spacing of doses allowing the reader to better address this issue.

Response : No text was added on this matter since the RfD was not a de novo assessment. This information is provided in IRIS, which is publicly available.

Comment #C-13: p. C-3, line 1: See previous comments about preferring 3/4 power scaling to surface area scaling.

Response : No change was made in the calculation, since the CTSA is only reporting the results of already-available assessments. A comment on the magnitude of the impact of a change in scaling factor, however, has been included in the footnote.

Comment #C-14: p. C-3, Effects Other Than Cancer, second paragraph, line 2: Specify the type of hepatotoxicity.

Response : According to IRIS, the hepatotoxicity observed in mice reported in the Buben and O'Flaherty study were increased liver triglycerides and increased liver/body weight ratios at the dose identified as the LOAEL (100 mg/kg/d), and the following liver effects at higher doses: decreased DNA content, increased SGPRT, decreased G6P, and hepatocellular necrosis, degeneration, and polyploidy.

Comment #C-15: p. C-3, Effects Other Than Cancer, third paragraph, line 2: Is *mild renal tubule damage* reversible? If so, say so; if not, say so.

Response : We are not sure whether the mild renal damage is reversible or not since the Franchini study inferred renal damage based on urinary biomarkers of renal function.

Comment #C-16: p. C-3, footnote 6: If you compare the unit risk based on the LED10 to the unit risk from the linearized multistage modeling procedure, they are remarkedly close, as I would expect: 7.1×10^{-7} vs. 6.9×10^{-7} per ug/m^3. This should be noted because it demonstrates that linear at low dose extends all the way up to 10% response levels!

Response : As identified in the response to Comment #4-148, this is truly no surprise since the same computer routine is used in that range. For that reason, we did not remark on its similarity, and we used the ED10 for discussions in the Risk chapter (now Chapter 5).

Comment #C-17: p. C-4, second paragraph, line 8: Specify the type of *Renal function impairment.*

Response : A parenthetic remark was added. Four types of urinalysis outcome were taken as indicators; the impairment is shown in the third full paragraph on page C-3.

Comment #C-18: p. C-4, third paragraph, second sentence: What are the implications of this mysterious statement:

Response : Regrettably, making some kind of clarifying change in this language was overlooked. We are reporting the outcomes of the authors' statistical analyses, but it is possible that their conclusions, regarding which indicators show differences for which occupational groups, are mistaken, owing to the potential for the post hoc multiple comparison to perform poorly with small groups (despite apparent normality after transformation).

Comment #C-19: p. C-4: The discussion of renal effects could also include the Mutti et al. [1992] study.

[Mutti A, Alinovi R, Bergamaschi E, Biagini C, Cavazzini S, Franchini I et al. [1992]. Nephropathies and exposure to perchloroethylene in dry cleaners. Lancet 340(8813):189-197.]

Response : We chose not to include Mutti et al. (1992) in this Appendix. Mutti et al. (1992) appears to be aimed at confirming that a group of urinary and serum markers of nephrotoxicity can be used to discriminate between workers who have been exposed to PCE and subjects who have not been exposed. It did not appear that the measures used in Franchini et al. (1983) were among those for which the authors wanted to confirm association. For this Appendix, where the interest is in quantifying the level at which exposure does not show effects, this study's information on exposure levels was insufficiently described. Mutti et al. (1992) is included in the ATSDR summary, which has been cited in what is now Appendix C.

Comment #C-20: p. C-7, line 2: The only reference to *neurotoxicity* in this appendix appears here. Yet neurotoxicity (dizziness??) was repeatedly cited in Chapter 4 as a potential adverse health effect. Isn't that kind of ludicrous?

Response : No change was made. While this may be the only use of "neurotoxicity" in what is now Appendix D, the current Appendix C includes Stewart et al. (1981) under the heading "Neurotoxicity". The Peer Review Appendix C (now Appendix D) explicitly indicated (page C-6, line 7) that this study refers to changes in electroencephalogram results.

Cleaner Technologies
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Response to Peer Review Comments
Addendum

Note: Comments are organized into general comments and then those pertaining to each chapter of the CTSA. For example, Comment #A4-1 is the first comment pertaining to Chapter 4.

General Comments

Comment #AG-1, Flow, Does each of these chapters clearly explain its purpose? If the chapter purpose is not clearly articulated, indicate what you believe the purpose of the chapter was: Yes I think the chapters are chosen in the correct order. However there is no mention of risk communication or employee training as a method to reduce exposure and health risk. Further given the depth, I think it would be good to place at the end of each chapter a lessons learned section with main points relating the new information in the chapter with the previous chapter's data, i.e., performance with exposure; performance with cost; cost with exposure etc.. And not wait to chapter 8.

Response: Employee training as a method of reducing exposure and risk is mentioned in the updated CTSA, Chapter 9. EPA has revised the CTSA to enhance the organization and readability of the document.

Comment #AG-2, Process Descriptions, Is the text clear and well presented? Can you suggest other ways to present the information to enhance its clarity?: Yes to all three questions - the only issue is whether all of the detail is needed. I would try to see if one could select elements that clearly discriminate between process as being key to health risk.

Response: Some extraneous details have been removed, and more focus has been placed on equipment that impacts release, exposure, and associated risk.

Comment #AG-3, Environmental Release Estimates, Do tables/figures enhance understanding of the information presented in these chapters? If not, how should the information be presented? Please provide an example: I can not judge water and environmental exposures to PCE well. It is not my training. However, I can speak to the occupational PCE and PS data. The perception by the reader is that there are no clear demarcations in exposure between type of worker in the drycleaning business which is not true. The zones of exposure are clear and reproducible by job title and type of process in the industry. Use our reported data as an example. [See comment #A2-1 references.]

Response: More and better differentiated data have been presented to demonstrate the "zones of exposure" that the commenter mentions.

Comment #AG-4, Environmental Release Assessments, Are there inconsistencies between the data presented in the tables and text? Can you suggest other ways to present the information? Please

provide an example: I was also looking for concentration of emissions to the air by type of process and found the data poorly developed and expressed in comparison with the occupational data.

Response: Concentrations in air are relevant to exposure, while releases to air are intended to be used to develop exposure information. Releases are expressed as amounts of mass per time. It appears that the commenter was looking for exposure information in the release section. Therefore, in some cases, concentrations by process type have been reported in the exposure section.

Expressing concentrations of emissions to air by type of process is probably not all that significant for the general population. This is because exposures received by the general population are generally low, unless individuals live in close proximity to a drycleaner. In contrast, measured air concentrations received by co-located residents have been reported based on the type of processes involved.

Comment #AG-5, Chapter 1-8, Are relevant references provided for the information contained in each of these chapters: There is a lot of redundancy of what is not in each section which is not very helpful and in some Chapters little that is really new given the sparsity of the data on alternative technologies. I would say this once and then not address it again unless data is available. [See comment #A2-1 references.]

See specific comments for each chapter.

Add some missing references that I have provided in the packet.

Response: EPA has revised the document to enhance readability. Some redundancy may exist across chapters; however, this is necessary to ensure that chapters are complete and can stand alone. EPA has moved information on emerging technologies to a separate chapter because of the sparsity and disparity of the information.

Comment #AG-6, Comment on the Clarification Statement of EPA's Position on the Carcinogenicity of Perc: We support inclusion of the statement attached to your letter of August 6, and believe that it better reflects current knowledge and the positions of IARC, EPA, and the SAB. However, we are not sure of the intended meaning of the following sentence contained in the statement: "Workers and residents working and living near drycleaning establishments that send clothes to another location for cleaning are likely to be at low risk." It is not clear whether this sentence refers to employees of such establishments. Although perchloroethylene is not used on-site at such facilities, we question whether workers in these facilities are really "at low risk," given that they work around and handle large volumes of freshly cleaned clothes, perhaps under conditions of poor ventilation. We suggest that the sentence be modified to clarify that it does not pertain to workers within such drycleaning establishments.

Response: This information has been clarified in the updated CTSA.

Comment #AG-7, Comments on Other Relevant Literature: We list here some additional references that can supplement the draft CTSA, particularly with regard to the non-cancer hazard identification (Appendix A) and risk characterization (Chapter 4 and Appendix C). A study by Mutti et al. (The

Lancet, 340:189, 1992) provides additional evidence of renal dysfunction among drycleaning works exposed to perchloroethylene. In addition, there have been several studies that have reported neurobehavioral effects among perchloroethylene-exposed drycleaning workers. Among these are:

Seeber, Neurotoxicology and Teratology, 11:579-583, 1989
Ferroni et al., Neurotoxicology, 13:243-248, 1992
Echeverria et al., JOEM, 37:667-680
Rao et al., Regulatory Toxicology and Pharmacology, 18:233-247, 1993.

The last paper on this list contains a quantitative meta-analysis of studies describing perchloroethylene-related neurotoxic effects.

Response: The Seeber and Ferroni articles were reviewed based on Peer Reviewer's comments. The Echeverria article was included in the draft seen by the Peer Reviewers, but was misidentified in the text as "Cheverria". The Rao et al. article was not included or reviewed in-depth for inclusion in this CTSA because a provisional RfC was derived specifically for the CTSA. The intent of the CTSA was to be a screening level risk assessment; not an exhaustive search of the literature and an associated comprehensive cancer/noncancer risk assessment. It is anticipated that this article will be included in the comprehensive assessment planned by the Agency in the future.

Executive Summary

Comment #AES-1, p. ES-1, first paragraph: The chapter order is not maintained in the first section of the executive summary. What is the true order? Assuming the chapter order is correct then follow it for the introduction and reorder every sentence to reflect the chapter order, i.e., risk, performance, and cost (chapters 4,5,6). The first sentence enumerates cost, risk, and performance (chapters 6,4,5) - please change it. The second and third paragraphs also have to be rewritten to reflect the order.

Response: EPA has revised the Executive Summary to more closely follow the organization of the CTSA.

Comment #AES-2, p. ES-3: Remove Box with Project Considerations - it is out of place here and never referred to and put it in the limitations section of chapter 1.

Response: EPA has removed this box from the CTSA.

Comment #AES-3, p. ES-4, first paragraph: Results from two of our studies found visual spatial memory and perception to be impaired (see enclosed publication). The same tests were used in both studies and agreed with each other. Short term memory of digits was not impaired in either study so it is visual not verbal short term memory. These studies were conducted in Detroit and Seattle 7 years apart with n≐80 and n≐200 respectively.

I am enclosing a BHARC report to NIOSH (public domain) and another publication on PCE. The BHARC report has 12 publications which are going to press this year and you may use any or all in a reference or citation as a Battelle Report or journal article.

Response: See response to A2-1, assuming that the studies referred to in AES-3 are the ones listed under Comment A2-1.

Comment #AES-4, p. ES-6: Order sections and paragraphs to reflect order of the chapters : here you have exposure, risk, cost, performance, trade-offs; reverse performance and cost to be consistent.

Response: EPA has revised the Executive Summary to more closely follow the organization of the CTSA.

Comment #AES-5, p. ES-7, Conclusions: Rewrite first sentence to reflect priorities of the report in that order. Also do not conclude with what it won't do - conclude with what it will do for the reader.

Response: EPA has revised the presentation of the Executive Summary and strengthened the conclusions.

Chapter 1

Comment #A1-1, General Comments: This chapter is very thorough. It suffers from too much detail and not enough road maps to make the content interesting to read. Also there is very little that is really new which is the state of the art but begs the question of the scope of the work.

Response: EPA has revised this chapter.

Comment #A1-2, General Comments: Eliminate redundancy.

Response: The CTSA has been revised and redundancy has been eliminated where appropriate. Some redundancy may remain across chapters to ensure that they are complete and can stand alone.

Comment #A1-3, General Comments: Bullet data in front of sections.

Response: The document has been revised to improve its presentation and readability.

Comment #A1-4, General Comments: Explain the importance of the external comparisons with other countries.

Response: Most of the information related to other countries has been removed and has explained its relevance where it has been maintained.

Comment #A1-5, General Comments: Define what is meant by alternative technology (not PCE?).

Response: Terms such as alternative technology have been clarified.

Comment #A1-7, p. 1-1, first paragraph: We have not been provided with a rationale for going outside the USA- why? Please provide a rationale for the expansion.

Response: Most of the information related to other countries has been removed and its relevance has been explained where it has been maintained.

Comment #A1-8, p. 1-2, first paragraph: Again list the topics in the order of chapters.

Response: EPA has revised text in the introductory chapter to follow the order of chapters

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Comment #A1-9, p. 1-3, third paragraph: Using PCE as a "baseline" from which to extrapolate the relative costs and exposures may be OK but note the "relative toxicity" of alternative compounds is problematic. I would not state this is your approach because you did not mean what you wrote. It may be true for costs but not health effects. I would change the word baseline and replace it with

a more accurate word say "Basis for comparison" and indicate that toxicity and health effects are not evaluated in the same way but on a case-by-case basis.

For example, the biological half-life of PCE (t.5) is 72 hours in blood so bioaccumulation is a reasonable but not for Stoddard solvent or freon.

Response: EPA has revised language to clarify the use of the PCE technology as a basis for technology comparisons, and has made clear that toxicity and health effects are not evaluated in a manner similar to costs and exposures.

Comment #A1-10, p. 1-4: Why is this exhibit located here? It has not been mentioned yet and I could not find the discussion that went with it.

Response: This exhibit has been removed from the document.

Comment #A1-11, p. 1-5, last paragraph: End with what this document will provide, not what it won't provide.

Response: The commenter's concern is not clear; however, EPA has revised the Executive Summary and conclusionary language in the text to better describe the relevance of information and conclusions.

Comment #A1-12, p. 1-6, box: Avoid jargon like "use cluster"; delete second sentence and move it to a place where limitations are discussed; last paragraph in the box is not the chapter order; Place the box on ES-3 under the 1-6 Box; add discussion.

Note that the same warning of missing data is sprinkled through-out the document and really gets in the way. It would be best to eliminate the redundancy.

Response: The CTSA has been revised to improve its presentation. Both the Executive Summary and Chapter 1 have been strengthened. Some redundancy across chapters may still remain, however, to ensure that chapters are complete and can stand alone.

Comment #A1-13, p. 1-7, second paragraph under Section 1.2.1: Delete what is in brackets which does not address the definition. This is true for the 3rd paragraph as well which starts with "Some consumers...."

Definitions need to be short and clear.

Response: This information has been revised in the CTSA.

Comment #A1-14, p. 1-7, last paragraph: Don't say PCE the first time. Use Perchloroethylene (PCE) and then PCE from then on...

Response: This change has been made.

Comment #A1-15, p. 1-7: Track this is several places...

Response: The comment is not clear. No action has been taken as a result of this comment.

Comment #A1-16, p. 1-8: Put exhibit 1.1 under the first paragraph.

Response: This exhibit has been removed.

Comment #A1-17, p. 1-8, Subheading under Section 1.2.2: Say " PCE Processes".

Response: This change would have been incorporated. However, the heading was changed to more appropriately represent the contents.

Comment #A1-18, p. 1-8, Section 1.2.2 before last paragraph: Insert Exhibit 1-2 here.

Response: EPA has revised and reorganized this material. The Exhibit has been appropriately placed.

Comment #A1-19, p. 1-8 through 1-18: This section reads very dryly and can be made more interesting by adding bullets in front of each subheading section with key points or technologies otherwise one gets bored very easily. The graphics will really help.

Also consider illustrating some of the points with data you present later, i.e., discuss filtration processes and then say (See Exhibit X-X which compares....). This will help the reader retain the technical information.

A boxed set of bullets might be another way which can be followed with the technical text. But right now I get lost with the detail. Give the reader roadmaps

Response: Although this is a good suggestion for editing, timing did not permit its implementation.

Comment #A1-20, p. 1-21, CO2 processes and p. 1-23 Ultrasonic Cleaning: Note this is first time I am reading anything new that I did not know before.

Response: No action necessary.

Comment #A1-21, p. 1-25, Section 1.3: This is a well written and clear section.

Response: No action necessary.

Comment #A1-22, p. 1-32, Section 1.4: Again why is this section useful to us as readers?

Response: This section has been removed from the CTSA.

Chapter 2

Comment #A2-1, General Comments: This chapter is very broad and very disparate in that it puts regulatory data with chemical data. You might want to segregate the components and eliminate redundancy.

Add our PCE and Stoddard Solvent studies into the health effects literature.

Rocskay AZ, Robins TG, Echeverria D. Renal Effects of Naphtha Exposure among Automotive Workers. *Journal of Occupational Medicine* 35(6):617-622, 1993.

Rocskay AZ, Robins TG, Echeverria D. Estimation of cumulative exposures to naphtha at an automobile fuel injector manufacturing plant. *Am Ind Hyg Assoc J* 54(9):480-487, 1993.

White RF, Robins TG, Proctor S, Echeverria D, Rocskay AZ. Neuropsychological effects of exposure to naphtha among automotive workers. *Occupational and Environmental Medicine* 51:102-112, 1994.

Checkoway, H, Echeverria D, Moon J-D, Heyer N, Costa LG. Platelet monoamine oxidase B activity in workers exposed to styrene. *Occupational and Environmental Health* 66(5):359-362, 1994.

Echeverria D, White RF, Sampaio C. A behavioral evaluation of PCE exposure in Patients and Drycleaners: A possible relationship between clinical and preclinical effects. *J of Occupational and Env Med* 37(6):667-680, 1995.

Publications in Press

Echeverria D, Heyer N, Bittner A, Checkoway H. (In press, 1995) A behavioral evaluation of PCE exposure in drycleaners in Seattle. *Neurotoxicol and Teratol.*

Proctor S, White RF, Robins TG, Echeverria D. Health Effects of naphtha exposure among automotive workers: III The Impact of Overtime on Behavior (in press, 1995). *British Journal of Industrial Medicine.*

Technical Reports

Echeverria D, Heyer N, Checkoway H, Bittner AC Jr., Toutonghi G, Ronhovde N. Behavioral Effects of Solvents: A comparison between perchloroethylene (PCE) exposure in drycleaners and Styrene Exposure in Reinforced Plastic Laminators. BHARC Rep. 100/94/040. Battelle, Seattle, WA, 1994.

Response: Due to the CTSA's being a screening level assessment, a decision was made early on to use Stoddard solvent as a representative hydrocarbon solvent for the analysis of hazard, exposure, and risk to the use of such solvents in dry-cleaning. Four (Rocskay et al. 1993a,b; White et al. 1994; and Proctor et al. 1995) of the eight articles you list in your comments deal with "naphtha" in an automotive plant setting. (NOTE: The *Journal of Occupational and Environmental Medicine*, formerly called the *British Journal of Industrial Medicine* was searched, but the Proctor et al. article listed as in press at BJIM could not be located. The author index for 1994, 1995, 1996, and 1997 were searched).

EPA understands that Stoddard solvent has several synonyms including "solvent naphtha". The Stoddard solvent used in the CTSA has a CAS Number (8052-41-3) and is made up primarily of C9 compounds. The naphtha described in the articles, for which no CAS Number is given, is simply listed as a mixture of hydrocarbons with from 5-15 carbons; 50% of which are paraffins. According to the Rocskay and White articles, it appears that the naphtha used in the commenter's studies was more similar to gasoline as opposed to the type of naphtha that might be used as a drycleaning solvent. In fact, the purpose of the naphtha used by the automakers was as a surrogate for gasoline to test fuel-injection mechanisms.

In addition, the ATSDR Toxicological Profile (1995) on Stoddard solvent that was used for the hazard section of the CTSA did not include any of the articles you cited on naphtha; presumably because it is a different mixture.

Three (Echeverria et al. 1994 and 1995a,b) of the remaining articles deal with PCE and one article deals with exposure to styrene (Checkoway et al. 1994). One of the Echeverria articles was indeed considered in the CTSA (misidentified in the text as "Cheverria"). There is no doubt that all of these PCE articles will be considered in the comprehensive assessment planned by the Agency in the future. The relevance of the styrene article to drycleaning is unclear.

Comment #A2-2, p. 2-10, second paragraph: Please read the studies we provided you with this enclosure [see comment #A2-1]. The Seattle study was conducted at the tie of the promulgation of the standard and I can assure that the Detroit levels in 1985 were twice that of Seattle 89'-93'.

Response: See response to Comment A2-1.

Comment #A2-3, p. 2-14, Section 2.2.7, second paragraph: See our attached publications [see comment #A2-1]; the chronic CNS effects we found were restricted to visual-spatial memory and perception which were only apparent post 3-years of exposure in the Detroit and Seattle studies. We replicated our findings twice.

Again given the long half-life of PCE, it is expected that these effects are linked to chronic exposure, especially since acute exposure was not high enough to kick in (<45 ppm).

Response: See response to Comment A2-1.

Comment #A2-4, p. 2-17: The chemical data that is presented in an accessible manner to a chemist and toxicologist but will leave most owners behind. Is an Appendix not more useful??

Response: The Hazard Summary (now Chapter 3) has been revised and most of the information alluded to now appears in Appendix A.

Comment #A2-5, p. 2-51: Page 2-51 of the CTSA describes OSHA requirements that are relevant to drycleaning operations using perchloroethylene or it substitutes. We have several comments here that are meant to clarify.

Paragraph one should make clear that OSHA currently enforces PELs that include 8-hour time-weighted averages (TWAs), ceiling limits, and peak limits; 15-minute STELs are found only in our comprehensive single-substance standards, none of which seem likely to apply to drycleaning operations. In addition, the document should clarify that employers may not legally permit employees to be exposed in excess of any PEL; the sentence that reads "A PEL is an eight-hour time-weighted average (TWA) exposure that workers should not exceed" should be revised accordingly. The paragraph also states that a PEL assumes a 40-hour work week, 50-week work year, and 40 years of work. Although OSHA uses similar kinds of assumptions in its risk assessments, the existing PELs contained in 1910.1000 are not based on any such assumptions,

given that they were adopted 27 years ago from recommendations of other organizations. We suggest deleting this sentence in the CTSA draft.

The first sentence of paragraph two should indicate that PELs for some substances (contained in 1910.1000 Table Z-2) were adopted from various standards issued by the American National Standards Institute (ANSI), the PELs for perchloroethylene being among these. The paragraph also refers to OSHA's 1988 proposal to revise the PELs, and should instead refer to the final standard promulgated in 1989. After the final rule was issued, the rule was vacated by the 11th Circuit Court in 1992. The basis for the Court's decision is complex and is not accurately represented in the CTSA draft. We request that EPA delete the portion of the sentence in the middle of the paragraph that explains the Court's reasons. We also suggest that the subsequent sentence be revised as follows: "Therefore, Federal OSHA is not currently enforcing the 212 revised PELs or the 168 new PELs promulgated in 1989." In addition, delete the sentence that refers to the general duty clause since it implies that OSHA is actively enforcing the 164 new PELs contained in the 1989 rulemaking.

In the 3rd paragraph (under the heading "PCE Cleaning), the first sentence should again refer to the "25 ppm level promulgated by OSHA in 1989." Also, OSHA has not issued a recommendation that exposures be maintained below 25 ppm; please delete this statement from the draft. The description of OSHA's current PELs for perchloroethylene is also inaccurate, and should read as follows: 100 ppm as an 8-hour TWA, a 200 ppm ceiling limit that may be exceeded for no more than 5 minutes in any 3-hour work period, and a 300 ppm peak concentration that may never be exceeded for any length of time. Paragraph (B)(3) of 1910.1000 contains a proper interpretation of Table Z-2.

In the section labeled "Petroleum Solvent Cleaning", you may wish to specifically identify 29 CFR 1910.106 (Flammable and Combustible Liquids) as an OSHA standard that may have particular relevance here.

Response: The Hazard Summary chapter (now Chapter 3) has been extensively revised and this text has been removed.

Comment #A2-6, p. 2-53: This section 2.4.7 appears out of place and sort of left hanging in space.

Response: EPA has revised its presentation of regulatory and other requirements affecting the professional fabricare industry and organized it into a separate chapter.

The Hazard Summary chapter (now Chapter 3) has been extensively revised and this text has been removed.

Chapter 3

Comment #A3-1, p. 3-3, paragraph at top of page: It is somewhat inconsistent to use 1991 figures for perchloroethylene consumption at this point when Chapter 1 quoted 1995 figures of 66,000,000 or 55,000,000 kg/year.

Response: This total PCE release from the PCE drycleaning NESHAP background document and all nationwide release estimates have been removed from the CTSA.

Comment #A3-2, p. 3-3, second paragraph: A great deal if not most of the waste water from the drycleaning process comes from the moisture or relative humidity contained in the textiles themselves. This is particularly true during the summer months and in humid areas. Also, water is almost never added during the distillation process. There was a great deal of research done on this technique a number of years ago but it was never adopted by the industry to any extent. Lastly, a great deal of separator water is now evaporated rather than discharged to sewers.

Response: Some of these points have been included in the discussion.

Comment #A3-3, p. 3-3, fourth paragraph: The data used to develop the NESHAP was collected approximately ten years ago. Given changes in physical plant since then, its relevance is questionable.

Response: When data from the NESHAP were used, it was either the best or the only data which were found. Uncertainties about data are explained in the CTSA. However, much of the data from the PCE drycleaning NESHAP background document and all nationwide release estimates have been removed from the CTSA.

Comment #A3-4, p. 3-5, sample calculation at top of page: It doesn't seem appropriate to mix metric and imperial measure in the same calculation.

Response: These calculations are no longer included in the CTSA.

Comment #A3-5, p. 3-6, first paragraph: The assertion that 9400 Mg/year represents eight percent of perchloroethylene consumption is difficult to reconcile. This would mean that total consumption is 117,500,000 kg per year. That would be the fourth figure quoted. The range is now 55,000,000 to 117,500,000 kg per year.

Response: The nationwide release estimates and issues have been removed from the CTSA, so the comment is no longer relevant.

Comment #A3-6, p. 3-7, fourth and fifth bullets: Configurations PCED-D and PCE-E were never particularly common and are now very rare. I think that the inclusion of these obscure, outdated technologies tends to confuse the issue.

Response: The updated CTSA has reduced the amount of information on "old and outdated technologies." PCE-D and PCE-E and other configurations using azeotropic vent control have been removed from the assessment.

Comment #A3-7, p. 3-14, second paragraph: There is repeated reference in the document to the use of carbon adsorption technology with petroleum solvent cleaning. As I noted in my general comments, this technology does not exist.

Response: The error of including carbon adsorption as a primary vapor emission control for HC (PS) processes has been corrected.

Comment #A3-8, p. 3-15, Exhibit 3-5: There is repeated reference in the document to the use of carbon adsorption technology with petroleum solvent cleaning. As I noted in my general comments, this technology does not exist.

Response: The error of including carbon adsorption as a primary vapor emission control for HC (PS) processes has been corrected.

Comment #A3-9, p. 3-16, last paragraph: In discussions on multiprocess wetcleaning, references to the use of a "wire brush" seem to come up from time to time. One would never use a wire brush on cloth. Normally, spots would be removed with a nylon spotting brush or a corn brush. I think this misconception developed during the early work on multiprocess wetcleaning. It is one of those silly little mistakes that reduces the credibility of the document.

Response: The multi-process wetcleaning process is no longer included in the CTSA.

Comment #A3-10, p. 3-16, paragraph at top of page: There doesn't seem to be any criteria in the document to determine whether plants operate 250 or 312 days per year. Both numbers are used but there doesn't seem to be a lot of logic in the choice. Actually, both scenarios are quite common but very often the sixth day is only half a day. In large urban centers, it is quite common now for plants to operate on Sunday as well. More research is needed in this area.

Response: The nationwide release estimates and issues, including this inconsistency, have been removed from the CTSA, therefore, issues of inconsistency of number of working days has been eliminated. Data on days of plant operation were not found in the readily available literature.

Comment #A3-11, p. 3-17, section on Solid Waste Releases: It is somewhat of a moot print but this residue would probably tend to accumulate on the floor and be mopped up. It seems more likely that it would be released to water rather than as solid waste.

Response: The multi-process wetcleaning process is no longer assessed in the CTSA.

Comment #A3-12, p. 3-18, section on Water Releases: This section is poor. What is the point of dealing with releases of unknown substances?

Response: This discussion has been removed from the CTSA.

Comment #A3-13, p. 3-19, Section 3.1.5, first paragraph: Again, I think I would have to question the wisdom of trying to make detailed calculations on such speculative data. The observation with respect to CFC-113 is almost anecdotal in nature.

Response: Information on CO_2 releases has been deleted from the CTSA.

Comment #A3-14, p. 3-23, second to last paragraph: Please add our PCE results [see comment #A2-1 references] to your health effects section where we used 8 hour TWA's.

Response: The commenter's data do not reflect any significant differences or new trends from the data presented in either the peer review and updated versions of the CTSA.

Comment #A3-15, p. 3-24, paragraph at top of page: This is very poorly done and indicates to me that little if any actual research was done on machine wetcleaning. All detergents and supplies are automatically fed to these units in liquid form. Powder feed is seldom if ever used in these processes.

Response: Because this case has not been demonstrated as even remotely likely, this method and estimation have been removed from the CTSA.

Comment #A3-16, p. 3-27, last paragraph: Your conclusion should be softened. It is true that we can distinguish job titles by air and breath levels in drycleaning establishments and it is not too difficult to conduct. It has been successfully done by at least three researchers. So please do not conclude that the variation in task is too great - 8 hour TWAs work to distinguish zones of exposure. See our results. There are clearly marked patterns between counter, pressor, and operators.

Response: No studies were found that reflect how the population of drycleaning workers may rotate through jobs of change jobs within a facility over time and how such rotation and changing jobs may affect exposures over time. Therefore, although exposure zones may be appropriately assigned to a job title, the same may not apply to the individuals working in those jobs.

Comment #A3-17, p. 3-27, last paragraph: I think this data needs to be reviewed carefully. It seems to be an excessively rigid view of a fairly flexible area. The notion of 108,300 "operators" seems particularly flawed.

Response: The method used to estimate numbers of workers has been improved, and a range of possible numbers has been presented in the updated CTSA.

Comment #A3-18, p. 3-28, box: Check your values against our own [see comment #A2-1 references] and you will see a drop from 1985 to 1990-93. This is very important to note from a regulatory point of view. Also add our data to this exhibit 3-9

Response: This drop in time is reflected in the data in both the peer review and updated versions of the CTSA. The regulatory issue is not relevant to this CTSA. The occupational data in all exhibits are each from a single literature or on-line source. The commenter's data do not reflect any significant differences or new trends from the data presented in the updated CTSA.

Comment #A3-19, p. 3-28, Exhibit 3-9: The exposure results for the "Manager" job description seem very odd. Under most circumstances, this individual would be considerably less exposed than most other workers. In order to really comment on this, we would need to see exactly what the "Manager's" job entailed. In any event, the data does seem to be highly suspect for this job description.

Response: The "oddity" of this result has been discussed briefly in the CTSA.

Comment #A3-20, p. 3-29: The exposure data that is shown for PCE should not be confused with the exposure levels that can be achieved for drycleaners. Most of the exposure data does not differentiate between the types of machines used or how long the sample was taken. A better comparison would be between dry-to-dry equipment to the other new technologies since transfer equipment is old technology and is no longer produced.

Response: The worker exposure data have been expanded to include additional differentiated data. The associated exposure issues have also been better explained.

Comment #A3-21, p. 3-45: The exhibit 3-19--how were these numbers derived? Why is it assumed that the exposure duration per event is 7, 8 or 9 days per even? Since earlier in the section the clothes are supposed to build to a maximum within a few hours and decrease exponentially. Also there is no mention on what the estimated exposure is during each event.

Response: This scenario has been revised using more recent study results from Consumers Union. Assumptions are discussed in the revised exposure chapter.

Comment #A3-22, p. 3-47, Exhibit 3-21: This data and the data presented in Exhibit 3-22 is really only useful in terms of evaluating conventional petroleum technology. It is quite misleading with respect to the technology that is now available. As I noted in my general comments, I think we have to anticipate that petroleum technologies will become more common as the quantity of perchloroethylene used declines. In this regard, I think it is important to present more data on the technologies that are being sold today as opposed to the outdated equipment that this data covers.

Response: Although the commenter's concern is valid, all occupational data found for PS technologies were included. No data were found for the "new" PS technologies.

Comment #A3-23, p. 3-55, first paragraph: Again, there is reference here to powder feed of supplies. This is seldom done today. The same comment would apply to Exhibit 3-27.

Response: This method was merely shown as a way to estimate exposures in this potential case, and the text does not de-emphasize the need for this method enough. Because this case has not been demonstrated as even remotely likely, this method and estimation have been removed from the CTSA.

Chapter 4

Comment #A4-1, General Comments: Data for occupational exposures is better than the data for environmental exposures. Emission levels from stacks should not be excluded - this is an EPA document. Add our occupational data which distinguishes Jobs and tasks quite well. [See comment #A2-1 references]

Response: Release estimates were made at a screening level of analysis. It was not possible to include in the revised CTSA all data received or suggested.

Comment #A4-2, General Comment: The risk characterization for cancer contained in Chapter 4 relies on two alternative approaches: (1) estimation of population risks based on an estimate of unit risk, and (2) a margin of exposure approach (MOE) along the lines of EPA's proposed cancer risk assessment guidelines.

The estimation of population risks is based on an aggregate unit risk estimate, given in the text as 7.1E-07 per ug/m^3 of continuous lifetime exposure. This estimate represents the geometric mean of unit risk estimates presented in EPA (1986) across 4 data sets: male and female mouse liver carcinoma or adenoma, and male and female rat MCL, combined with the use of a PBPK model to estimate human equivalent doses for bioassays (see p. C-2 of draft CTSA). Table 4-9 of the EPA 1986 Review Draft Addendum provides a summary of the estimated unit risks for each bioassay data set; the unit risks for the 4 data sets relied on in the CTSA range from 2.85E-06 to 1.06E-05 per ug/m^3, with a geometric mean of 4.7E-06 per ug/m^3 as shown in the tale below (all estimates are based on the LMS model). The figure given in the CTSA is almost 7-fold lower than that GM estimate presented here.

Unit Risk per ug/m^3 as reported in EPA 1986 Tables 4-7, 4-8

Mouse carcinoma and adenoma	PBPK Method unit risk	Method 1 ln (unit risk)	sum ln (unit risk
male	1.1E-05	-11.4547	-12.2612371
female	4.9E-06	-12.2304	
Rat leukemia			GM unit risk
male	3.4E--06	-12.5917	4.73E-06
female	2.85E-05	-12.7682	

If the CTSA estimate is based on analysis different from that shown here, it should be described explicitly. Perhaps 7.1E-07 per ug/m^3 is a unit estimate adjusted for the occupational rather than the continuous environmental exposure shown above.

Response: No change was made in the numbers. The commenter seems to have read a different set of numbers from the source. The estimate on pages C-1 and C-2 of the Peer Review draft is based on a calculation direct from a human as shown in Table 4-6 of EPA (1986). In Table 4-9, this is described as Method II (not Method I as the commenter chose), and its footnote refers to urinary metabolites estimated to be 7.83 E-06 mg/(body weight)$^{2/3}$/day at 1 μg/m^3. These calculations are the ones consistent with those identified on page 60 of EPA (1991), the most recent official EPA position. The only modification for the CTSA has been the correction to avoid double counting animals. No PBPK modeling has been officially incorporated to date.

Comment #A4-3, General Comment: To determine the MOE for each exposure scenario addressed in Chapter 4, EPA estimates the ED10 to be 2.7E05 ug/m^3 (with a lower bound of 1.4E05 ug/m^3), based on the same 4 animal data sets as described above. These estimates were generated by first estimating the ED10 based on metabolized dose, and dividing by 7.83E-06 mg/(body weight)^2/3/day to convert back to units of ug/m^3 for the ED10 (see pages C-2 to C-3 of the CTSA). However, EPA's 1986 document estimates that 1 ug/m^3 continuous exposure is equivalent to 4.65E-05 mg/(body weight)^2/3/day, almost 6-fold higher than the figure used in the draft CTSA (see p. 4-24 of EPA 1986, footnote "a" to table 4-9). Again, if the draft CTSA's figure is based on something other than the EPA 1986 document, it should state so explicitly. (Note that the CTSA's conversion factor of 7.83E-06 mg/(body weight)^2/3/day resembles the EPA 1986 figure of 7.89E-04 total mg metabolized for continuous human exposure to 1 ug/m^3). The table below shows our estimates of the ED10 for each data set, along with the GM ED10, based on use of the multistage model; this analysis estimates the ED10 concentration to be 4.1E5 ug/m^3.

ED-10 Analysis MLE ED-10 mouse carcinoma and adenoma	ED10 (ug/m^3)*	ln ED10	sum ln ED10
male	2.3E+04	10.06104	10.62582394
female	3.8E+04	10.54975	
rat leukemia			GM ED10
male	5.4E+04	10.8967	4.12E+04
female	6.0E+04	10.99581	
LCL ED-10 mouse carcinoma and adenoma			sum ln ED10
male	9.9E+03	9.196089	9.978345447
female	1.9E+04	9.858141	
rat leukemia			GM ED10
male	3.1E+04	10.34112	2.16E+04
female	3.7E+04	10.51803	

*Calculated by dividing the ED10 for mg/W^(2/3)/d by the metabolized dose corresponding to 1 ug/m^3 continuous exposure (4.65E-05 mg/W^(2/3)/d).

Again referring to the occupational risk characterization contained in Exhibit 4-3, p. 4-11 of the CTSA draft, using the conversion factor of 4.65E-05 mg/(body weight)^2/3/day for continuous human exposure to 1 ug/m^3 results in a substantial decrease in the MOE estimates. The estimated ED10, expressed as a concentration, would be 41 mg/m^3, rather than 270 mg/m^3 as indicated in footnote "c" to Exhibit 4-3. The MOE for "All Jobs" combined would be 2.9 (as compared to 19), and the lowest MOE among all listed job descriptions would be 0.8 (as opposed to 5.5).

Response: As described in the response to comment #A4-2, the commenter appears to have read the wrong numbers from the source table. Once the correct ones are substituted, the calculations match.

Comment #A4-4, p. 4-5, third paragraph from the bottom: Define moderate and high exposure in mgs/m^3 or ppm.

Response: The hazard characterization section cited by the commenter has been eliminated from the Risk Chapter (now Chapter 5). A more detailed discussion of acute and chronic hazards, including a section on neurotoxicity can be found in the new Appendix C. In response to numerous comments by Peer Reviewers, the Risk Chapter (now Chapter 5) has changed extensively. Risks are discussed for major exposure scenarios using relevant hazard data.

Comment #A4-5, p. 4-7, first paragraph: Mechanistic arguments for elevated cancer risk can not be omitted; I am concerned that we are forgetting that PCE can form an epoxide and despite weak evidence in humans this is the most powerful argument you have. The animal data can be shot down for species specific outcomes.

Response: In response to numerous comments by Peer Reviewers, the Risk Chapter (now Chapter 5) has changed extensively. We hope these revisions address your comments.

Comment #A4-6, p. 4-9, last paragraph: Occupational groups - inhalation
General population groups - inhalation and oral from drinking water

Response: The comment is not clear and EPA is unable to respond.

Comment #A4-7, p. 4-9, Section 4.2.3, second and third paragraph: We have exposure data for each of these situations - why not refer the reader to the levels here? Or at least tell them where to find it.

Response: This section has been eliminated in the revised Risk Chapter (now Chapter 5). The revised Exposure Chapter (now Chapter 4) lists exposure data for many of these situations.

Comment #A4-8, p. 4-9, third paragraph: The statement "Dry cleaned clothes brought into the home may be a major source of PCE indoor air levels "is excessively dramatic. Although true in an absolute sense, if we look at Exhibit 4-6, the level of risk characterized for this source is fairly minimal. I think the word "major" should be replaced with the word "significant."

Response: The presentation of this information has been revised.

Comment #A4-9, p. 4-11: The aggregated unit risk estimate provided in the CTSA is used along with the estimated lifetime average daily concentration (LADC) associated with several exposure scenarios to estimate a "risk index" for each exposure scenario. For example, Exhibit 4-3 on page 4-11 of the draft CTSA provides the risk index for occupational exposures among drycleaning workers. Using the GM unit risk estimate above (4.73E-06) unit risk for continuous environmental exposure to have the same units as the LADC (see CTSA), rather than the figure used in the draft CTSA, the risk index would exceed 1E-02 for all job descriptions. Footnote "b" to this table erroneously reports the unit risk as 0.0071 per mg/m^3; this figure should be 7.1E-04 per mg/m^3 if

the draft CTSA unit risk estimate is used, or 4.73E-03 per mg/m^3 if the GM unit risk estimate above is used.

Response: As described in the response to comment #A4-2, the commenter appears to have read the wrong numbers from the source table. Once the correct ones are substituted, the calculations match. The commenter correctly notes the unit risk error in the footnote; the footnote has been updated.

Comment #A4-10, p. 4-17, third paragraph: Replace manager with machine operator. Also your conclusion is wrong. There is a meaningful discrimination between Jts and tasks despite the interchanging nature of the work - see our results in JOM. [See comment #A2-1 references]

Response: The Risk Chapter (now Chapter 5) has been revised, and this text has been eliminated.

Comment #A4-11, p. 4-17 to p. 4-21, Occupational Exposure Scenarios: The characterization of risks to drycleaning workers is based on using the geometric mean exposure level from post-1990 OSHA compliance inspection monitoring data and from a University of Michigan study. On page 4-20, the draft states, without explanation, that the geometric mean best describes occupational exposure data. We believe strongly that, for purposes of risk calculation and characterization, the arithmetic mean of an exposure data set is the correct statistic to use when point estimates of risk are desired since risk is assumed linear with exposure. (The arithmetic mean also better represents the variation in exposure levels that exist over time and between plant location). Reliance on the geometric mean as a point estimate of exposure will cause risks to be underestimated because exposures at the high end of the distribution are virtually ignored.

Response: EPA agrees with the commenter. The Risk Chapter has been revised and the language cited has been eliminated. New data are included which present arithmetic means. Maximum exposure concentrations are also included to illustrate high end exposures in Exhibit 5-3 where geometric means are still shown.

Comment #A4-12, first paragraph: Please use our data which better illustrates your points; also I actually did the chemical analysis for the UM study you cited which was for another graduate student. [See comment #A2-1]

Response: It is not clear from the comment to what data EPA is being referred, and what points were illustrated. Therefore, EPA cannot respond directly to this comment. Exhibit 4-4 , however, which used University of Michigan data on exposures of drycleaning workers to PCE (AIHA,1990 has been replaced by Table 5-4 which includes a large sample of workers.

Comment #A4-13, p. 4-17, last paragraph: The suspect "manager" data resurfaces here. As noted above, this is a highly unlikely scenario. It demonstrates the folly of building a framework of assumptions on such limited data.

Response: The Risk Chapter (now Chapter 5) has been extensively revised. This text has been removed.

Comment #A4-14, p. 4-18, second to last paragraph: I'm sure that the authors realize that the average duration of employment in the industry is considerably less than forty years.

Response: No data or information were found to indicate an average duration of employment in the industry.

Comment #A4-15, p. 4-20, first paragraph: Add our exposure work here. [See comment #A2-1 references]

Response: It was not possible within the scope of this screening level assessment to include all articles received. No doubt, all PCE articles you sent will be used in the Agency's comprehensive assessment of PCE planned for the near future.

Comment #A4-16, p. 4-31, first paragraph: There is no real basis for making the statement "known to cause cancer." This is a giant leap of faith! It would be better to substitute the word "suspected" for the word "known."

Response: EPA agrees. The sentence was modified to read "there is concern for cancer".

Comment #A4-17, p. 4-32: Add a bullet

* what is the impact of observed CNS deficits on a test battery with that of performance on the job and quality of life?

Response: The commenter's addition would not be a relevant bullet because the appropriate studies (see comment A2-1 and associated response) were not included in the CTSA, and so the point would not be clear to the reader.

Comment #A4-18. p. 4-33, second paragraph: Not true. A large team of researchers from UM studied Stoddard Solvent (I was the IH) in a General Motors plant that was only exposed to C6-C14 carbon chains where C-9 and C-10 were key components. I have enclosed some of the publications and references. [See comment #A2-1 references]

Response: See response to Comment #A2-1.

Comment #A4-19, p. 4-37, last paragraph: You can consider using the GM study since it was the only solvent exposure despite that it was not in dry-cleaning but another industry

Response: See response to Comment #A2-1.

Comment #A4-20, p. 4-46, Exhibit 4-14: It is highly questionable whether or not any of this data on substances of unknown composition is of any real value.

Response: Agree; Exhibit 4-14 has been extensively revised. The section on substances of unknown composition has been eliminated.

Chapter 5

Comment #A5-1, General Comment: In general, this is a wonderful compendium of research. Very comprehensive. Studies in Chapter 5 show that many garments marked for drycleaning only can successfully be wetcleaned.

p. 5-4 and 5-36. The report should caution that the results are possibly affected by sample selection bias. Since the store was self-identified as an alternative, pro-environment shop it may have affected both the type of clothes brought there as well as the objectiveness of the customer's evaluation. There is no accounting for why the shop lost money in its year of operation. Was volume low? Are wetcleaning methods more labor intensive? Were there more returns for recleaning?

Response: EPA has reviewed these comments and made modifications in the text where it deemed necessary.

Comment #A5-2, p. 5-1: Rename the title to state this is a comparison between PCE and PS — otherwise it is misleading.

Response: EPA has not renamed the chapter because data from processes other than PCE and PS is also included.

Comment #A5-3, p. 5-2, third paragraph: The EWCC data is attributed to Otter, 1996. I believe the gentleman's name is Walter den Otter.

Response: EPA has corrected this error.

Comment #A5-4, p. 5-4 (CNT Chicago): The surveys showed high satisfaction however it was also noted in the survey that 64% of the sample population went to this cleaner because of environmental concerns. This will skew your results on satisfaction. Likely does not represents the general population.

There is little data on the size of the new types of equipment, the cycle times and the yearly capacity. This type of information can be important when assessing the potential costs. EPA uses 39,465 lb/yr of clothes (approximately 780 lb/wk) while the NIOSH study uses an estimate of 1,926 lb/wk (approximately 100,000 lb/yr).

Response: EPA has considered the potential biases associated with the results in making any potential conclusions, however the Agency is only reporting study results. EPA has considered the suggestion to incorporate additional equipment-specific data into the chapter, but does not have the data necessary to make the suggested modifications to the chapter.

Comment #A5-5, p. 5-4, first sentence: The statement "after multiple times" is probably better expressed as "after multiple treatments."

Response: EPA has changed the language to more clearly present the information.

Comment #A5-6, p. 5-10, second paragraph: Your most important result is buried behind customer satisfaction comparisons. I think the discussion of Exhibit 5-6 should be presented first followed by the more detailed components separately.

Response: EPA significantly altered the presentation of this information.

Comment #A5-7, p. 5-13, Section 5.2.2: The abbreviation for Ontario is ON not OT.

Response: EPA has revised the abbreviation.

Comment #A5-8, p. 5-15, Exhibit 5-10: These numbers are highly problematic. Wage costs are extremely high which confirms the stereotypic fears that most drycleaners have of wetcleaning. I think there are ways to present this without creating the problems this information will almost certainly create.

Response: EPA has reformatted the chapter and removed information on costs from it.

Comment #A5-9, p. 5-16, Exhibit 5-11: The location line should read "Toronto, Ontario, Canada."

Response: EPA has made this change.

Comment #A5-10, p. 5-27, Exhibits 5-21, 5-22, 5-23: This data is for a completely different study. The text on page 5-23 seems to indicate that it is the same study. I am very familiar with this data because it was generated in one of my plants. This whole section needs reworking.

Response: EPA revised the section and this data was removed from this chapter.

Comment #A5-11, p. 5-36, second paragraph: "Given the limited number of performance studies...it is difficult to draw conclusions." One clear conclusion that the report has established is that wetcleaning methods can often be used as an adequate substitute for drycleaning methods. The current sentence says they "may" be and this is too weak based on the evidence presented in the report.

The sentence "There continues to be a debate as to the actual percentage of clothing types...that can be safely and effectively wet cleaned" should be stricken since it introduces topics and information outside the report. We are not interested here in the debate but how the studies in this section shed light on the central topic, which is What do these studies tell us about the proportion of clothing that can be successfully wetcleaned? This is indeterminate and is not surprising since none of the studies had that as a clear study goal.

Response: EPA has reviewed these comments, but no modifications were made based on the comments. EPA did not attempt to interpret data nor make general conclusions based upon the studies presented.

Comment #A5-12, p. 5-36, Section 5.3: This section needs to be rewritten to group comments on individual subjects into single paragraphs. The summary should review the contents of the studies rather than introduce overreaching claims and positions that are not part of the studies themselves. Parts of the section are contradictory and overall the section is subjectively written.

Response: EPA has reformatted the chapter and included a summary at the beginning, which precedes the summary of individual studies.

Comment #A5-13, p. 5-36, Section 5.3: This chapter was the most difficult one to follow because it presented the results of separate experiments in a disparate manner and (I know this is difficult) found no way to pull findings together so that a story could be told. Cross-comparisons are the most interesting stuff and I had a hard time putting the results of one study against another. The amount of detail for each study is very high. I would suggest perhaps a revisit to the data might find at least some elements in common across studies; present those first and then get into the nuances of how they differ.

The chapter spends more time on satisfaction than how performance relates to perceived differences in environmental impact. It is clear that wetcleaning is better environmentally than drycleaning, yet wetcleaning does not work as well and alters the shape of clothing. This is the discussion we should have seen more frequently in the chapter.

Also, could the previously seen environmental comparisons be placed below the boxed performance data in order to better understand the performance characteristics more fully? I wanted to compare the performance with exposure and going between chapters was too hard.

This chapter was the most interesting one.

Response: EPA has reviewed this formatting suggestion, but will continue to use the present format for the final document. EPA has included the performance and exposure together in the chapter on trade-offs.

Comment #A5-14, p. 5-36, second to last paragraph: There are some giant leaps of faith here. Much more work is needed in this area before we can really start to talk about feasible percentages in a meaningful way.

Response: EPA has reviewed this section and has not made changes based on the comment. EPA believes that its presentation of summary results is reasonable. EPA agrees that more work is needed in the area of performance measurement, and has stated so in the text.

Chapter 6

Comment #A6-1, p. 6-4, Section 6.2.4: This seems to be a peculiar section. The major source of energy in most drycleaning plants would be some sort of fossil fuel as opposed to electricity.

Response: A more complete analysis of energy use by technology has been included.

Comment #A6-2, p. 6-8, Exhibit 6-2: As I noted in my general comments, a number of these technologies are no longer available. I'm really not sure that it is valid to factor in the capital cost of a technology that can't be purchased. This whole section is unnecessarily complex. It should be limited to three or four readily available technologies.

Response: The number of technologies analyzed for hydrocarbons and PCE in the chapter has been updated.

Comment #A6-3, p. 6-11, second paragraph: A 30' load time is accurate but most operations I saw did 2-3 loads per hour.

Response: EPA has modified the cost model to account for number of load times per day of operation.

Comment #A6-4, p. 6-11, Section 6.3.2: All of the solvent mileage quoted in Sections 6.3.2 through 6.3.13 seem unrealistically low. They are well below current industry standards. The assumptions and sources of data used to calculate them should be re-checked.

Response: Solvent mileages have been modified based on EPA engineering estimates.

Comment #A6-5, p. 6-17, Section 6.3.8: It is incorrect to characterize a vented machine fitted with a carbon adsorption unit as closed loop. By definition, the adsorber must itself be vented hence such a unit can never be described as closed loop.

Response: Some "third generation" machines have "door fans" that activate when the door opens at the end of the drying cycle after the cool-down step. These fans pull air into the open door, through the drum, and "vent" the air passing through the drum to atmosphere or to a carbon adsorber. These machines meet the criteria to be termed "closed-loop" machines because there is no venting during the cleaning or drying cycles. The confusion may come from considering the word "vent" to apply only to the aeration step in machines that are not closed-loop.

Comment #A6-6, p. 6-23, Section 6.4.1: Again, the solvent mileage quoted in Section 6.4.1 through 6.4.4 seem impossibly low and should be re-checked. For both petroleum solvents and perchloroethylene, there seems to be some sort of flaw in the engineering studies used to develop the mileage numbers.

Response: Solvent mileages have been modified based on EPA engineering estimates.

Comment #A6-7, p. 6-26, Section 6.4.2: Once again, I must emphasize that to the best of my knowledge this technology is not available.

Response: This error has been corrected throughout the updated CTSA.

Comment #A6-8, p. 6-29, Section 6.5.1: Discussion of energy costs - it is interesting to note that the energy cost of the primary solvent recovery phase of both perchloroethylene and petroleum solvent recovery phase of both perchloroethylene and petroleum solvent drycleaning does not seem to have been factored into costs in the previous sections. This makes wetcleaning look excessively energy intensive. These costs will always be somewhat lower for drycleaning because of the volatility of solvents as compared to water. The costs are, however, not insignificant and must be factored in. Again, I would have to comment that these sorts of flaws indicate a serious lack of understanding of textile care processes.

Response: EPA has included a more thorough analysis of energy use which includes hydrocarbon and PCE dry to dry technologies.

Comment #A6-9, p. 6-31, Section on Labor Cost: This is a complex area of consideration. I think there is considerable folly in basing calculations on only one anecdotal observation. Our numbers indicate that the cost difference is considerably less than ten percent if wetcleaning pieces are properly selected. Again, however, this is a complex area of consideration and deserves a more thorough treatment than it receives here. I think this problem is also recognized in the text of the document but better treatment is needed before final publishing.

Response: EPA has not included labor costs in its analysis.

Comment #A6-10, p. 6-33, Section 6.5.3, Section on Solvent Use: Again, this solvent mileage figure seems unrealistically low. The same comment would apply to Section 6.5.4.

Response: Solvent mileages were modified based on EPA engineering estimates.

Comment #A6-11, p 6-33, Section on Energy Cost: I suspect that hanging garments in the boiler room to dry was a fairly common practice at one time. I'm not sure that its inclusion here adds to the scientific credibility of the document, however. I think it might be better to simply say that the garments are hung to dry.

Response: EPA has modified the text of the document to eliminate this comment in the text.

Comment #A6-12, p. 6-35, Section 6.5.5: I think it is very premature to make some of the detailed comments that are made in this section. This is particularly true of the sections on Filters/Cleaning Supplies and Maintenance Costs.

Response: No response is necessary.

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO. EPA 744-P-98-001	2.	3. Recipient's Accession No.
4. Title and Subtitle Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes: Response to Peer Review Comments			5. Report Date: June 1998 6.
7. Author(s) Brandon J. Wood			8. Performing Organization Rept. No.
9. Performing Organization Name and Address Battelle Memorial Institute 505 King Avenue Columbus, Ohio 43201-2693			10. Project/Task/Work Unit No. G003470-0108 11. Contract(C) or Grant(G) No. (C) 68-D5-0008 (G)
12. Sponsoring Organization Name and Address U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics (7401) 401 M Street, S.W. Washington, D.C. 20460			13. Type of Report & Period Covered Final Report 14.
15. Supplementary Notes			

16. Abstract (Limit 200 words)

This report contains the response to peer review comments for the *Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes*, EPA 744-B-98-001. The objective of the peer review was conducted to uncover any technical problems or unresolved issues for use in revising the preliminary work product so that the final work product reflects sound technical information and analyses and enhance the scientific technical work product.

The review process began with a conference call between CTSA stakeholders and EPA on July 24, 1998. The peer review panel consisted 40 reviewers, each of whom was specialized in at least one of the four following categories: Technology and Economics, Exposure Assessment, Hazard Assessment, and Risk Assessment. The panel encompasses a large, balanced independent panel of experts from the dry cleaning industry and the environmental and scientific communities. Peer reviewers of the CTSA document submitted a total of 1,855 comments comprising 340 pages.

The EPA Technical Workgroup in charge of developing and revising the CTSA document based on reviewers' comments drafted responses to every peer review comment. Additional investigations and revisions were made to the CTSA document based on the peer review comments.

17. Document Analysis

a. Descriptors: drycleaning, wetcleaning, clothes cleaning, perchloroethylene, perchloroethene, PCE, Perc, Stoddard Solvent, chlorinated solvents, petroleum solvents, hydrocarbon solvents, alternative solvents, dry cleaning, wet cleaning, DF 2000, liquid carbon dioxide, Rynex, propylene glycol ether, Biotex, ultrasonic cleaning, drycleaning cost, drycleaning performance, wetcleaning cost, wetcleaning performance.

b. Identifiers/Open-Ended Terms: Possible carcinogens, pollution prevention

c. COSATI Field/Group: Not applicable

18. Availability Statement	19. Security Class (This Report)	21. No. of Pages
EPA Docket AR-199 NCEPI: (800) 490-9198	Unclassified	410
	20. Security Class (This Page) Unclassified	22. Price

(See ANSI-239.18)

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce