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July 1998

Air

NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS (NESHAP) FOR THE PHARMACEUTICAL MANUFACTURING INDUSTRY:

SUMMARY OF PUBLIC COMMENTS AND RESPONSES

EPA-453/R-98-002

NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS (NESHAP) FOR THE PHARMACEUTICAL MANUFACTURING INDUSTRY

Background Information for
Promulgated Standards - Summary of
Public Comments and Responses

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July 1998

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ENVIRONMENTAL PROTECTION AGENCY

National Emission Standards for Hazardous Air Pollutants for the
Pharmaceutical Manufacturing Industry–
Summary of Public Comments and Responses

Prepared by:

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Research Triangle Park, NC 27711

7/28/98
(Date)

1. The final National Emission Standards for Hazardous Air Pollutants (NESHAP) will regulate emissions of hazardous air pollutants from pharmaceutical manufacturing operations. Only those operations that are part of major sources under section 112(d) of the Clean Air Act as amended in 1990 will be regulated.

2. Copies of this document have been sent to the following Federal Departments: Labor, Health and Human Services, Defense, Transportation, Agriculture, Commerce, Interior, and Energy; the National Science Foundation; and the Council on Environmental Quality; members of the State and Territorial Air Pollution Program Administrators; the Association of Local Air Pollution Control Officials; EPA Regional Administrators; and other interested parties.

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   http//www.epa.gov/ttn

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1.0 SUMMARY

On April 2, 1997, the U. S. Environmental Protection Agency (EPA) proposed national emission standards for hazardous air pollutants (NESHAP) for pharmaceutical manufacturing operations (62 FR 15754) under authority of Section 112 of the Clean Air Act (Act). Public comments were received from 46 sources consisting mainly of States, pharmaceutical manufacturers, industry trade associations, environmental groups, and other interested parties.

All of the comments that were submitted and the responses to these comments are summarized in this document. This summary is the basis for the revisions made to the standards between proposal and promulgation.

1.1 SUMMARY OF CHANGES SINCE PROPOSAL

Numerous changes have been made since the proposal of these standards. Major changes include revising the applicability provisions and definitions to clarify what sources are subject to the standards, incorporating the provisions of the wastewater requirements directly into the rule, as opposed to cross-referencing other Part 63 standards, revising the equipment leak provisions and consolidating the Leak Detection and Repair (LDAR) requirements of Subpart I with the provisions in GGGA, providing an alternative standard for sources complying with a state-of-the-art technology, allowing for testing under representative worst-case conditions, and allowing for the use of the 1978 CTG equations in calculating emissions.

1.2 SUMMARY OF IMPACTS OF PROMULGATED REGULATIONS

The final standards will reduce nationwide emissions of hazardous air pollutants (HAP) from pharmaceutical manufacturing operations facilities by 22,000 megagrams per year (Mg/yr) 24,000 tons per year [tons/yr]), or 65 percent compared to the baseline emissions that would result in the absence of the standards. An average of 900 tons of additional solid waste per year per facility was estimated to determine impacts. Also, an additional energy usage of

$2{,}400 \times 10^9$ British thermal units per year (Btu/yr) was determined to result from promulgation of these standards.

The implementation of this rule is expected to result in an overall annual cost of $62.0 million for existing sources and $11.0 million for new sources. The economic impact analysis shows that the estimated price increase from compliance with the recommended standard for process vents, storage tanks, and wastewater is 1.1 percent. Estimated reduction in market output is 1.9 percent.

2.0 OVERVIEW OF PUBLIC COMMENTS

The public comment period following the April 2, 1997 Federal Register notice (proposed rule) lasted from April 2, 1997 to July 2, 1997. Late comments received after July 2, 1997 were also accepted. A total of 46 letters commenting on the proposed rule were submitted and these comments have been placed in the docket for this rulemaking (Docket A-96-03) under categories IV-D (received on or before July 2, 1997) and IV-G (received after July 2, 1997). Table 2-1 presents a listing of all persons submitting written comments on the supplemental notice, their affiliations, and the recorded docket item number assigned to their correspondences.

In some instances, commenters incorporated by reference their earlier comments on the previous/draft proposal language into their comments on the proposed rule. When this occurred, each of the comments (or group of comments) were summarized and assigned a unique docket item number.

In other cases, commenters supported their comments by referencing comments submitted by other commenters. In these instances the supporter's docket item number is listed each time the supported docket item number is listed. For example, commenter IV-D-23 supported the comments of commenter IV-D-17 in their entirety. Therefore, the comments of IV-D-17 are listed as "IV-D-23/17 and IV-D-17" to reflect the support of two separate commenters. This was particularly true for the comments submitted by the Pharmaceutical Research and Manufacturers of America (PhRMA) which were referenced several times by their member companies.

2.1 ORGANIZATION OF COMMENT SUMMARIES

Chapters 3.0 through 22.0 present a summary of the comments on the proposed rule along with EPA responses. The comments are grouped by subject areas, and the organization of topics is similar to the organization of the preamble to the final rule.

TABLE 2-1. LIST OF COMMENTERS ON THE PROPOSED NESHAP FOR THE PHARMACEUTICAL MANUFACTURING INDUSTRY

Item No [a]	Commenter and Affiliation
IV-D-01	T. White, Pharmaceutical Research and Manufacturers of America (PhRMA)
IV-D-02	P. Piccard, Parke-Davis
IV-D-03	D. McKinnon, Manufacturers of Emission Controls Association
IV-D-04	R. Warland, New York State Department of Environmental Conservation
IV-D-05	G. Thompson, International Association of Color Manufacturers
IV-D-06	L. Hughes, Bayer Corporation
IV-D-07	R. Randolph, Missouri Department of Natural Resources
IV-D-08	J. McClain, Abbott Laboratories
IV-D-09	J. Pierce-Sander, Eastman Kodak Company
IV-D-10	D. Gustafson and T. Threet, Dow Chemical Company
IV-D-11	W. Wehrum, Swidler & Berlin for PhRMA
IV-D-12	K. Boudreaux, Albemarle Corporation
IV-D-13	G. Brier, Pharmacia & UpJohn Company
IV-D-14	W. O'Sullivan, New Jersey Department of Environmental Protection
IV-D-15	J. Wilson, Briston-Meyers Squibb Company
IV-D-16	M. Blair, State of Colorado Department of Public Health and Environment
IV-D-17	A. Holmer, Pharmaceutical Research and Manufacturers of America (PhRMA)
IV-D-18	M. Mullins, Chemical Manufacturers Association
IV-D-19	S. Edwards, Synthetic organic Chemical Manufacturers Association, Inc.
IV-D-20	D. Bowers, Merck & Company, Inc.
IV-D-21	L. Lowe, Nycomed Inc.
IV-D-22	J. Grumet and W. Cass, Northeast States for Coordinated Air Use Management (NESCAUM)
IV-D-23	C. Ehlhardt and M. Smith, Eli Lilly & Company
IV-D-24	S. DeTommaso, Hoffman-LaRoche Inc.
IV-D-25	M. Wax, Institute of Clean Air Companies
IV-D-26	T. Kovacic, Dow Corning Corporation
IV-D-27	B. Higgins and R. Colby, STAPPA/ALAPCO
IV-D-28	T. Stewart, Schering-Plough Corporation
IV-D-29	J. Grant, Mallinckrodt Group Inc.
IV-D-30	U. SenGupta, Vara, International
IV-D-31	W. Wehrum, Swidler & Berlin for PhRMA
IV-D-32	S. Blankenbecler, Eastman Chemical Company
IV-D-33	W. Flis, Exxon Company
IV-D-34	C. Keffer, Jr., Monsanto Company
IV-D-35	W. Huhn, Pfizer Inc.
IV-D-36	T. White, Pharmaceutical Research and Manufacturers of America (PhRMA)
IV-D-37	W. Wehrum, Swidler & Berlin for PhRMA

TABLE 2-1. (continued)

Item No.[a]	Commenter and Affiliation
IV-D-38	J. Powell, Glaxo Wellcome
IV-D-39	A. Hatfield, Mitchell-Scientific, Inc.
IV-D-40	C. Jimenez-Barber, Schering-Plough Products, Inc. (Puerto Rico)
IV-G-01	L. Bocchino, Syntex, Inc.
IV-G-02	N. Roy, National Pollution Prevention Roundtable
IV-G-03	S. Risotto, Center for Emissions Control (CEC)
IV-G-04	A. Slesinger, Boehinger/Ingelheim Corporation
IV-G-05	A. Deshmukh, Occidental Chemical Corporation
IV-G-06	R. Reibstein, Commonwealth of Massachusetts

[a]The docket number for the pharmaceutical manufacturing NESHAP is A-96-03.

2.2 LIST OF ACRONYMS AND ABBREVIATIONS FOR UNITS OF MEASURE

ACRONYMS

Act	Clean Air Act
ACT	Alternative Control Technologies
Administrator	EPA Administrator
Agency	EPA
ANSI	American National Standards Institute
APCD	air pollution control device(s)
CAA	Clean Air Act
CAM	Compliance Assurance Monitoring
CAR	Consolidated Air Rule
CEM	continuous emissions monitor
CEMS	continuous emissions monitoring system(s)
CFR	Code of Federal Regulations
CTG	Control Techniques Guideline
CWA	Clean Water Act
EG	emission guidelines
EPA	U. S. Environmental Protection Agency
FBCA	fixed-bed carbon adsorber
FDA	Food and Drug Administration
FID	Flame Ionization Detector
FR	Federal Register
GMP	Good Manufacturing Practice
H_2	hydrogen
HAP	hazardous air pollutant(s)
HCl	hydrogen chloride
HON	Hazardous Organic NESHAP
LDAR	Leak Detection and Repair
MACT	maximum available control technology
MON	Miscellaneous Organic NESHAP
N_2	nitrogen
NAAQS	National Ambient Air Quality Standards
NAICS	North American Industrial Classification System
NESHAP	national emission standards for hazardous air pollutants
NO_x	nitrogen oxides

NPDES	National Pollutant Discharge Elimination System
NSM	New Source MACT
NSPS	new source performance standards
NSR	new source review
O_2	oxygen
OAQPS	Office of Air Quality Planning and Standards
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
OVA	Organic Vapor Analyzer
P_2	Pollution Prevention
PEC	Purchased Equipment Costs
PhRMA	Pharmaceutical Research and Manufacturers of America
PM	particulate matter
PMPV	Pharmaceutical Manufacturing Process Unit
POD	Point of Determination
POTW	Publicly - Owned Treatment Works
PSD	prevention of significant deterioration
QA/QC	quality assurance/quality control
R&D	Research and Development
RACT	Reasonably Available Control Technology
RCRA	Resource Conservation and Recovery Act
SIC	Standard Industrial Classification
SO_2	sulfur dioxide
SOCMI	Synthetic Organic Chemical Manufacturing Industry
TOC	Total Organic Carbon
TRE	Total Resource Effectiveness
TRI	Toxic Release Inventory
TSCA	Toxic Substances Control Act
USDA	United States Department of Agriculture
VOC	volatile organic compounds

ABBREVIATIONS FOR UNITS OF MEASURE

Btu	=	British thermal unit
C°	=	degrees Celsius
dscf	=	dry standard cubic foot (@ 14.7 psia, 68°F)
dscfm	=	dry standard cubic foot per minute (@ 14.7 psia, 68°F)
dscm	=	dry standard cubic meter (@ 14 psia, 68°F)
°F	=	degrees Fahrenheit
ft^3	=	cubic feet
gr	=	grains
hr	=	hour
K	=	degrees Kelvin
lb	=	pound
L	=	liter
mg	=	milligrams (10^{-3} grams)
Mg	=	megagram (10^6 grams)
MMm^3	=	million cubic meters
MW	=	megawatt
MW-hr/yr	=	megawatt-hours per year
ng	=	nanogram (10^{-9} grams)
ppm	=	parts per million
ppmdv	=	parts per million by dry volume
ppmv	=	parts per million by volume
ppmw	=	parts per million by weight
ton/yr	=	tons per year
μg	=	microgram (10^{-6} grams)
wk	=	week
yr	=	year

3.0 APPLICABILITY AND DEFINITIONS

3.1 GENERAL APPLICABILITY: DEFINITION OF PHARMACEUTICAL PRODUCT

Status at proposal. Pharmaceutical product was defined as "any material described by the Standard Industrial Classification (SIC) Code 283, or any other fermentation, biological or natural extraction, or chemical synthesis product regulated by the Food and Drug Administration, including components (excluding excipients) of pharmaceutical formulations, or intermediates used in the production of a pharmaceutical product."

Issues/data:

1. Many commenters (IV-D-08, IV-D-09, IV-D-10, IV-D-12, IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-D-18/26, IV-D-33, IV-G-04, and IV-G-05) stated that, based on the definition of pharmaceutical product, the general applicability of the standard is too broad, ambiguous, and appears to overlap with other MACT standards.

2. During the development of the proposed NESHAP, information was collected from facilities under the following SIC codes:

2833--Medicinal Chemicals and Botanical Products

2834--Pharmaceutical Preparations

2835--In-Vitro and In-Vitro Diagnostic Substances

2836--Biological Products, Except Diagnostic Substances

However, the 101 pharmaceutical facilities that are referred to in the Basis and Purpose Document and the Economic Analysis as being affected by the pharmaceutical NESHAP are primarily classified under SIC codes 2833 and 2834.

3. As of January 1, 1997, a new numerical coding system for classifying industries has been implemented by the U.S. Census Bureau; this system will "replace" the SIC Code system

and is referred to as the North American Industrial Classification System (NAICS). The NAICS codes that correspond to industries formerly classified under SIC code 283 are as follows:

2833---> 325411 Medicinal and Botanical Manufacturing

2834---> 325412 Pharmaceutical Preparation and Manufacturing

2835---> 325412 Pharmaceutical Preparation and Manufacturing

---> 325413 In-Vitro Diagnostic Substance Manufacturing

2836---> 325414 Biological Product (except Diagnostic) Manufacturing

Comment: Many commenters (IV-D-08, IV-D-09, IV-D-10, IV-D-18/12/26, IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-D-33, IV-G-04, and IV-G-05) stated that the definition of pharmaceutical products is too broad and should be revised to make it consistent with both the supporting background information document and the intent of the regulation and to prevent overlap with other MACT standards that cover the chemical industry. Comments on the definition of pharmaceutical product focused on the following four areas: (1) the use of SIC codes, (2) the scope of products regulated by the FDA, (3) the meaning of the term "intermediates," and (4) the exclusion of specific products/processes.

Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38) suggested that instead of referencing SIC code 283, the definition of pharmaceutical product should be narrowed to include only SIC codes 2833 and 2834 because facilities classified under these two SIC codes produce pharmaceuticals as their primary product, and were the source of information and data that formed the basis for the proposed rule. Two other commenters (IV-D-10 and IV-D-32) stated that the use of SIC codes or the new NAICS codes in defining pharmaceutical products was inappropriate because of the ambiguous nature of SIC and NAICS code applicability, and that instead of using SIC or NAICS codes, the definition should clearly describe the characteristics of the processes that are subject to the rule. One of the commenters (IV-D-10) provided the following specific objections to the use of SIC and NAICS codes in determining applicability: (1) SIC and NAICS codes were not developed with environmental regulation in mind and lack the required specificity; (2) the SIC code system no longer exists and the new system approved by OMB, NAICS, has different codes; (3) EPA does not specify which edition of the SIC code manual to use; and (4) not all establishments classified under SIC code 283 are pharmaceutical production units, and conversely, some emission sources associated with

pharmaceutical production units that are collocated at large, integrated chemical manufacturing plants could be classified under a different SIC code based on the guidance provided in the 1987 SIC Code manual regarding auxiliary establishments (the manual says that auxiliary establishments should take their SIC code from the establishments they primarily serve). The other commenter (IV-D-32) provided a recommended definition of pharmaceutical product based upon the definitions of "drug product," "component," "active ingredient," and "inactive ingredient" already established by the Food and Drug Administration at 21 CFR 210.3 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs).

Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-D-06, IV-D-09, IV-D-18/12/26, IV-G-05, and IV-D-32) stated that the inclusion of the phrase, "regulated by the Food and Drug Administration" should be deleted from the definition of pharmaceutical products because many nondrug products such as cosmetics, food additives, plastics (food contact films) and dietary supplements, are regulated by the FDA and could be interpreted as being pharmaceutical products based on the proposed definition of pharmaceutical products. These commenters provided numerous examples of specific "nonpharmaceutical' products regulated by the FDA that could become subject to the pharmaceutical NESHAP based upon the proposed definition of pharmaceutical product. The commenters also stated that inclusion of these "nonpharmaceutical products" in the pharmaceuticals NESHAP would be inappropriate because they were not considered in the development of the proposed NESHAP, and consequently, were excluded from the development of MACT floors and environmental and economic impact estimations. However, another commenter (IV-D-07) requested that EPA expand the definition of pharmaceutical products to include products regulated by the U.S. Department of Agriculture (USDA) as well as the FDA because the pharmaceutical industry produces animal biologics using the same processes used to produce human biologics, and therefore, HAP emitted from the production of animal biologics also should be regulated as part of the pharmaceutical NESHAP.

Many commenters (IV-D-06, IV-D-10, IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-D-18/12/26 IV-D-32, IV-G-01, IV-G-04, and IV-G-05) stated that the use of the term "intermediates" in the definition of pharmaceutical product was confusing and brings many unintended chemicals and processes into the pharmaceutical NESHAP; and therefore, the term should be either clarified or deleted from the definition of pharmaceutical product. One

commenter (IV-D-10) stated that depending on how "intermediate" is defined, "virtually any basic chemical is ultimately used as an 'intermediate' in the manufacture of almost anything." Another commenter (IV-D-32) stated that the inclusion of the term "intermediate" in the definition of pharmaceutical product makes it "unclear how far back in the manufacturing chain a regulated entity must look when determining applicability." The commenter (IV-D-32) further stated that according to "due process," regulated entities must have fair notice of EPA's intent to regulate, and the inclusion of the term "intermediates" in the pharmaceutical product definition does not provide fair notice. Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that operations that manufacture raw materials (such as acids and solvents) that are not precursors to active ingredients in pharmaceutical products should not be regulated as part of the pharmaceutical NESHAP. Several commenters (IV-D-06 and IV-D-18/12/26) stated that the rule should only apply to processes which produce materials which exclusively or primarily are used to make drug active ingredients. One commenter (IV-D-34) stated that, if the intermediate is not an active pharmaceutical ingredient, it may best be covered under the miscellaneous organic NESHAP (MON). Another commenter (IV-D-29) stated that EPA needs to clarify that intermediates already regulated by the hazardous organic NESHAP (HON) are excluded from the pharmaceutical NESHAP.

Four commenters (IV-D-05, IV-D-09, IV-D-10, and IV-D-35) requested that EPA specifically exclude certain "nonpharmaceutical products" from the definition of pharmaceutical products. One commenter (IV-D-09) expressed concern that due to the inclusion of SIC code 2835 and the phrase, "regulated by the FDA," in the pharmaceutical product definition, equipment used to manufacture medical devices or substances used in the manufacture of medical devices could be subject to the pharmaceutical NESHAP instead of the "MACT rule intended to cover such equipment, namely, the MON." Therefore, the commenter (IV-D-09) requested that "medical devices" be exempted from the rule by adding a phrase to the definition of pharmaceutical products that specifically excludes medical devices. A second commenter (IV-D-35) stated that the rule should not apply to specialty chemical manufacturers who occasionally engage in tolling a pharmaceutical intermediate. The commenter (IV-D-35) further stated that tolling of pharmaceutical intermediates could be driven overseas if U.S. specialty chemical operations require long lead times to identify MACT requirements, develop compliance

systems, and amend Title V requirements. A third commenter (IV-D-10) suggested that EPA exclude contract manufacturing from the pharmaceutical rule, and allow it to be covered by the MON. The commenter (IV-D-10) provided the following reasons why EPA should exclude contract manufacturing from the pharmaceutical rule: (1) the concept of a "production unit" does not apply well to contract manufacturing processes due to frequent component reconfigurations; (2) a contract manufacturing unit could change source categories frequently because the same contract manufacturing process that is currently used to produce a pharmaceutical active ingredient could be used to manufacture a pesticide, industrial chemical, a consumer product, or a polymer next; and (3) owners or operators of contract manufacturing units cannot provide 5-year projections of primary product (as required by the HON for flexible operations) because they cannot predict which contracts will be awarded to them, and thus, they also cannot accurately predict annual average HAP concentrations, wastewater flow rates, or total annual hours components will be in HAP service. The fourth commenter (IV-D-05) requested that EPA specifically exclude "color additives and other inactive ingredients" from the definition of pharmaceutical product because the commenter interpreted EPA's exclusion of excipients from the definition of pharmaceutical products to mean that the pharmaceutical NESHAP was only intended to cover active ingredients. The fourth commenter also provided a definition of excipients developed by the International Pharmaceutical Excipients Council, and requested a 90-day extension of the comment period if EPA determines that the manufacture of color additives used in pharmaceutical products is covered under the pharmaceutical NESHAP. Some commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) suggested that limiting the applicability of the rule to facilities classified under SIC codes 2833 and 2834 would exclude commercial solvent recovery facilities, facilities that manufacture products that are only precursors to pharmaceutical active ingredients, facilities used by specialty chemical manufacturers to perform complex tolling operations for pharmaceutical manufacturers, but whose primary function is not the production of pharmaceuticals, and other operations not principally engaged in pharmaceutical manufacturing. One commenter (IV-D-19) further stated that those facilities under SIC code 283 that are excluded from the pharmaceuticals NESHAP "presumably" would be covered by the MON.

Response: The EPA has considered the above comments and has revised the definition of pharmaceutical product based on these and other considerations. The rationale for the revised definition is presented below.

The EPA agrees with the commenters that SIC codes may be ambiguous, were not developed with environmental regulation in mind, and may not reflect individual processes within a facility, and therefore, that the use of SIC codes to define pharmaceutical product may introduce unintended ambiguity into applicability determinations. Secondly, EPA believes that the use of the newer NAICS codes in defining applicability would result in the same problems with ambiguity and intended use; however, based on industry survey responses, EPA recognizes that facilities primarily claiming SIC codes 2833 and 2834 produce medicinals and pharmaceuticals as their primary products. Therefore, for the sake of clarity and consistent with the survey responses, EPA has retained these SIC Codes and their corresponding NAICS codes (325411 and 325412) in the definition of pharmaceutical product.

The EPA also agrees that the term "regulated by FDA" is also ambiguous. As noted by one commenter, in 21 CFR Section 207.10 (e), FDA exempts from registration and drug listing, "manufacturers of harmless inactive ingredients that are excipients, coloring, flavorings, emulsifiers, lubricants, preservatives, or solvents that become components of drugs, and who otherwise would not be required to register under this part." The EPA agrees that some of the processes used to manufacture such substances were not intended for coverage by this rule, and that was the intent of including the phrase "regulated by FDA" in the definition of pharmaceutical product in the proposed rule. Based on the comments, however, EPA believes that a less ambiguous way to define pharmaceutical product would be based on definitions contained in 21 CFR 210.3 (Current Good Manufacturing Practice in Manufacturing, Processing, or Holding of Drugs; General) for drug product or active ingredient. These definitions capture formulation products as well as pharmaceutical active ingredients and their precursors.

The proposed rule also was intended to cover intermediates that are manufactured prior to the final processing steps in which a compound becomes a pharmaceutical product. However, EPA recognizes the ambiguity associated with defining an intermediate, especially the point at which a chemical becomes associated with pharmaceutical manufacturing. Because the pharmaceutical industry is characterized by numerous processes that may be conducted prior to

the actual synthesis and isolation of active ingredients, EPA rejects the notion that, in order to simplify applicability, only the processes yielding active ingredients should be covered by the rule. Rather, EPA agrees with the suggestion that the rule be based on the primary intended use of the materials manufactured. By defining applicability according to primary use as pharmaceutical products or as their precursors, intermediates that are further processed to become active ingredients or drug components can be covered. However, commodity chemicals would not be covered. Therefore, in order to clarify the boundaries of the coverage of such precursors or intermediates, the applicability language under § 63.1250 (a) has been changed in the final rule to clarify that the provisions of the subpart apply to materials whose "primary use" is as a pharmaceutical product or precursor.

The "primary use" approach also addresses the comment regarding the exclusion of contract manufacturing from the pharmaceutical rule. To simplify the determination of applicability for facilities that conduct contract manufacturing, some commenters suggested that the rule apply to processes whose primary product is a pharmaceutical active ingredient. The concept of primary product has been used in past regulations (e.g., HON, P&R IV, etc.) and was not considered in the proposed rule because there was a conscious effort to disengage production equipment from products manufactured. Because the standards are process-based, the intent of the proposal was to cover the production of pharmaceutical products, no matter what pieces of equipment were used to manufacture them in the course of a year. Conceptually, the primary product definition makes sense for process lines that can be used to manufacture more than one product. In this industry, however, process equipment is reconfigured such that the same pieces of equipment may not always be part of the same process line. Under the current concept of primary product that appears in other rules, it would still be difficult to determine the primary product of a nondedicated process, because not all the same equipment would be associated with the "process." However, by reverting back to the concept of "primary use," owners and operators can clearly delineate applicability based on the intended use of materials they manufacture, and not the equipment they are manufactured in. Therefore, contract manufacturers are subject to this MACT standard when they manufacture a pharmaceutical product.

The revised definition for pharmaceutical product contained in the final rule borrows heavily from definitions contained in 21 CFR 210.3, which are presented below.

Drug product means a finished dosage form of a drug, for example, a tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

Active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

Based on the above definitions, the definition of pharmaceutical product has been revised in the final rule as follows. Additionally, definitions for "active ingredient," "component," "excipient," and "primary use" have been included in the final rule.

Pharmaceutical product means: (1) any material described by the SIC code 2833 or 2834; (2) any material described by NAICS codes 325411 or 325412; (3) a finished dosage form of a drug, for example, a tablet, capsule, solution, etc., that contains an active ingredient generally, but not necessarily, in association with inactive ingredients, or (4) any component whose intended primary use is to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals (the term does not include excipients, but includes drug components such as raw starting materials or precursors that undergo chemical change or processing before they become active ingredients).

Active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. The term includes those components that may undergo chemical change in the manufacture of the pharmaceutical product and be present in the pharmaceutical product in a modified form intended to furnish the specified activity or effect.

Component means any ingredient for use in the manufacture of a drug product, including those that may not appear in such drug product.

Excipient means any substances other than the active drug or product which have been appropriately evaluated for safety and are included in a drug delivery system to either aid the processing of the drug delivery system during its manufacture, protect, support or enhance stability, bioavailablity, or patient acceptability, assist in product identification, or enhance any other attribute of the overall safety and effectiveness of the drug delivery system during storage or use.

Primary use means the single largest use (of a material).

For reasons described above and in subsequent responses, the applicability language in § 63.1250 (a) has been changed in the final rule as follows:

(a) **Definition of Affected Source.** The affected source subject to this subpart is the pharmaceutical manufacturing operation, as defined in Section 63.1251 of this subpart. Except as specified in paragraph (d) of this section, the provisions of this subpart apply to pharmaceutical manufacturing operations that meet the criteria specified in paragraphs (a)(1) through (a)(3) of this section as follows:

(1) Manufacture a pharmaceutical product, as defined in § 63.1251;

(2) Are located at a plant site that is a major source as defined in Section 112(a) of the Act; and

(3) Process, use, or produce HAP.

3.2 DEFINITION OF PHARMACEUTICAL MANUFACTURING OPERATIONS, PHARMACEUTICAL MANUFACTURING PROCESS UNITS, AND GENERAL APPLICABILITY

Status at proposal. Pharmaceutical manufacturing operations were defined to "include PMPU's and other processes and operations as well as associated equipment such as heat exchange systems that are located at a facility for the purpose of manufacturing pharmaceuticals."

Pharmaceutical manufacturing process unit (PMPU) was defined as "any processing equipment assembled to process materials and manufacture a pharmaceutical product and associated storage tanks, wastewater management units, or components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves

or lines, valves, connectors, and instrumentation systems that are used in the manufacturing of a pharmaceutical product."

Applicability–Sections 63.1250 (a) through (c)

(a) Except as specified in paragraph (d) of this section, the provisions of this subpart apply to pharmaceutical manufacturing operations located at a major source of HAP emissions.

(b) The affected source subject to this subpart is the facility-wide collection of pharmaceutical process vents, storage tanks, wastewater and associated treatment residuals, heat exchanger systems, cooling towers, and equipment components (pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems) associated with pharmaceutical manufacturing operations.

(c) If an additional pharmaceutical manufacturing process unit(s) is added to a plant site that is a major source, as defined in Section 112(a) of the Act, the addition shall be subject to the requirements for a new source in this subpart if: It is an addition that meets the definition of construction in § 63.2 of subpart A of this part; the addition has the potential to emit 10 tons per year or more of any HAP or 25 tons per year or more of any combination of HAP, unless the Administrator establishes a lesser quantity; and the process unit(s) is dedicated to the manufacture of a single product or isolated intermediate.

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, IV-G-04, IV-D-32, and IV-D-08) provided comments on the definitions of pharmaceutical manufacturing operations and pharmaceutical manufacturing process unit (PMPU). One commenter (IV-D-32) stated that having both "pharmaceutical manufacturing operation" and PMPU in the proposed rule was confusing and redundant. The commenter stated that by having both terms, the rule implies that the definition of PMPU does not cover all of the equipment to be regulated by subpart GGG. The commenter further stated that the inclusion of the phrase "associated equipment" in the pharmaceutical manufacturing operations definition was unclear because the definition of PMPU already covers "associated" equipment. The commenter also stated that heat exchangers were given as an example of "associated equipment" under the definition of pharmaceutical manufacturing operation, but not included as an example in the definition of PMPU. For these reasons, the commenter suggested that the definition of

pharmaceutical manufacturing operation be deleted entirely, and that heat exchangers be added to the list of examples of "associated equipment" in the PMPU definition.

Two commenters (IV-D-08, IV-D-20) stated that wastewater management units should not be included in the definition of PMPU. One commenter (IV-D-20) stated that wastewater management units are not subject to the standard, but instead are used to comply with the standard. This commenter also pointed out that neither the HON's definition of chemical manufacturing process unit (CMPU) nor the Polymers and Resin I NESHAP definition of elastomer product process unit (EPPU) includes wastewater management units. The commenter further stated that including wastewater management units in the definition of PMPU could be interpreted to require new source MACT at an existing wastewater management unit if a new, major, dedicated PMPU is built that will contribute wastewaters to that unit. Another commenter (IV-D-32) stated that packaging operations (e.g., "placement of dose forms, such as tablets, into containers, and assembly, closure, and labeling of these containers") are not pharmaceutical manufacturing operations, and thus, should be explicitly excluded from the definition of pharmaceutical manufacturing operations.

Many commenters (IV-D-08, IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that the definition of PMPU should be modified to make it clear that a PMPU is a *group* of equipment. These commenters were concerned that, as written, the definition of PMPU could be interpreted to mean that an individual piece of equipment constitutes a PMPU, and thus, the addition of a single piece of equipment to an existing dedicated process line could trigger new source MACT.

Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that a PMPU should be identified by its primary product and suggested adding language to the definition that makes it clear that PMPU's manufacture pharmaceutical products as their primary product.

Response: The terms "Pharmaceutical Manufacturing Operations" and "Pharmaceutical Manufacturing Process Unit (PMPU) " were not intended in the proposed rule to refer to the same sources entirely. While the term "Pharmaceutical Manufacturing Operations" is the broadest term used in the rule and covers all emission sources within a given facility that are the direct or indirect result of pharmaceutical manufacturing, the term "PMPU" was intended to

encompass each process unit within the facility and its associated equipment. Therefore, the pharmaceutical manufacturing operation encompasses all PMPU's at a given facility as well as equipment that is not included in individual PMPU's. The EPA believes that the broader term for pharmaceutical manufacturing operations is necessary to include sources that cannot be associated with single PMPU's. In the proposed rule, the PMPU is used exclusively to define new source applicability in § 63.1250(c). In the final rule, PMPU's have replaced "processes" in the pollution prevention standard (see Section 10.2--Clarification of P2 Alternative), and therefore, PMPU's serve two functions in the final rule.

By including wastewater management units in the definition of PMPU at proposal, EPA intended that all wastewater streams and residuals would be considered part of the PMPU. Therefore, any PMPU subject to new source MACT would be required to control emissions from those sources to the required level, and if the only way to meet new source MACT for the new PMPU involves upgrading the existing wastewater management unit, then the source must do so. However, EPA reviewed the definition of process and PMPU for consistency with the HON and other MACT standards and realized that, although wastewater may be generated in a PMPU, it is not specifically defined as part of the PMPU, but rather can be associated with it. This convention is analogous to process vent emissions; although they are not specifically identified as part of the PMPU, a PMPU may generate process vent emissions; in deciding whether the PMPU has the potential to emit 10 or 25 tons of HAP, emissions from all sources associated with the PMPU, including process vents and wastewater, must be considered. Therefore, the definition of PMPU was modified to not specify wastewater streams, residuals, and wastewater management units, as part of the PMPU.

Although the Agency recognizes that rarely will one piece of equipment comprise a PMPU, the Agency disagrees with the commenters that a PMPU must always be defined as a *group* of equipment. The definition of PMPU in the final rule, however, includes the term, "process" which is defined as a "logical grouping of processing equipment which collectively function to produce a pharmaceutical product" and "may consist of one or more unit operations." (See Section 3.4 Definition of Process, for the full revised definition.)

In response to suggestions that EPA define a PMPU by it's primary product, the EPA has included a primary use concept in the applicability section of the final rule as discussed previously in Section 1.2.

In response to the comments, the proposed definitions of PMPU and pharmaceutical manufacturing operations were revised, as follows:

Pharmaceutical manufacturing process unit (PMPU) means ~~any processing equipment assembled to process materials and manufacture a pharmaceutical product and~~ *the process, as defined in this subpart*, and *any* associated storage tanks, ~~wastewater and associated treatment residuals management units~~, equipment identified in § 63.1252(f), and components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used in the manufacturing of a pharmaceutical product."

"**Pharmaceutical manufacturing operations** ~~include PMPU's and other processes and operations as well as associated equipment such as heat exchange systems~~ *means the facility-wide collection of PMPU's and any other equipment such as heat exchanger system, or cooling towers,* ~~or storage tanks~~ *that are not associated with an individual PMPU, but* that are located at a facility for the purpose of manufacturing pharmaceuticals~~.~~ *products and are under common control."*

In keeping with the revised definitions, the applicability Section 63.1250 (a) through (c) was revised as follows:

63.1250 Applicability.

~~(a) Except as specified in paragraph (d) of this section, the provisions of this subpart apply to pharmaceutical manufacturing operations located at a major source of HAP emissions.~~

~~(b) The affected source subject to this subpart is the facility-wide collection of pharmaceutical process vents, storage tanks, wastewater and associated treatment residuals, heat exchanger systems, cooling towers, and equipment components (pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems) associated with pharmaceutical manufacturing operations.~~

(a) Definition of Affected Source. The affected source subject to this subpart is the pharmaceutical manufacturing operation, as defined in Section 63.1251. Except as specified in paragraph (d) of this section, the provisions of this subpart apply to pharmaceutical manufacturing operations that meet the criteria specified in paragraphs (a)(1) through (3) of this section as follows:

(1) Manufacture a pharmaceutical product, as defined in § 63.1251;

(2) Are located at a plant site that is a major source as defined in Section 112(a) of the Act; and

(3) Process, use, or produce HAP.

(b) New Source Applicability. A new affected source subject to this subpart and to which the requirements for new sources apply is: an affected source for which construction or reconstruction commenced after April 2, 1997 *and the standard was applicable at the time of construction or reconstruction*; or a PMPU, dedicated to manufacturing a single product, that has the potential to emit 10 tons per year of any one HAP or 25 tons per year of combined HAP, for which construction commenced after April 2, 1997.

3.3. GENERAL APPLICABILITY: AFFECTED SOURCE (63.1250 (A) AND (B))

Status at proposal.

Applicability--Sections 63.1250 (a) and (b):

(a) Except as specified in paragraph (d) of this section, the provisions of this subpart apply to pharmaceutical manufacturing operations located at a major source of HAP emissions.

(b) The affected source subject to this subpart is the facility-wide collection of pharmaceutical process vents, storage tanks, wastewater and associated treatment residuals, heat exchanger systems, cooling towers, and equipment components (pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems) associated with pharmaceutical manufacturing operations.

Comment: One commenter (IV-D-09) stated that the use of the term, "facility-wide," in Section 63.1250 (b) could result in a collection of equipment owned and operated by different companies that are collocated at one "facility" being considered as one "affected source." Because the affected source definition is the key factor in determining when new source MACT

is triggered, the commenter is concerned that a new pharmaceutical manufacturing line constructed by one company could trigger new source MACT for other companies located at the same site/facility. For these reasons, the commenter suggested that the term "facility-wide" be deleted and the phrase "under common control at a major source" be added to the end of Section 63.1250 (b).

Response: As defined in the General Provisions, "major source" refers to any stationary source or group of stationary sources within a contiguous area and under common control. Therefore, only those sources within a contiguous area and under common control would be considered when determining whether or not a facility is a major source. However, if both pharmaceutical-related and nonpharmaceutical-related manufacturing operations are located at the same facility and are under common control, the total emissions from all of these manufacturing operations would be summed to determine the major source status of the facility. Therefore, the Agency has added the phrase, "under common control," but retained the phrase "facility-wide." In keeping with other revisions to the proposed rule, the two aforementioned phrases are included in the definition of pharmaceutical manufacturing operation, and are no longer used directly in Section 63.1250--Applicability. (See revised definition of pharmaceutical manufacturing operation and revised § 63.1250 in Section 1.2, above.)

As further clarification, the Agency points out that if a new pharmaceutical line is constructed at a facility (regardless of whether or not more than one company is operating at the facility), only the new line would be subject to new source MACT (assuming the addition met the criteria in 63.1250(b)--the new line has the potential to emit 10 tons per year of any one HAP or 25 tons per year of combined HAP). The other existing sources (manufacturing areas) at the facility would have to continue meeting MACT for existing sources.

Comment: Commenter IV-D-08 was concerned that sites which may be major HAP sources due to an incidental by-product of combustion are subject to the rule even if the pharmaceutical operations at the site are well below 10/25 tons per year thresholds. The commenter provided an example where HCl emissions produced as a by-product of fuel (coal) combustion were not directly related to the production of any pharmaceutical. The commenter stated that the definitions or the applicability section should be revised to limit the applicability to only those sites where pharmaceutical production operations are major sources of HAP, or

provide an exemption for sources of HAP which presently are, or will eventually be, covered under separate NESHAP regulations (e.g., boilers).

Response: In general, the Agency disagrees with the commenter and refers the commenter to the July 21, 1995 D.C. Circuit Court decision, National Mining Association vs. U. S. Environmental Protection Agency, where the NMA challenged EPA's definition of major sources. The Court's decision reaffirmed EPA's implementation of the definition of major source which requires the aggregation of all hazardous air emissions within a plant site.

Comment: One commenter (IV-D-32) stated that while the proposed rule covers all processes at a facility which is determined to be major source, some processes at those major sources do not emit HAP. The commenter also stated that although this situation may not pose a significant compliance problem, the lack of an exclusion for these non-HAP emitting processes "poses an unwarranted regulatory burden."

Response: The EPA agrees with this comment and has added the condition in § 63.1250(a)(3) that defines the affected source according to whether the operations "process, use, or produce" HAP.

Comment: One commenter (IV-D-20) suggested that EPA should establish a *de minimis* HAP quantity of 100 pounds (after controls) of any one HAP per facility. The commenter pointed out that the instructions for the Section 114 survey of the pharmaceutical industry stated that HAP emissions below 100 lb need not be quantified, thereby establishing a *de minimis* level of 100 lb of emissions of any one HAP per facility. The commenter further stated, that, because this was a reasonable *de minimis* level for setting the MACT floor, EPA should extend this precedent to establish a *de minimis* HAP cutoff in the rule.

Response: The EPA disagrees with the need to establish a de minimis cutoff for applicability, especially if based on HAP emissions after control. However, the final rule contains several low-HAP potential exemptions. The final rule eliminates from the affected source, operations that do not produce, use, or process HAP. Additionally, *de minimis* levels for process vents and wastewater sources have been established, including a 100 lb HAP per process *de minimis* for control of uncontrolled HAP emissions from process vents.

3.4 DEFINITION OF PROCESS

Status at proposal. Process was defined as "a logical grouping of processing equipment which collectively function to produce a pharmaceutical product or isolated intermediate. A process may consist of one or more unit operations. For the purposes of this subpart, process includes all or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a product or isolated intermediate. The physical boundaries of a process are flexible, providing a process ends with a product or isolated intermediate, or with cessation of onsite processing. Nondedicated solvent recovery and nondedicated formulation operations are considered single processes that are used to recover or formulate numerous materials and/or products."

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) requested that the definition of process be clarified to indicate that Quality Assurance and Quality Control (QA/QC) laboratories are not considered part of the process. These commenters were concerned that, although it may be clear that QA/QC labs are not "processing equipment" or "an activity or an operation used to produce a product," the words, "or other activity, operation," may lead to confusion as to whether QA/QC labs are part of the process. The commenters suggested that EPA explicitly exclude QA/QC labs from the definition of process to avoid "time-consuming nonapplicability demonstrations" that will (only) "show what everyone already knows, that these laboratories emit insignificant quantities of HAP."

Several commenters (IV-G-02, IV-D-22, IV-D-27) recommended that EPA include storage tanks in the definition of process so that sources that choose to comply using the pollution prevention alternative (Section 63.1252(f)) are not exempted from the storage tank requirements in Section 63.1252(b) of the proposed rule. The commenters stated that emissions from storage tanks may be significant, and that sources should be required to comply with the storage tank standards under all circumstances.

Many commenters (IV-D-03, IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) requested that EPA modify the definition of process to clarify how the process vent provisions will apply to formulation facilities. These commenters were concerned that the use of the term "nondedicated" in reference to formulation facilities results in confusion as to how to apply the standard. The commenters pointed out that, unlike equipment used in pharmaceutical

chemical synthesis facilities, equipment in a formulation facility are only used to formulate products, and therefore, formulation facilities are "dedicated" to formulation operations. However, the commenters also pointed out that the equipment at the formulation facility is used to produce many different products, and therefore, is "nondedicated." For these reasons, the commenters recommended that, for formulation operations, the term, "nondedicated," be applied to the equipment within the facility and not the facility itself. The commenters also requested that for formulation operations, EPA limit the definition of process to formulation activities *within a contiguous area* (such as a formulation building or a contiguous area within a multipurpose building in which formulation takes place). The commenters cited examples where separate formulation operations are located at the same plant site, but are physically separate, and thus would require separate emission control systems. To incorporate these suggestions into the definition, the commenters recommended that the definition be revised as follows:

"Process means... Nondedicated solvent recovery operations are considered single processes that are used to recover numerous materials and/or products. Nondedicated formulation operations occurring within a contiguous area shall be considered a single process that is used to formulate numerous materials and/or products. For the purposes of formulation, the determination of nondedicated shall be applied to the equipment within the area, not the area itself."

Another commenter (IV-D-09) was concerned that use of the term "nondedicated" could be interpreted as including solvent recovery or formulation operations that process small quantities of pharmaceutical-related materials, but whose primary use is for a process subject to another MACT rule. The commenter "strongly opposes" regulation of a single process by multiple MACT rules and recommended that this issue be resolved by (1) deleting the term "nondedicated" from the proposed definition of process, and (2) adding the phrase, "whose primary use is associated with the manufacture of pharmaceutical products" after the word "operations" in the last sentence of the proposed definition of process.

One commenter (IV-D-10) also has two additional suggested changes to the definition of process. First the commenter recommended that the phrase, "may consist of one or more unit operations" be changed to "consists of two or more unit operations" because a single unit operation (e.g., a distillation unit) is not a complete process by itself. Secondly, the commenter

suggested that the phrase "or isolated intermediate" (used throughout the definition) be deleted because "processes produce products," but "*portions* of processes produce intermediates." The commenter further explained that although the product of one process may be used as a raw material in another process, the product serving as the raw material is not typically thought of as an intermediate.

Response: The EPA agrees with the commenters that QA/QC laboratories are not part of the process, and the definition of process in the final rule excludes QA/QC laboratories.

In response to the comments regarding the inclusion of storage tanks in the definition of process to clarify that storage tanks are included in the pollution prevention alternative, the final rule includes storage tanks in the definition of PMPU and then refers to PMPU's instead of "processes" in the pollution prevention provisions (see also Section 3.2--Definition of Pharmaceutical Manufacturing Operations, Pharmaceutical Manufacturing Processes Units, and General Applicability, and Section 10.2--Clarification of the P2 Alternative). However, storage tanks are not required to be controlled separately if the P2 alternative is selected.

The EPA disagrees with the commenters who believe that the term, "nondedicated," as applied to formulation facilities, should be applied to the equipment within the facility and not to the facility itself. As explained in Section 3.1, the pharmaceutical NESHAP regulates processes, not equipment, and the concept of primary use is applied to the pharmaceutical product, not to the equipment used to manufacture the product. The final rule clarifies the intent of the proposed rule with regard to formulation and solvent recovery operations: these operations occurring within a contiguous area are to be considered as single processes, regardless of the final product of that formulation or recovery.

The EPA agrees with the suggestions provided by commenter IV-D-10 to delete all references to "isolated intermediate" and has incorporated these comments into the definition of process in the final rule. Also, the definition of pharmaceutical product in the final rule (see Section 3.1--General Applicability: Definition of Pharmaceutical Product) states that pharmaceutical product "includes drug components such as raw starting materials or precursors that undergo chemical change or processing before they become active ingredients." Therefore, drug components such as raw materials and precursors, which are themselves products of processes, are defined as products, rather than "intermediates," thus eliminating the need for the

concept of "intermediates" (see also Section 3.11--Definition of Isolated Intermediate). The EPA has retained the phrase "one or more" unit operations in the definition of process, since some formulation and solvent recovery operations would be considered single unit operations.

For the reasons stated above, the definition of "process" in the final rule is as follows (strikeouts represent deletions, italics represent additions):

"Process means a logical grouping of processing equipment which collectively function to produce a pharmaceutical product. ~~or isolated intermediate~~. A process may consist of one or more unit operations. For the purposes of this subpart, process includes all or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a *pharmaceutical* product. ~~or isolated intermediate~~. ~~The physical boundaries of a process are flexible, providing a process ends with a product or isolated intermediate or with cessation of onsite processing~~. Cleaning operations conducted are considered part of the process. *The holding of the pharmaceutical product in tanks or other holding equipment for more than 30 consecutive days, or transfer of the pharmaceutical product to containers for shipment, marks the end of a process, and the tanks are considered part of the PMPU that produced the stored material. When material from one unit operation is used as the feedstock for the production of two or more different pharmaceutical products, the unit operation is considered the endpoint of the process that produced the material, and the unit operations into which the material is routed mark the beginning of the other processes.* Nondedicated ~~solvent~~ recovery devices ~~and nondedicated formulation operations located~~ within a contiguous area are considered single processes. *Nondedicated formulation operations occurring within a contiguous area within the affected source are considered a single process that is used to formulate numerous materials and/or products. Quality Assurance and Quality Control laboratories are not considered part of any process.*"

3.5 DEFINITION OF PROCESS VENT

Status at proposal. Process vent was defined as "a vent from a unit operation through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Process vents do not include vents on storage tanks regulated under Section 63.1252(b), vents on

wastewater emission sources regulated under Section 63.1252(d), or pieces of equipment regulated under Section 63.1252(e)."

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) requested that EPA modify the definition of process vent to exempt any vent that contains a gas stream with less than 50 ppmv HAP averaged over the unit operation. These commenters cited 40 CFR Part 63.113(g) of the HON, which exempts vents with less than 50 ppmv from monitoring or any other provisions of Sections 63.114 through 63.118. One of these commenters (IV-D-23) provided a cost analysis, using an EPA biofilter cost model, for an existing fermentation operation, the emissions from which typically contain less than 50 ppmv methanol. The cost effectiveness of biofiltration for this scenario was estimated to be $27,000/Mg, with a percent control of 60 percent (i.e., 50 ppmv to 20 ppmv, EPA's established practical limit of control), a value that the commenter stated was "clearly unreasonable." The commenter further stated that for fermenter and fermenter preparation vents, a cutoff of 100 to 200 ppmv could be justified (as opposed to 50 ppmv) and requested that EPA consider such a cutoff.

Two commenters (IV-D-08 and IV-D-28) stated that the proposed definition of process vent implies that every process vent is connected to a single piece of unit operations equipment, which often is not the case at multiproduct, multibatch facilities. One of the commenters (IV-D-28) suggested that the definition include a statement indicating that "multiproduct facilities having multiple production trains may have large numbers of process vents, which could discharge directly to the atmosphere; discharge through a dedicated control equipment; or which can be manifolded from many process units into a common header leading to a common control equipment." The other commenter (IV-D-08) stated that compliance with the process vent standards would be more difficult and expensive if the definition of process vent included the combined or commingled vents from several pieces of unit operations equipment, rather than just one piece of equipment. This commenter also questioned if standard industrial hygiene type exhaust pickups and general room ventilation exhaust points are meant to be included in the definition of process vents. The commenter pointed out that those types of systems may exhaust through a stack, which may be interpreted as being an emission point, but noted that some states do not consider these emission points for the purposes of Title V permits. The commenter stated

that, if these emission points were not considered in developing the MACT floors, they should not be included as process vents, and requested clarification from EPA.

Response: As explained in Section 7.1.1, De minimis Cutoffs for Processes and Process Vents, the definition of process vent in the final rule includes a de minimis cutoff of 20 ppmv, the practical limit of control. Regarding multiple vents (from the same process) being manifolded together into a common header, the Agency views the common header as a single process vent, and has revised the definition of process vent to reflect this view.

The Agency does not believe that compliance with the process vent standards would be more difficult and expensive if the definition of process vent included the combined or comingled vents from several pieces of unit operations equipment, rather than just one piece of equipment. For existing sources the standards for the sum of all process vents from a single process require either a 93 percent reduction from uncontrolled, or a limit of 2,000 lb/yr HAP emissions. Even if all vents from unit operations within a process are physically combined through one single vent, the Agency believes that owners and operators must still quantify uncontrolled emissions on a per-unit operation basis. Therefore, the applicability determination is not affected by this change in definition. Further, the demonstration of compliance may actually be simplified since the determination of uncontrolled emissions would be based solely on the operating characteristics of the single control device, rather than on numerous control devices and emission points throughout the process.

An additional requirement for existing sources is that process vents having a certain yearly mass of uncontrolled emissions are required to be controlled to 98 percent. By defining combined vents from unit operations within a process as single vents, it is possible that the 98 percent control requirement will more likely be triggered than if vents from unit operations that are physically combined were required to be evaluated separately. However, this requirement, which is above the floor, was evaluated for technical and economic feasibility and found to be cost effective. For batch process vents, the Agency has found that combining vents prior to control can be effective.

In response to one commenter's (IV-D-08) question about whether or not industrial hygiene exhausts and general room ventilation exhausts would meet the definition of process vent, these sources generally would not be considered process vents. However, some equipment

exhaust pickups might fit the definition of process vents, since they could exhaust material from unit operations such as open reactors or centrifuges.

Based on the changes discussed above, the definition of process vent in the final rule is as follows:

"Process vent means a vent from a unit operation, *or vents from multiple unit operations within a process that are manifolded together into a common header*, through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. *Emission streams that are undiluted and uncontrolled containing less than 20 ppmv HAP, as determined through process knowledge that no HAP are present in the emission stream or using an engineering assessment as discussed in § 63.1257(d)(2)(ii), test data using Method 18 of 40 CFR Part 60, Appendix A, or any other test method that has been validated according to the procedure in Method 301 of Appendix A of this subpart, are not considered process vents.* Process vents do not include vents on storage tanks regulated under Section 63.1253, vents on wastewater emission sources regulated under Section 63.1256, or pieces of equipment regulated under Section 63.1255."

3.6 DEFINITION OF PROCESS CONDENSER

Status at proposal. Process condenser was defined as "a condenser whose primary purpose is to recover material as an integral part of a unit operation. The condenser must support vapor-to-liquid phase change for periods of source equipment operation that are above the boiling or bubble point of substances(s). Examples of process condensers include distillation condensers, reflux condensers, process condensers in line prior to the vacuum source, and process condensers used in stripping or flashing operations."

Issues/data. The numerous comments on the definition of process condenser primarily dealt with the dual role of condensers as both process condensers and air pollution control devices, and in which category recirculating drying systems should be classified.

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) took issue with the phrase *"integral part* of a unit operation" and "process condensers *in line prior to the vacuum source*." These commenters cited examples where it

could be concluded that a condenser is not integral to a process because it does not perform any necessary process function. The commenters also stated that if there were two condensers in series prior to a vacuum source, and the first condenser effected a phase change, then the second condenser should be considered an air pollution control device, even though it is located "prior to a vacuum source." For these reasons, the commenters provided the following recommended definition of process condenser:

"Process condenser means, during periods of source equipment operation that are above the boiling or bubble point of the contents of the equipment, or where other bulk vaporization of a HAP occurs, the first condenser, located after the process equipment, which supports a vapor-to-liquid phase change for the vapors produced in the process equipment."

Three commenters (IV-D-20, IV-D-28 and IV-D-40) suggested that the intended use be considered when determining whether a condenser is a process condenser or an air pollution control device. Two of these commenters (IV-D-28 and IV-D-40) stated that, "if the condenser is acting as a control unit, so that its presence is intended to prevent chemicals from reaching the uncontrolled environment; if the materials collected are led towards management and disposal systems; and if the collected materials are in no way used, reused, nor sold for fuel value, then the condenser is serving as a control unit regardless of the fact that the bubble point is met or not at the source." The commenters (IV-D-28 and IV-D-40) also suggested that the performance of these types of condensers could be checked by monitoring the temperature of exit gases and flowrate. The other commenter (IV-D-20) disagreed with the condition that to be a process condenser, the condenser must support a vapor-to-liquid phase change for periods of source equipment operation that are above the boiling or bubble point of the substance(s). This commenter pointed out that under the proposed definition, the same condenser will sometimes be a process condenser and sometimes an air pollution control device, and tracking when the condenser switches from one to the other would be burdensome. Therefore, the commenter recommended that the facility which operates the condenser (and knows the process best) be allowed to determine whether it is a process condenser or an air pollution control device, and recommended the following definition of process condenser:

"Process condenser means a condenser whose primary purpose is to recover material as an integral part of the unit operation, or is essential to effectively run the process."

Another commenter (IV-D-13) suggested that EPA distinguish between process condensers and condensers serving as air pollution control devices by including a specific temperature limit as part of the definition, as follows: "Process condenser should be defined to mean actually lowering the exit gas stream to a temperature of 20°C, during periods of source equipment operation that are above the boiling point or bubble point of the content of the equipment, or where other bulk vaporization of a HAP occurs. Any colder temperatures resulting from the use of one or more condensers, located after the process equipment, which supports a vapor-to-liquid phase change for the vapors produced in the process equipment, should be considered an air emission control for the incremental cooling and condensation."

Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) requested that EPA specifically address process condensers that belong to recirculating drying systems. Most commenters (IV-D-17/13/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that condensers in recirculating drying systems should be considered pollution control devices. However, one commenter (IV-D-15) stated that condensers in recirculating drying systems should be defined as neither process condensers nor air pollution control devices, but defined separately, with "management systems to account for their pollution prevention effects to be worked out at a later date for the promulgated standard." The major concern of all of these commenters, however, was that under the proposed definition, the condensers in recirculating drying systems would be considered process condensers, and thus uncontrolled emissions, and the resulting emissions reductions would be considerably lower than if the condenser was considered an air pollution control device. Even though these systems generate considerably lower emissions as compared to once-through systems, owners and operators could not take advantage of the high emission reductions in the process vent standard that requires 93 percent control or 2,000 lb/yr after control from the entire process.

Response: The Agency disagrees with the commenters, in general. The EPA agrees with the commenter's clarification that the first condenser prior to a vacuum source that effected a phase change would be a process condenser. However, the second condenser would also be considered a process condenser, based on the definition contained in the final rule.

All condensers prior to the vacuum source are considered to be process condensers; prior to vacuum discharge, the characteristics of potential emission streams differ significantly from

discharge conditions (post-vacuum, atmospheric conditions). Additionally, emissions occur only as a result of the discharge of noncondensables saturated with HAP at the outlet conditions. The calculation of control efficiency is not straightforward for prevacuum source conditions. Therefore, the final rule defines uncontrolled emission at the outlet of the vacuum source.

The EPA disagrees with the suggestion that the owner or operator should be allowed to determine whether a condenser is a process condenser or an air pollution control device based on "intended use." Because one of the formats of the process vent standard requires that a reduction from uncontrolled be applied across a process (i.e., 93 percent), EPA is concerned about the opportunity for crediting reductions achieved by condensing boiling streams on other sources in the process. In fact, in requesting data from industry (which was later used to set the MACT floor), the MACT partnership specifically confirmed from responders that the data reported was based on the definition of process condenser as described in the final rule.

Regarding the commenter's issue that a single condenser could be defined as a process condenser in some situations and an APCD in other situations, EPA believes that this situation will occur, but the conditions for each situation are well-defined in the final rule. The EPA believes that this result is preferred over an arbitrary designation of a condenser as an APCD purely on the basis of whether another condenser exists prior to it, for example. The EPA also considered the suggestion to use 20°C as a temperature cutoff in determining whether a condenser is a process condenser or an air pollution control device. This approach would provide a single and effective way to identify a process condenser from an APCD. It might also encourage owners and operators to operate all condensers as APCD's to achieve maximum reductions. However, the MACT floors and the data used to set them are not based on this approach. In order to implement this approach, EPA would have to request more data in order to recalculate floors, which is not feasible at this time. Finally, EPA disagrees with the requests that condensers in recirculating drying systems be considered as pollution control devices or defined separately. Emissions from the recirculating drying systems typically occur only during periodic depressurizations, and these uncontrolled emissions may be low enough such that the process may be under the 2,000 lb/yr cutoff. Processes with recirculating drying systems also may be able to take advantage of the P2 standard.

The definition of process condenser remains essentially the same as in the proposed rule, with several clarifying changes: the final rule changes the phrase "integral part of a unit operation" to "integral part of a process" and clarifies that "all condensers up to and including the first condenser with an exit gas temperature below the boiling point or bubble point of the substance(s) at the liquid surface are considered process condensers." Additionally, all condensers in line prior to a vacuum source are considered process condensers. The final rule also requires that process condensers be "properly operated" such that they do function in reducing material to below its boiling or bubble point. Owners and operators are required to conduct a demonstration, either by measuring temperature before and after the condenser or by conducting a mass balance around the still and receiver, to demonstrate the efficiency of the process condenser.

3.7 DEFINITION OF PROCESS TANK

Status at proposal. Process tank is defined as "a tank that is physically located within the bounds of a process that is used to collect material discharged from a feedstock storage tank or unit operation within the process and transfer this material to another unit operation within the process or a product storage tank. Surge control vessels and bottoms receivers that fit these conditions are considered process tanks."

Comment: One commenter (IV-G-01) stated that the definition of process tank should exclude the phrase, "physically located" because that phrase is ambiguous.

Response: EPA agrees with the comment. Therefore, the phrase "physically located" was removed from the definition of process tank in the final rule.

3.8 DEFINITION OF BATCH CYCLE

Status at proposal. Batch cycle "refers to manufacturing an intermediate or product from start to finish in a batch unit operation."

Comment: One commenter (IV-D-10) stated that the definition of batch cycle should not refer to a batch "unit operation," but instead should refer to "batch unit operation cycle." The commenter explained that a batch cycle "includes all processing steps in the combination of all unit operations throughout the entire batch process, from raw materials to finished product."

Response: The EPA agrees with the commenter that batch cycle is intended to refer to the production from start to finish. However, EPA eliminated the definition of batch cycle in the final rule and referred instead to the length of time required for a batch process.

3.9 DEFINITION OF CLOSED VENT SYSTEM

Status at proposal: Closed vent system was defined as "a system that is not open to the atmosphere and is composed of piping, ductwork, connections, and, if necessary, flow inducing devices that transport gas or vapor from an emission point to a control device or back into the process."

Comment: One commenter (IV-D-10) stated that the definition of closed vent system should not include the phrase "or back into the process" because (as the HON clarifies in subpart G) closed-vent systems go to a control device and not to the process, and "anything not going to a control device should not be called a closed-vent system." The commenter pointed out that when emissions are routed to a process, it is referred to as "hard-piping," not a closed vent system, such that the piping is subject to equipment leak requirements but not the requirements for closed vent systems. (See also the definition of hard piping in Section 3.10, below)

Response: The EPA agrees with the commenter. The definition of closed vent system in the final rule deletes the phrase, "or back into the process." The EPA also has added requirements for closed vent systems as they are used to transport emissions from emission sources other than waste management units as they were inadvertently left out of the proposed rule.

3.10 DEFINITION OF HARD PIPING

Status at proposal: Hard piping was defined as "tubing that is manufactured and properly installed using good engineering judgement and standards, such as ANSI B31-3."

Comment: One commenter (IV-D-10) requested that EPA modify the definition of hard piping to match the definition of hard piping in the HON, which replaced the term "tubing" with "pipe or tubing" to clarify that "rigid" pipe can be considered hard piping.

Response: The EPA agrees with the commenter. The definition of hard piping in the final rule includes the suggested revision.

3.11 DEFINITION OF ISOLATED INTERMEDIATE

Status at proposal: Isolated intermediate was defined as "any intermediate that is removed from the process equipment for temporary or permanent storage or transferred to shipping containers."

Comment: One commenter (IV-D-10) stated that EPA should not use or define the term, "isolated intermediate," in the proposed rule. (The same commenter also stated that the term, "isolated intermediate," should be removed from the definition of process [see also Section 3.4--Definition of Process].) The commenter pointed out that the term is "peculiar to the Toxic Substances Control Act (TSCA), where a long history of interpretation has been developed," and if EPA uses this same term in the proposed rule, "inconsistencies in interpretation will be inevitable."

Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-D-40, IV-G-01, and IV-G-04) suggested the definition of isolated intermediate be modified so that the physical removal of an intermediate from the process equipment is not required as a condition for meeting the definition of isolated intermediate. These commenters pointed out that, in some cases, an intermediate may remain in a storage tank or other retention equipment prior to being used in a different process step, and without ever being removed from either set of process equipment. The commenters further stated that the fact that retention tanks are used as separation lines as an alternative to storing the material in drums or separate containers "is a matter of convenience." Therefore, the commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) recommended the following modified definition of isolated intermediate:

"Isolated intermediate means any intermediate that is stored in storage tanks or other holding equipment for later use, or that is transferred to containers for shipment or storage."

Response: As explained in Section 3.4--Definition of Process, EPA has deleted the term, "isolated intermediate," from the definition of process to avoid confusion. Also, the definition of process in the final rule specifies when a process "ends" and to which process emissions from tanks or other holding equipment should be attributed.

3.12 DEFINITION OF MAXIMUM TRUE VAPOR PRESSURE

Status at proposal. Maximum true vapor pressure was defined as "the equilibrium partial pressure exerted by the total organic HAP in the stored or transferred liquid at the temperature

equal to the highest calendar-month average of the liquid storage or transferred temperature for liquids stored or transferred above or below the ambient temperature or at the local maximum monthly average temperature as reported by the National Weather Service for liquids stored or transferred at the ambient temperature, as determined:

1. In accordance with methods described in American Petroleum Institute Publication 2517, Evaporative Loss from External Floating-Roof Tanks (incorporated by reference as specified in Section 63.14 of subpart A of this part); or

2. As obtained from standard reference texts; or

3. As determined by the American Society for Testing and Materials Method D2879-83 (incorporated by reference as specified in Section 63.14 of subpart A of this part); or

4. Any other method approved by the Administrator."

Comment: One commenter (IV-D-28) requested that EPA provide an alternate vapor pressure cutoff for an annual average vapor pressure. The commenter cited the direct final rule to expand and clarify the definition of true vapor pressure included in the petroleum refining NESHAP (62 FR 7937). The commenter stated that, although providing this alternative will not change the end result, "the availability of an annual average vapor pressure would provide a different and flexible way to determine applicable control requirements."

Response: The EPA has not changed the definition of true vapor pressure, per the commenter's suggestion. The format for vapor pressure ranges and the definition of vapor pressure is identical to that provided in other rules covering the storage of organic liquids, such as NSPS Kb and the HON. The Agency believes that the definition of maximum true vapor pressure is clear and sees no benefit in offering an additional option for this rule.

3.13 DEFINITION OF METALLIC SHOE SEAL

Status at proposal. Metallic shoe seal (or mechanical shoe seal) was defined as "a metal sheet that is held vertically against the wall of the storage vessel by springs, weighted levers, or other mechanisms and is connected to the floating roof by braces or other means. A flexible coated fabric (envelope) spans the annular space between the metal sheet and the floating roof."

Comment: One commenter (IV-D-10) suggested that EPA modify the definition of metallic shoe seal to allow multiple metal sheets to be considered one metallic shoe seal. The commenter stated that the proposed rule seems to suggest that a metallic shoe seal can include

only a single metal sheet, which is not the common practice. The commenter suggested that EPA revise the definition of metallic shoe seal to match the definition contained in the HON.

Response: The EPA agrees with the commenter. The definition of metallic shoe seal in the final rule is the same as that provided in the HON.

3.14 DEFINITION OF RESEARCH AND DEVELOPMENT FACILITY

Status at proposal. Research and development facility was defined as "research or laboratory operations whose primary purpose is to conduct research and development into new processes and products, where the operations are under the close supervision of technically trained personnel, and is not engaged in the manufacture of products for commercial sale, except in a de minimis manner."

Issues/data. The definition of "research and development facility" was based on the definition of "research or laboratory facility" provided in Section 112(c)(7) of the Clean Air Act.

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) support the proposed definition of research and development facilities because it draws a clear distinction between activities related to manufacturing (which will be covered under the proposed rule) and those related to research and development (which will not be covered by the proposed rule). The commenters further stated that such a clear distinction is necessary because pharmaceutical manufacturing operations and research and development activities are often located at the same site. However, one of these commenters (IV-D-15) also suggested that, to avoid any possible confusion, the same terminology should be used in both the proposed pharmaceutical rule as in Section 112(c)(7), i.e., the term, "research and development facility," should be changed to "research or laboratory facility."

Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) requested that EPA make it clear that pilot plants are not subject to the proposed pharmaceutical standards if they meet the definition of "research and development facility." These commenters provided suggested language for the preamble to the final rule to explain that, when determining whether an operation or a facility constitutes a research and development facility, the implementing agency should use the definition of research and development facility as the principle guide, rather than company designations or facility names because often an R&D facility and a manufacturing facility are under a common name. The commenters also stated that

if the pilot plant was, in fact, dedicated to production for commercial sale (except in a de minimis manner), then it would not meet the definition of research and development facility and thus would be subject to the proposed rule (assuming that it is located at a major source and meets the definition of pharmaceutical manufacturing operation). Two commenters (IV-D-08 and IV-D-27) were concerned the term "de minimis" is not defined in the proposed rule. One of the commenters (IV-D-27) stated that "without clarification (of de minimis) the definition will lead to exhaustive and potentially contentious negotiations between sources and regulatory agencies, and may result in inequitable exemption decisions at similar facilities located in different jurisdictions." The commenter also pointed out that some states have included more specific provisions, such as limiting the number of products produced, establishing maximum daily emission rates, or requiring segregation of the R&D activities from the production areas. One commenter (IV-D-08) requested that EPA include demonstration runs required by the Food and Drug Administration under R&D activities. The commenter pointed out that one of the FDA's requirements for approval of a new product is the validation of the manufacturing process in the actual facilities where commercial production is expected to occur, and thus, during the demonstration runs, the manufacturing facility should be considered an R&D facility.

Response: The EPA disagrees with commenter IV-D-15 that the term "research and development facility" should be changed to "research or laboratory facility" to match the terminology in Section 112(c)(7) of the CAA. Laboratories are frequently found in facilities where no research occurs. In some cases, these laboratories could contribute to emissions and should not be excluded by the rule solely on the basis of terminology. When determining if a facility is a "research and development facility," the implementing agency should use the definition of research and development facility, rather than company designations or facility names because R&D facilities and manufacturing facilities may be under a common name.

Regarding establishment of a de minimis level for R&D facilities, the EPA does not have sufficient data to establish a de minimis level for R&D facilities. Furthermore, EPA plans to issue a separate NESHAP for R&D facilities that would cover emissions from these sources.

3.15 DEFINITION OF RECOVERY DEVICE

Status at proposal. Recovery device was defined as "an individual piece of equipment used for the purpose of recovering chemicals for fuel value (i.e., net positive heating value), use,

reuse, or for sale for fuel value, use, or reuse. Air pollution control devices are not recovery devices. Process condensers are recovery devices. Other examples of equipment that may be recovery devices include organic removal devices such as decanters, strippers, or thin-film evaporation units."

Comment: One commenter (IV-D-28) requested that EPA modify the definition of recovery device to include condensers at multi-product facilities that "recover" materials from air streams that cannot be reused due to cross-contamination problems. The commenter suggested that the definition be modified as follows:

"Recovery device means an individual unit of equipment used for the purpose of recovering chemicals for fuel value, use, reuse, for sale for fuel value, or for accumulation and disposal..."

Response: The definition of process condenser versus air pollution control device has been addressed in this document. Based on this definition, the fate of the material "recovered" by the condenser has no bearing on the determination of whether the condenser is an APCD or a process condenser. The term "recovery device" is used in the wastewater provisions and in the definition of "process." It is not used in defining an air pollution control device.

3.16 DEFINITION OF STORAGE TANK

Status at proposal. Storage tank was defined as "a tank or other vessel that is used to store organic liquids that contain one or more HAP. The following are not considered storage tanks for the purposes of this subpart: (1) vessels permanently attached to motor vehicles such as trucks, railcars, barges or ships; (2) pressure vessels designed to operate in excess of 204.9 kilopascals and without emissions to the atmosphere; (3) vessels storing organic liquids that contain HAP only as impurities; (4) wastewater storage tanks; and (5) process tanks."

Comment: One commenter (IV-D-23) requested that EPA clarify the definition of storage tank as it relates to movable vessels permanently attached to motor vehicles to indicate that both truck trailers and railcars are not considered storage tanks. The commenter explained that while it seems clear that railcars, not attached to an engine, are not storage tanks, it is not clear whether truck trailers, not welded to an engine, may be storage tanks, because they are not permanently attached.

Response: The EPA agrees that railcars and truck trailers are not storage tanks, even though they may not always be "permanently attached" to motor vehicles. The EPA further notes that this rule applies to stationary sources. The EPA further modified the definition of storage tank to clarify that storage tanks store feedstocks or products of processes.

3.17 DEFINITION OF WASTE MANAGEMENT UNIT

Status at proposal. Waste management unit was defined as "a component, piece of equipment, structure, or transport mechanism in conveying, storing, treating, or disposing of wastewater streams or residuals." Examples of waste management units include wastewater tanks, air flotation units, surface impoundments, containers, oil-water or organic-water separators, individual drain systems, biological treatment units, waste incinerators, and organic removal devices such as steam and air stripper units, and thin film evaporation units. If such equipment is used for recovery then it is part of a pharmaceutical process and is not a waste management unit.

Comment: One commenter (IV-D-20) requested that EPA modify the definition of waste management unit to exclude incinerators because waste incinerators are scheduled to be covered under other Part 63 standards, and no single emission point should be regulated by more than more Part 63 standard.

Response: The EPA disagrees with the commenter; however, the final rule includes a section that discusses consistency with similar regulations and specifies how owners or operators determine which regulations are applicable.

3.18 ADDITIONAL DEFINITIONS

Comment: One commenter (IV-D-23) suggested EPA allow for openings of safety devices as described in RCRA Subpart DD (Offsite Waste and Recovery Operations).

Response: The EPA agrees with this comment and has incorporated both the definition of safety device from the referenced regulation, as well as the relevant language in the standards allowing for the opening of such devices during unsafe conditions.

4.0 NEW SOURCE MACT ISSUES

4.1 NSM--INCORPORATION OF GP LANGUAGE INTO RULE

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) expressed strong support for the new source MACT (NSM) applicability provisions in the proposed rule, and made four specific comments. The commenters recommended improving the clarity of § 63.1250 (c) by incorporating language from the General Provisions (§ 63.5(b)) rather than referencing the General Provisions (see similar comments on cross-referencing in Section 6.3 of this document). The commenters suggested composite language that specifies the three triggers for NSM (including the construction/reconstruction date limit and the three ways a new PMPU qualifies as an NSM trigger). The commenters also noted that if the recommended language is accepted the following changes will be necessary:

1. In § 63.1250(b) change "pharmaceutical manufacturing operations" to "PMPU's subject to this subpart."

2. In Table 1, indicate that § 63.5(b) is not applicable. This is because it is expressly incorporated into Subpart GGG.

Response: The Agency appreciates the commenters' support for NSM and has decided to specify some of the criteria for having to meet NSM in the final rule. However, the Agency has decided to maintain the referencing to the General Provisions as in the proposed rule, including references to 63.5(b). To incorporate all of the General Provisions language and requirements into the final rule would involve significant time and effort and in most cases not provide any real benefit to the regulated entities. Most of the provisions of 63.5(b) apply as written. However, the Agency has tried to incorporate into the final pharmaceutical NESHAP those areas of the General Provisions and other referenced rules that were confusing to the commenters in the proposed rule. Those changes are also reflected in revised Table 1 of the final rule.

4.2 NSM--WASTEWATER SYSTEMS

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) objected to applying NSM to common wastewater systems that handle wastewater from new and existing sources (§ 63.1250(c) and (b)). These commenters said that the definition of PMPU could be interpreted to require that an existing wastewater system be upgraded to NSM because a new, dedicated, major-emitting PMPU discharges into it. According to commenter IV-G-01, options for the plant would be installation of a separate system for the new source or total reconstruction or replacement of the wastewater system, and both options seem to be unreasonable. (See also Section 3.2--Definition of Pharmaceutical Manufacturing Operations and PMPU.)

Response: If a new PMPU generates a wastewater stream that is required to be controlled, then the more stringent new source standard would apply for that wastewater stream only, not the entire waste management system. There are several options for complying with the more stringent new source standards, as the commenter suggests. However, another option would be to treat offsite. The Agency, in estimating costs for treatment of these streams, assumed that all wastewater subject to the new source standards would be disposed of, rather than treated onsite.

4.3 NSM--AREA SOURCES

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) said that § 63.1250(d) does not specifically address whether new or existing source MACT applies to area sources that become major sources after the date of the proposal. References to §§ 63.6(b)(7) and (c)(5) in Table 1 of the proposed rule indicate that the applicable MACT (i.e., new vs. existing MACT) is determined by the date of construction or reconstruction of the area source. However, the commenters believe that a more appropriate guideline would be to require NSM only upon construction or reconstruction of an affected source or construction of a major-emitting PMPU. The commenters gave an example in which an area source becomes a major source due to an unrelated but nearby activity. Commenters stated that requiring this source to adhere to strict NSM "makes no sense" because there are no changes into which the NSM could be reasonably integrated.

The commenters suggested that area sources that become major sources are only subject to NSM in one of these two instances:

1. The increase from area source to major source occurs after April 2, 1997 and is due to construction of one or more dedicated, major-emitting PMPU's, or

2. The increase from area source to major source occurs after April 2, 1997 and is due to reconstruction of the affected source.

The commenters suggested specific language and added that if the recommended language is accepted, it will be necessary to indicate, in Table 1, that § 63.6(b)(7) and (c)(5) are not applicable. The commenters also suggested that similar provisions be included for existing manufacturing operations and R&D equipment that are converted to pharmaceuticals usage.

Response: The commenter's interpretation of how NSM would be triggered is correct. The final rule specifies that if a process or product is changed at an area source and the HAP emissions increase to major source levels, then the source of those emissions is subject to NSM requirements only if the addition itself has the potential to emit 10 or 25 tons per year, on an uncontrolled basis, or if the changes trigger reconstruction. Additionally, the final rule also specifies that new source MACT applies to sources that are constructed or reconstructed after April 2, 1997, and the standard was applicable at the time of construction or reconstruction. This language addresses applicability of new source MACT to manufacturing operations that are converted to pharmaceutical manufacturing operations after the proposal date of this standard, such as contract manufacturers.

Relating to the referenced General Provisions, the Agency notes that the provisions of 63.6(b)(7) are no longer applicable and therefore are not referenced in the final rule. However, the compliance dates in 63.6(c)(5) do still apply. Existing sources that become subject to the standards by increasing emissions from area source to major source levels are allowed 3 years to comply with the existing source standards.

4.4 NSM--MAJOR-EMITTING PMPU

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) recommended that the determination of whether a new PMPU is dedicated and major-emitting should occur only once and at the time of construction. These commenters suggested that these determinations be explained in the preamble as well, and gave an example of

a nondedicated, major-emitting PMPU added to a plant site and later changed to a dedicated, major-emitting PMPU. The commenters pointed out the burdens for the owner/operator to comply with NSM after construction.

Response: The Agency does not believe that this argument is valid or consistent with earlier comments. If the nature of the industry is variable and prone to continual process changes to produce new products, then the resulting emissions have to be variable as well. Deciding how the emissions for a PMPU are to be controlled and regulated has to depend on how the PMPU is to be used. The only available option for the source to use to minimize the burden associated with NSM is to comply with NSM upon startup of the PMPU, if there is any chance that the new PMPU would be dedicated to the manufacture of a single product.

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) suggested that the rule provide case-by-case determination of the control efficiency required when a dedicated PMPU subject to NSM is converted to nondedicated use. The commenters provided an example where the control equipment installed for the dedicated unit achieves 98 percent control efficiency. Several years later the process is changed and the control equipment cannot achieve 98 percent control. The commenters suggested that to accommodate such circumstances, the final rule should provide that if the PMPU is subject to NSM at the time of construction, but is later converted to nondedicated operations, the Administrator (or the permitting authority) may establish a required control efficiency for the nondedicated operations that is between 93 and 98 percent if the owner/operator demonstrates that the existing control equipment cannot achieve 98 percent control efficiency after it is converted to nondedicated operations.

Response: In the example provided by the commenter, the dedicated process is no longer in operation and a new process is instead operating, using all or part of the same equipment that was used to make the original product. This "new" process is no longer associated with the original process, regardless of the equipment used. Therefore, the determination of whether the "new" process triggers new source MACT reverts back to the considerations described under Section 4.2; unless the source is reconstructed or the new process is effectively an "addition" that has potential uncontrolled emissions of 10 or 25 tons/yr HAP, new source MACT is not

triggered. Additionally, if the facility reverts back to the original process that triggered NSM, NSM would again be applicable for that process.

Comment: Two commenters (IV-D-08 and IV-D-28) raised the issue of emissions credits and/or offsets. Commenter IV-D-08 suggested that a new PMPU "net out" of or not be subject to NSM if its HAP emissions are "offset" with credible contemporaneous emission reduction credits. Similarly, Commenter IV- D-28 recommended that new PMPU could net out of NSM if it "involves no addition of new equipment in HAP service and does not trigger new air control efficiency requirements and/or new wastewater treatment requirements."

Response: There are no provisions in the rule that allow a facility to "net out" or trade emission credits associated with a source subject to the more stringent requirements of NSM.

5.0 GENERAL PROVISIONS ISSUES

5.1 COMPLIANCE EXTENSIONS

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that the final rule should include express procedures for obtaining compliance extensions at any time prior to the applicable compliance deadlines, as in the revised HON. The proposed rule incorporates by reference Section 63.6(i)(4)(i) from the General Provisions, which provides that affected sources may obtain a compliance extension of up to 1 year provided certain procedural requirements are satisfied. While the commenter supports the need for general provisions regarding compliance extensions, the proposed general provisions for compliance extensions must be replaced with provisions tailored to the needs of the pharmaceutical industry. The commenter's solution to this problem was to provide express compliance extension requirements that mirror those contained in the recent modifications to the HON. Table 1 also should be revised to indicate that the deadlines for submission of compliance extensions in 63.6(i)(4)(i) do not apply.

Response: The EPA agrees with the commenter and has incorporated the appropriate language from the revised HON and revised Table 1 in the final regulation.

5.2 PROVISIONS FOR STARTUP, SHUTDOWN, AND MALFUNCTION

Comment: Many commenters (IV-D-10, IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated the rule should include provisions for startup, shutdown, and malfunction. These commenters pointed out the requirements of 63.1250 conflict with 63.1254. These commenters also stated that this concern/conflict can be eliminated by defining the terms "startup" and "shutdown" in the rule and provided example language (definitions). Commenter IV-G-04 stated the EPA should recognize that the batch campaigns and processes used by the industry cause some products to be infrequently produced. As such, the first batch may not be nearly as efficient as the later batches. The startup and shutdown exemption should

note this change and have it included as part of the exemption process reporting. Commenter IV-D-35 requested that the final rule be modified so that it is absolutely clear that the startup and shutdown provisions apply to batch as well as continuous process operations. Likewise, the startup, shutdown, and malfunction provisions must be extended to monitoring equipment as well as to process and control equipment. The Table of General Provisions indicates that § 63.8(c)(4) and (7) does not apply to this rule. Commenter IV-D-35 recommended that this provision be incorporated into the pharmaceutical MACT to eliminate ambiguity as to the applicability of startup, shutdown, and malfunction (SSM) to monitoring equipment.

Response: The EPA has reconsidered the exclusion of startup and shutdown provisions for batch processes from the startup, shutdown, and malfunction plan provisions and agrees that the provisions can apply to batch processes in some instances. Therefore, the final regulation allows exemptions from the standard's requirements during startup, shutdown and malfunction, where the terms startup and shutdown have been defined considering batch processing. For example, startup is defined as the first time a new or reconstructed source begins production. The term shutdown has been clarified to not apply during routine batch operations or in between batches. The EPA has also clarified in the final rule that the provisions can apply to processing equipment, as well as control, monitoring, and recordkeeping equipment. Therefore, new language from the HON has been added to the final rule to include details of the SSM plan and the associated recordkeeping and reporting requirements.

5.3 EXCESSIVE CROSS-REFERENCING

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04, and IV-D-08) requested that the Agency eliminate cross-referencing with the Part 63 General Provisions and other regulations by putting all substantive requirements in the rule. The commenters further stated that in general, the rule is too complicated and the cross-referencing creates another layer of complexity. Example problems were cited where a section of another rule is cross referenced that describes conditions or situations that are not relevant to pharmaceutical manufacturing. Many of the commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that the reliance on extensive cross-referencing creates so much potential confusion and ambiguity that the rule may violate the "fair notice" doctrine.

Commenter IV-D-23 urged the EPA to review several areas and associated requirements in the General Provisions table and clarify their applicability.

Response: The Agency agrees with the commenters that the various requirements associated with this rule are complicated, due in large part to the fact that the pharmaceutical manufacturing industry involves varied and complex processes and emissions. However, the Agency has decided to maintain portions of the referencing to the General Provisions as in the proposed rule. To incorporate all of the General Provisions language and requirements into the final rule would involve significant time and effort and in most cases not provide any real benefit to the regulated entities. The Agency has tried to incorporate into the final rule those areas of the General Provisions and other referenced rules, particularly the HON's wastewater provisions, that were confusing to the commenters in the proposed rule .

5.4 PSD/NSR AND DESIGNATION OF POLLUTION CONTROL PROJECTS (PCP'S)

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that the rule should include a provision for sources to automatically qualify for the pollution control project exclusion from major NSR or PSD permit requirements if measures taken to comply with the rule result in a net emissions increase of other regulated pollutants. The commenters referenced previous actions where EPA has proposed revisions to its PSD and NSR regulations which will require permitting agencies to relax PSD and NSR review for these types of projects. (See generally, 61 FR 38250.)

Response: While potential emission increases resulting from new pollution control devices installed to meet the requirements of the rule will presumably be viewed as environmentally friendly by permitting agencies, it is not the Agency's position to incorporate specific pollution control project exclusions into NESHAP or any other rules. These exclusions are envisioned to be handled on a case-by-case basis through the permitting authority.

6.0 STANDARDS: PROCESS VENTS

6.1 GENERAL ISSUES RELATED TO THE PROCESS VENT STANDARDS

6.1.1 De Minimis Cutoffs for Processes and Process Vents

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) suggested that the rule should contain provisions excluding PMPU's or processes that have essentially no potential to emit HAP. The commenters recommended that a de minimis cutoff be set at 0.1 percent by weight HAP usage versus other material for carcinogens and 1.0 percent for all other HAP, consistent with OSHA hazard communication requirements, below which the processes would not be subject to the rule.

Related to the above comment, but specifically targeted to individual vents is the suggestion by many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) that the definition of process vent should include a concentration threshold below which the emission stream would not be considered a process vent, and therefore, would be exempt from further applicability determinations, control or monitoring requirements. The suggested levels for this de minimis concentration are 50 ppmv or 50 ppmw. Additionally, the procedure for estimating this concentration is suggested as an average over the unit operation generating the process vent.

(See also section 3.5--Definition of Process Vent.)

Response: The EPA agrees with the above comment, and has established a de minimis cutoff for process vents at 50 ppmv HAP from uncontrolled, undiluted process vents. Additionally, the final rule contains an alternative standard for process vents that limits outlet emissions to 20 ppmv TOC or hydrogen halide. This is the practical limit of control. The de minimis cutoff is contained as part of the definition of process vent. Emission streams containing less than 50 ppmv HAP are not considered process vents.

6.1.2 Rule Should Provide a Compliance Alternative for Process Vents and Tanks Based on Condenser Exhaust Temperature

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) suggested a compliance alternative for process vents and tanks that consists of applying low end temperature defaults based on HAP. This alternative would apply to emission sources equipped with vent condensers. The alternative is patterned after the control requirement contained in the 1978 Pharmaceutical CTG for sources emitting over 15 lb/d. The commenters recalculated the temperature ranges required to get 93 percent control of the inlet emission rate, assuming the inlet emission rate was calculated the same way as was done in the 1978 CTG.

Response: The EPA has decided not to establish low-end temperature defaults for process vents for the following reasons:

1. The temperature defaults would be applied to individual process vents, not processes; therefore achieving these defaults would not provide any indication of whether the standard was met without a reevaluation of the MACT floor considering exhaust temperature defaults. However, not enough detailed information on processes was collected to conduct this determination.

2. The 1978 CTG temperature defaults provide the temperatures required to get approximately 90 percent reduction from streams that are saturated at ambient to slightly higher temperatures. Because inlet stream conditions for process vents vary, there is, in fact, no guarantee that any level of control, even on an individual vent basis, would be achieved by using these defaults.

Conversely, establishing low-end defaults may be a reasonable alternative for tanks, since emission stream characteristics from both breathing and working losses entering the condenser could be assumed to be at ambient conditions, and therefore, a prediction of temperature required to reduce emissions by 93 percent could be generated, based on a fairly narrow range of inlet conditions. Also, because control requirements on tanks are imposed on individual tanks as opposed to processes, the issue described in reason No. 1 above for process vents would not apply. However, the rule currently allows the owner or operator to use exit gas temperature to demonstrate control efficiency of condensers; the benefit of allowing prescribed defaults for HAP falling within vapor pressure ranges would be to eliminate the calculation necessary for the

compliance determination. Because this is a straightforward calculation, using defaults provides negligible benefits. Therefore, EPA has not added that defaults to the final rule.

6.2 98 PERCENT TRE

Several commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) noted in their response to the proposed rule a number of concerns with the 98 percent TRE for individual process vents included in § 63.1252(c)(4)(I) of the proposed rule. Briefly, these commenters discussed issues relating to the development of the MACT floor (including the EPA's authority to implement a requirement above the MACT floor), the model processes and cost models (both thermal incineration and condensation) used in the analysis, as well as the cost analysis itself. Additionally, comments were received on the implementability of the TRE, and its inappropriateness for batch processes. The following paragraphs summarize these concerns.

6.2.1 MACT Floor Justification

Comment: The commenters believe that the EPA's justification for the 98 percent TRE for individual vents is unacceptable because it does not take into account the increase in stringency caused by establishing standards on a process basis using data gathered on a facility-wide basis. They believe that the EPA has already gone above the MACT floor by selecting 93 percent control on a process basis (with a 2,000 lb/yr cutoff) instead of 93 percent control on a facility-wide basis. This opinion is substantiated in the resulting emissions reduction for the two MACT floor options (113 tons/yr reduction on a facility-wide basis and 160 tons/yr reduction on a process basis). Therefore, the EPA has exceeded what the MACT floor should be by 42 percent without any economic justification. According to Executive Order No. 12866, to go above the floor, EPA must show that the increased stringency can be economically justified.

Response: In developing the process vent control standards and selecting the format for the standards, EPA, in agreement with the PMACT partnership, decided that the most workable format for implementing control requirements would be on a process basis. Therefore, the standards are on a process basis. In evaluating the floor, however, the Agency also wanted to consider facility-wide control levels in conjunction with the levels of control achieved on an individual process basis. The EPA found that a significant percentage of processes in the industry have relatively low emissions. Therefore, EPA undertook an analysis to compute the floor on a process basis that incorporated an emission cutoff (below which no additional control

would be required) and that was at least equivalent to the facility-wide floor. In addition to enabling the calculation of an equivalent floor, the cutoff would also function in reducing the implementation burden of the standard.

In calculating the cutoff, EPA found that the reduction in HAP emissions from the MACT floor facilities achieved by imposing 93 percent control on a facility basis was 113 tons/yr, compared to 160 tons/yr achieved by imposing 93 percent control only on processes with emission greater than 2,000 lb/yr. Logically, the result of this analysis would have yielded less reductions on a process basis because fewer emissions were considered to begin with. However, the resulting reduction was greater because the effect of emissions averaging was inherently considered in the facility analysis; it could not be considered in the process analysis.

The rule, however, does allow for emissions averaging. Therefore, it is likely that credits from some "over controlled" processes will be applied to processes that require additional control, and that the resulting reductions would indeed approach the numerical reductions achieved on a facility wide basis. As the results indicate, the reductions appear to be at least equivalent, but not significantly higher (because of the possibility of emissions averaging). Therefore, EPA rejects the notion that the process-based standard is actually more stringent than the floor.

6.2.2 Model Processes

Comment: The commenters believe that the methodology used to develop the model process streams used in the cost analysis was "poor" for a number of reasons. First, averages of HAP mass emission rate, flow, concentration, and hours of operation were used for streams expected to be controlled with either a condenser (>= 3,500 ppmv) or a thermal incinerator (<3,500 ppmv). The commenters conclude that the resulting model emission streams "may or may not be real," and that by "breaking streams apart and looking at the pieces separately, EPA destroyed this integrated entity." According to the commenters, a better way to look at the data would have been to look at all processes controlled to a certain level by a single type of device and select one process as typical, and extrapolate this to represent other similar processes controlled by that device.

The commenters also believe that the models are incomplete. In addition to the low-flow, high-concentration process model and a high-flow, low-concentration model, other models

should have been included (e.g., low-flow, low-concentration and high-flow, high-concentration). Also, the EPA did not develop a model for a lower efficiency (93 percent) incinerator or consider controlling pollutants other than methanol or multicomponent streams.

Response: The EPA developed model streams in order to estimate nationwide costs of implementing the standards. The model streams were not used to estimate actual reductions from the industry, however. Rather, the EPA calculated actual reductions based on information in the data base. It would not have been as easy , however, to calculate costs of controls for actual processes in the data base because of the many variables associated with how control across each process would be achieved, since owners and operators have the discretion to control whatever streams are necessary to yield 93 percent across each process. Therefore, EPA decided to develop model emission streams that would generally approximate costs of control for this industry. The EPA acknowledges that the models may not be representative of emission stream characteristics of all vents, but believes that the models are acceptable in approximating control costs. While a more refined approach to costing might have included the development of more model streams, EPA also notes that this approach would also have only yielded an estimate, and not the true costs, and questions the benefit of such an approach.

6.2.3 Cost Models

Comment: The commenters noted a number of concerns with the cost models used by the EPA to estimate costs of the process vent standards. Generally, the commenters suggested that the cost models underestimated the costs of both condensation and thermal incineration, and these inadequacies resulted in flawed impacts of the process vent requirements. When the commenters conducted their own cost analysis they concluded that both the MACT floor and Regulatory Alternative 1 are substantially more expensive than the EPA analysis indicates. Additionally, the commenters believe that Regulatory Alternative 1 would cost more than the floor. Specific cost concerns are listed below:

1. Manifolding costs are underestimated; a member company recently spent $15,000,000 on manifolding for a project whose total capital was $19,500,000. Compared to the EPA analysis, the commenters increased the length of pipe per source (from 300 feet to 500 feet), and doubled the number of elbows per source (from two to four).

2. The EPA did not take into account compounding cost factors, such as vent and product segregation needed for FDA GMP requirements, over-designing of processes to meet future growth, and employment of unusual chemistry with varied and hazardous compounds.

3. The EPA estimated the direct and indirect installation costs of the thermal incinerator to be 25 percent of the purchased equipment cost (PEC). The commenter believes that direct costs should be 30 percent of the PEC, and indirect costs should be an additional 31 percent of the PEC.

4. The commenters believe that the hours of operation for the thermal incinerator should be continuous (8,760 hours per year) rather than 5,280 hours per year.

5. Additional cost estimates should be included for thermal incinerators that are only required to achieve 93 percent HAP control.

6. For condensers, the EPA estimated the direct and indirect installation costs to be 15 percent of the PEC. The commenters believe that this factor may be appropriate for package systems getting 93 percent control, but for superchillers required to meet the 98 percent control level the commenters suggest using the full 30 percent direct and 31 percent indirect installation cost factors in the OAQPS Cost Manual.

7. Costs for condenser performance tests are the same for both 93 and 98 percent systems. The commenters believe this is inappropriate because the rule allows for an exemption from testing for condensers equipped with a thermocouple.

Response: The EPA believes that the cost models used in support of these standards, while simplistic and probably not representative of all circumstances that can occur in this industry, are adequate for conducting the analyses described. The cost models were used not only to cost out controls of the model streams, but also to establish the TRE equation that requires streams with certain loads and flows to be controlled to 98 percent. In developing cost models, EPA used guidance contained in the OAQPS cost manual where it was appropriate. Several of the above comments relate to manifolding costs, which are not specifically treated in the cost manual. In estimating costs for manifolds, EPA used costs for ductwork developed from industry trade journals, as well as data supplied by the industry for specific components, such as detonation arrestors. The EPA assumed that 20 emission sources would be manifolded into each incinerator and 3 sources would be manifolded into each condenser. A comparison of the costs,

on a per source basis with costs for manifolds submitted by industry, indicate that EPA's manifolding costs ranged from $11,000 per source (capital cost) to $15,000 per source, compared to an average cost per source of approximately $21,000 as supplied by the industry (see December 5, 1995 memo on Impacts for Process Vents). Therefore, while EPA agrees that the costs for manifolding systems are highly variable, and could be significantly higher in some circumstances, EPA believes that the manifolding costs considered in the analysis are adequate for purposes of this analysis.

Regarding incinerator installation costs, EPA developed costs based on a 25 percent factor for installation costs for small incinerator units, based on guidance contained in the cost manual for units with less than 20,000 scfm gas flows. Performance test costs and arguably, some manifolding costs, are covered in the 61 percent installation factor recommended in the OAQPS Cost Manual for large units. The EPA notes that the costs considered separately for performance tests and manifolds easily account for more than 36 percent (i.e., 61 percent minus 25 percent) of the capital cost of the control systems that would otherwise be considered with the 61 percent installation factor. Nevertheless, EPA evaluated the difference in using 61 percent versus 21 percent installation factors on the model incinerator costs. As part of the analysis, EPA also retained separate cost elements for performance tests and manifolds. While capital costs for the model incinerator increase from $628,000 to $737,000 annualized costs resulting from this change increased from $318,000 to $338,000, or approximately 6 percent. Therefore, the difference in the two approaches is not significant on the overall cost-effectiveness estimates.

Lastly, incorporation of several of the other commenters suggestions would actually have resulted in cost effectiveness calculations that are less than the estimates presented in the proposal package, such as eliminating costs for performance tests of condenser systems, and extending incinerator operating hours. Again, EPA sees no reason to revise estimates for these elements at this time.

6.2.4 Cost Analysis

Comment: The commenters noted a number of concerns with the cost analysis performed to estimate the national impacts of the rule.

As a result of the underestimated costs included in the cost models, the commenters believe that the MACT floor and Regulatory Alternative 1 are substantially more expensive than

the EPA indicates, and that Regulatory Alternative 1 is more expensive than the MACT floor option. This is in contrast to what the EPA believes, in that, the Agency estimated a lower cost effectiveness for Regulatory Alternative 1 than the MACT floor option, and the incremental cost effectiveness to go above the floor was estimated to be approximately $1,000/Mg.

In calculating impacts, the commenters note that when an individual vent stream met the 98 percent TRE requirement, the EPA ended up controlling the entire process by 98 percent instead of just the individual vent stream within the process. The commenters believe that because the rule does not require this level of control for the entire process, the EPA should not have taken credit for this incremental emissions reduction. The final issue of concern with the cost analysis deals with the extrapolation of costs developed for dedicated streams to nondedicated streams. The commenters do not believe this is a valid assumption because emission controls for nondedicated processes must be designed based on maximum flow, and the model processes used in the analysis were based on average flows at dedicated processes.

In estimating the national impacts of Regulatory Alternative 1, the EPA found 22 individual streams (from dedicated processes) that would trigger the 98 percent TRE, and thus require 98 percent control. Of these 22 streams, 20 of them had concentrations high enough to warrant control by condensation, while the remaining two streams would be controlled by thermal incineration. The commenters do not believe that this is representative of how streams required to meet the 98 percent control option will actually meet the requirement. Based on industry's experience, 75 percent of the individual streams requiring 98 percent control would meet this requirement using thermal incineration. Furthermore, the commenters point to significant limiting design factors including water vapor content, HAP vapor pressure, and highly variable flow which prevent condensers from typically achieving 98 percent control.

Response: In developing the option above the floor, EPA tried to target emission streams that would be cost effective to control to a level of 98 percent. Generally, the cost effectiveness of controls increases with the concentration of the streams. Therefore, it follows that a majority of process vents in the data base that would require 98 percent control per the TRE would be those streams rich enough to control by condensation. The EPA also notes that no streams in the data base that were already controlled by 93 percent that met the equation criteria were identified for further control to 98 percent, which is consistent with the standards.

In developing nationwide impacts, EPA did cost out only one device for each process that contained a single vent that met the TRE. Because the regulatory alternative also requires process vents not meeting the conditions of the TRE equation to be controlled to 93 percent, EPA assumed that the device used to control the single vent at 98 percent could also control the remaining process vents. The EPA did not, however, take credit for controlling the remaining streams to 98 percent, contrary to the commenter's assertion. Without this "single control device" assumption, it follows that any option requiring control of individual vents within a process would cost more because a control system would have to be costed out for each individual stream. In actual practice, manifolds are employed by this industry to control multiple process vents. Further, the cost models do, as discussed above, consider manifolding of more than one source.

Beyond the above discussion of nationwide impacts based on a population of streams in the data base, it is important to note that, in evaluating the cost effectiveness of the TRE option, the TRE equation targets streams that are cost effective to control at $3,500/Mg, which is lower than the nationwide cost effectiveness estimated for the MACT floor ($8,500/Mg). At a minimum, 50,000 lb/yr of uncontrolled HAP must be emitted from a process vent in order to trigger control to 98 percent via the TRE equation. The EPA believes that this level of emissions warrants the 98 percent control requirement and has retained it in the final rule.

6.2.5 TRE Implementation

Comment: A number of commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/ IV-G-01, and IV-G-04) believe that the TRE should be deleted because it will create a significant recordkeeping burden, will be practically impossible to implement, and will significantly hamper operational flexibility.

The major concern noted, was that the TRE, though fairly straight-forward for dedicated processes, is extremely difficult if not impossible for multipurpose nondedicated processes. Because nondedicated processes allow individual pieces of equipment to be used to make numerous products, the emission stream characteristics will change depending on the product being manufactured.

The commenters argued that the TRE for individual vents would require burdensome recordkeeping requirements for a single vent. This burden would be magnified based on the fact

that a facility may have 200 to 300 individual vents. Another concern raised was that in forecasting production, any slight variance may trigger the TRE for a vent not expecting to need 98 percent control. In turn, the uncertainty related to the control level required would hamper operational flexibility because facilities would be forced to impose limitations on production to ensure they would not trigger 98 percent control. Applying the TRE requirements to manifolded vents further complicates the problem because more sources emitted through the same vent will result in greater variability of vent stream characteristics.

However, the commenter requested that, if the TRE is retained, § 63.1252(c)(4) should be revised to clearly describe how to apply the TRE equation. As mentioned above, using the actual annual HAP emissions is subject to correction because the production of many products varies from year to year, and in order to apply the TRE equation the facility will either use a historical or forecasted annual HAP emission estimate. Additionally, the proposed rule does not clearly establish how to determine the process vent's actual flowrate to be compared to the TRE equation's calculated flowrate. Finally, the rule should specify that the TRE equation should apply to individual pieces of equipment in a formulation facility.

Response: The TRE equation applies to individual process vents within a process. With the exception of formulation and solvent recovery facilities, the definition of process is based on the product manufactured, not the equipment used to manufacture it. Therefore, the determination of which vents to control per the TRE for nondedicated process vents should be as straightforward as it is for dedicated processes; namely, owners and operators should anticipate the total uncontrolled HAP emissions per year from the vent, and the average flowrate of the vent. The total uncontrolled emissions should be based on the potential (e.g., permitted) number of batches per calendar year that the facility can run for each process. Based on this projection, the owner or operator can decide whether to install or use an existing 98 percent control device or limit the number of batches to stay below applicability thresholds. Compliance with this standard is based on the actual emissions from each vent. The final rule contains a requirement to record the number of batches that are conducted each year for all processes that are part of the affected source in order to demonstrate compliance with the rule. The average flowrate has been clarified in the final rule as the weighted average flowrate of the emission events contributing to the process vent. For solvent recovery or formulation operations, the definition of process has

been clarified (see definition of process vent in Section 3.5) to include all operations within a contiguous area; for these operations, the product manufactured does not affect the definition of process.

6.3 NEW SOURCE PROCESS VENT STANDARD

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that the standard for new process vents should include a 2,000 lb/yr controlled emissions compliance alternative, since it is unreasonable and unwarranted to require vents with low HAP emissions to achieve 98 percent control. The commenters agreed with EPA's conclusion that 98 percent control represents the best controls in practice for certain sources; however, the commenters believe that the applicability cutoff for new source MACT for process vents is legally flawed because the cutoff did not consider two of the four process types in the industry (fermentation and extraction). The commenters also stated that the process on which the 400 lb/yr cutoff is based is not representative of the industry's processes and appears to be only a portion of a process based on the EPA's definition of process in the proposed rule. Citing other rules that set new source MACT as the average level of control achieved by sources using the MACT control technology, the commenters performed an analysis of the MACT floor data base and determined that the average level of controlled emissions from the best-performing 12 plants was approximately 1,400 lb/yr. The commenters excluded two processes from their analysis that had uncontrolled emissions greater than 1 million lb/yr because these processes are much larger than the typical pharmaceutical manufacturing process and would skew the data. According to the commenters, if these two (larger) processes are included in the analysis, the average level of controlled emissions from the best-performed 12 plants would equal 6,400 lb/yr.

Response: The EPA has reviewed the data used to set the MACT floor for process vents at new sources. Based on this review, the EPA has concluded that the data support the level of the proposed standard for new sources.

The commenters addressed two aspects of new source MACT: (1) the level of the standard and (2) the applicability cutoff. These aspects are discussed separately below.

The EPA based the 98 percent control requirement on the 26 processes (under the proposed definition) at 7 plants in the data base that achieve or exceed this control level. These processes include dedicated and nondedicated formulation, chemical synthesis, and fermentation

processes. The EPA has concluded that these processes are representative of the control challenges faced by the industry despite the fact that the data do not include an extraction process. The EPA has further concluded that the 98 percent control level achieved at the best controlled processes is applicable to all four process types.

The EPA does not believe that the variation in exhaust gas characteristics among the four types of processes in the industry is significant enough to warrant individual evaluation of achievable control levels. In any case, extraction processes are typically solvent-intensive, resulting in the highest average HAP concentration of the four types of processes. High HAP concentrations are conducive to high percent control levels.

The commenters suggested that the EPA adopt a 2,000 lb/yr controlled emissions compliance alternative to account for variability within the industry. The commenters based this alternative on the average level of controlled emissions from 24 of the processes in the data base that achieve 98 percent control or greater. (The commenters excluded the other two processes in the data base because they were atypically large.) The EPA does not believe that the analysis presented by the commenters is an appropriate basis for a new source compliance alternative. First, while the commenters imply that the alternative is needed to account for variability in the control level that is achievable by the wide variety of pharmaceutical processes, the analysis does not address control efficiency at all. Because the commenters evaluated only processes that achieve at least 98 percent control, only variability in uncontrolled emissions truly figures into the analysis. Second, the alternative standard suggested by the commenters is not equivalent to the percent reduction standard and would result in greater total emissions of HAP from the industry. Finally, the EPA analyses cited as precedents address different situations and provide scant support for the commenters' analysis.

While the EPA has rejected the alternative standard suggested by the commenters, the final rule provides a 20 ppmv outlet concentration alternative to 98 percent control for process vents at new sources. This alternative addresses the primary impediment to achieving 98 percent control, i.e., low inlet concentration gas streams.

The EPA based the proposed applicability cutoff for new source process vents on the smallest representative process in the data base that achieves 98 percent control or greater. The commenters questioned whether this operation actually qualifies as an entire process under the

proposed definition of "process" and whether the operation is representative of processes in the industry. Although the EPA continues to believe that the operation selected as the basis for the proposed cutoff is a process under the proposed definition, it may not qualify as a process under the final definition. Consequently, the EPA has reanalyzed the data based on the final definition of "process."

The new analysis was similar to the original analysis. After revising the data base of well-controlled sources to conform to the final definition of "process," the EPA identified the smallest processes that are controlled by 98 percent or more. As in the previous analysis, formulation and chemical synthesis processes are the smallest processes. Two chemical synthesis processes, one emitting 85 lb/yr uncontrolled, and another emitting 304 lb/yr uncontrolled, were identified as achieving control of 98 percent. Although these processes were reported as individual (single) processes, EPA summed emissions from both, since the product name listed for each was very similar, and EPA wanted to use a conservative estimate. The total uncontrolled emissions from the sum of these two processes is 390 lb/yr, which is the same level of emissions as the proposed cutoff (400 lb/yr). Therefore, EPA has retained the 400 lb/yr uncontrolled cutoff in the final rule.

Despite the fact that no fermentation or extraction processes were among the smallest well-controlled processes, the EPA believes that the analysis is representative of the control capabilities of all process types. As discussed previously, the EPA has concluded that the gas streams generated by the four types of processes in this industry are similar enough that an individual analysis by process type is not warranted. Fermentation and extraction processes are typically much larger than formulation and chemical synthesis processes. Thus, the absence of fermentation and extraction processes in the list of the smallest well-controlled processes is the result of this size differential, not a difference in the control level that can be achieved. In fact, the average uncontrolled HAP concentration of fermentation and extraction process vents exceeds those of formulation and chemical synthesis process vents. Higher concentrations are more conducive to high percent control.

Practically speaking, new source MACT will apply to small processes only at completely new facilities, where 98 percent control will apply to virtually all processes. (At existing sources, new source MACT will apply only to dedicated new PMPU's with a potential to emit 10 tons/yr

of a single HAP or 25 tons/yr of all HAP combined.) Thus, sources will not be faced with the need to install 98 percent-efficient controls dedicated to small new processes, which could be very costly for a small amount of emission reduction. Instead, the EPA expects that sources will achieve the new source MACT standard using large control devices that treat multiple manifolded gas streams. Because this is the control situation most typically found for the small processes in EPA's data base of well-controlled sources, the EPA believes that the final rule's applicability cutoff accurately reflects what will be achievable at new sources in this industry.

6.4 FORMAT OF THE STANDARD

The following items were grouped together as they pertain to the format of the process vent standard--the format of the standard, the 2,000 lb/yr cutoff, and proposed exclusions and clarifications.

6.4.1 Format of the Standard

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-D-40, IV-G-01, and IV-G-04) submitted text in agreement with the process-based standard for process vents. However, one commenter suggested that the 93 percent control requirement should be on a facility-wide basis versus a process-basis. Additionally, several commenters stated that they support the proposed annual compliance period and noted the inconsistency with the daily continuous compliance provisions. If the final rule includes a shorter compliance period, the commenters have stated that either the standards must be adjusted to avoid an increase in stringency above the floor or a demonstration must be made that the increased stringency (i.e., going above the floor) is justified according to the requirements of the Clean Air Act.

Response: The EPA, in the final rule, has clarified the compliance period of the standard to be either on a 24-hour basis, or on a batch or "block" basis. Additionally, compliance periods for emissions averaging are on a quarterly basis, while compliance periods for the P2 standard are on an annual basis. For batch operations, the annual compliance period contained in the proposed rule was determined by EPA to be too difficult to implement and therefore not practical. The annual compliance period implies that owners and operators could control processes to varying degrees during the course of a year, as long as the yearly percent reduction target could be met. While this format would offer flexibility to owners and operators who would want to change control strategies to accommodate production scheduling and operational

changes, EPA believes that the demonstration of compliance over such an extended time period would result in delayed compliance determinations and the possibility for extended periods of violations. The EPA notes that the final rule offers some flexibility to owners and operators in addressing variability within the processes themselves by providing numerous compliance options. Lastly, it is not clear that the data used to develop MACT floors reflected an annual compliance period. Therefore, EPA does not believe that by clarifying the final rule to reflect a daily compliance period, the stringency of the standard was increased.

Regarding the facility-wide standard, EPA, as described earlier in this document, decided to establish process-based standards rather than facility-wide standards. While the facility-wide control level is a useful parameter for evaluating the level of control in the industry, it is difficult to implement because of the predominant use of batch processes in this industry. Facilities typically run multiple processes at any given time, and can cease and restart operations often. In addition, the emission stream characteristics of batch emission sources are not constant, so that control devices do not yield constant control levels. The application of a facility-wide standard would therefore require an enormous amount of effort to track site-wide emissions to ensure that a single control level would be met over the entire plant site. Therefore, EPA maintained the process-based standard format in the final rule.

Comment: One commenter (IV-G-03) does not believe that the EPA has provided sufficient supporting information for the 2,000 lb/yr cutoff alternative. Another commenter (IV-D-04) believes that the 2,000 lb/yr cutoff is based on a cost effectiveness that is too low ($1,000/Mg), and suggested that this target cost effectiveness be raised.

Response: The justification for the 2,000 lb/yr cutoff was described in the response to Section 6.2.1. The cutoff was not based on a $1,000/Mg cost effectiveness. The 2,000 lb/yr cutoff is an alternative way of expressing the floor, and the cost effectiveness of the floor expressed in this way is much higher than $1,000/Mg, about $7,500/Mg. In the final rule, EPA also added a limitation on the number of processes within a facility that are allowed to comply using the 2,000 lb/yr alternative. This number, 7, was based on the average number of processes with emission less than or equal to 2,000 lb/yr at the MACT floor facilities.

6.4.2 Exclusions/Clarifications

Comment: Several commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that the rule should provide special provisions for process vents that are not safe or technically feasible to control using conventional technologies.

Response: The EPA believes that the format of the process vent standard, which requires 93 percent reduction across a process, coupled with the emissions averaging provisions and the pollution prevention alternative standard, should provide enough flexibility to allow owners and operators the flexibility to overcontrol some process vents and undercontrol others. Therefore, EPA has not provided special provisions in the final rule for process vents that are not safe or technically feasible to control using conventional technologies.

Comment: One commenter (IV-D-40) requested clarification that the percent reduction requirement for process vents is over total HAP.

Response: Yes. The intent of the rule is to require control of total HAP. For example, the 93 percent control requirement for process vents requires a reduction of HAP emissions equal to 93 percent of the sum of all HAP from a process.

Comment: One commenter (IV-D-28) requested clarification on conducting an overall efficiency determination around control devices in series.

Response: The EPA would like to clarify that the standard requires 93 percent reduction from uncontrolled emissions. For devices in series, the overall reduction from an uncontrolled basis should consider the control achieved by all devices. For control devices generating HAP such as HCl from combustion activities, HCl is required to be controlled by 95 percent or to a concentration of less than or equal to 20 ppmv.

Comment: One commenter (IV-D-13) requested clarification on whether solid HAP are covered in the standard, or whether only volatile HAP are subject to the process vent standards.

Response: This regulation does not cover emissions of particulate HAP. The EPA did not set a separate MACT floor for particulates due to a lack of emissions data and information regarding the types of particulate HAP that could be emitted from this industry.

Comment: One commenter (IV-D-32) requested clarification on how to aggregate emissions and determine compliance with the process vent standard for vents that handle emissions from multiple processes. The commenter suggested that the standards should clearly

state that only emissions attributable to a particular process are to be included in the sum for that process.

Response: The commenter is correct in this interpretation. In cases where process vents are made up of emissions from multiple processes, compliance is assessed on each process, and therefore each determination is made with only the emissions attributable to each process.

Comment: One commenter (IV-D-25) suggested that the rule should allow for ducting of emissions across processes to a 98 percent control device and stressed that the rule should allow for cryogenic refrigeration systems.

Response: The proposed and final rules allow for ducting of emissions across processes. Additionally, the final rule's alternative standard simplifies the compliance determination in these situations. Also, while cryogenic refrigeration systems may be very effective in controlling emission streams from this industry, EPA, in general, did not specify "types" of control devices that would be acceptable for use. This determination has been left to the industry.

7.0 STANDARDS: STORAGE TANKS

A number of parties submitted comments on the proposed standards for storage tanks (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, IV-G-04, IV-D-36, and IV-D-12). The principal concerns defined by the commenters included the following items: (1) Concern about the stringency of the standard above the floor, (2) inclusion of a compliance alternative for storage tanks that is based on annual controlled emissions; and (3) specifying in the rule that vapor balancing systems for storage tanks meet the requirements of the standard, for storage tanks with capacities greater than or equal to 10,000 gallons.

7.1 STORAGE TANKS STANDARDS AND COMPLIANCE ALTERNATIVE

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, IV-G-04, and IV-D-36) believe that the portion of the standard that requires tanks with a capacity of 20,000 gallons or more to control HAP emissions by 95 percent is more stringent than the MACT floor which, for all categories of tanks with at least 10,000 gallons of storage capacity, was shown to be 90 percent control. Therefore, the commenters believe that the pharmaceuticals MACT represents an increase in stringency without precedent. One commenter (IV-D-12) suggested that the 90 percent control level for storage tanks with capacities less than 20,000 gallons be extrapolated to all storage tanks greater than 10,000 gallons.

In developing the standards, commenters also found problems with the analysis. Many of the commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) believe that the use of models to develop costs of regulatory alternatives was unnecessary since the EPA had most of the industry's tanks in its data base. They believe that using actual data would have provided a more realistic estimate of the costs associated with the rule, especially since the tank standards are more stringent than the MACT floor. The commenters also question the use of floating roof technology for tanks with capacities greater than 20,000 gallons since they are not

used in the industry. Additionally, commenters stated that some of the assumptions made and supporting backup documentation was not provided in the rulemaking docket.

Regarding the compliance alternative, the MACT partnership had agreed on a 500 lb/yr cutoff, below which no control was required. The EPA eliminated this alternative during the development of the rule and did not address the alternative in the proposal. The commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) believe the alternative is justified, particularly because the EPA went above the floor, and believes that the alternative should be reinserted into the rule. A subsequent analysis by PhrMA concluded that an additional 150 lb/yr per tank would not be controlled had the 500 lb/yr alternative been kept. The cost effectiveness of controlling this additional 150 lb/yr per tank was estimated to be over $115,000/Mg. Since the EPA has authority under the law to establish de minimis provisions for exceptions from statutory directives when the benefits of regulation are significantly outweighed by the associated costs and other burden, the commenters believe that the 500 lb/yr compliance alternative is exactly the sort of provision for which the de minimis doctrine was developed. One commenter (IV-G-01) also pointed out that the State of Missouri uses 200 lb/yr as a cutoff below which no additional control if necessary.

Response: As explained in the Basis and Purpose Document (Docket No. A-96-03), EPA chose 95 percent control (as opposed to the MACT floor) for storage tanks greater than 20,000 gallons because floating roof technology has been demonstrated to achieve 95 percent control and is considerably less expensive than other technologies. Although floating roofs currently may not be in use on storage tanks in the pharmaceutical industry, EPA is not aware of any technical obstacles to their use, except in the case of horizontal tanks. Also, owners or operators still have the option of using add-on controls instead of floating roofs.

The EPA used models to estimate cost of control options for storage tanks because the effort required to develop separate condenser models for every tank in the data base (each of which contains a specific material or combination of materials with different chemical and physical properties) would have been excessive, and because the cost models, which do incorporate data from actual tanks, are a reasonable and acceptable alternative to plant-specific costing. Regarding the lack of supporting documentation for tank control costs, EPA has

included a memorandum in the docket (Item IV-B-3) that details costs and assumptions used in generating cost and estimated impacts.

With regard to the 500 lb/yr cutoff for storage tanks, the Agency concluded that this alternative was less stringent than the MACT floor, and thus, was not legally acceptable.

7.2 VAPOR BALANCING SYSTEMS FOR STORAGE TANKS

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) suggested that the rule should specify that vapor balancing systems meet the requirements of the storage tank provisions. The commenters stated that vapor balancing systems are a well-recognized and well-understood control technology that have been specified by both NSPS and NESHAP. One of the commenters (IV-D-20) provided a response to EPA concerns that if a truck involved in storage tank vapor balancing then vents to the atmosphere upon leaving the facility, no control would be achieved. The commenter stated that "the truck will have the same amount of HAP vapor regardless of whether the storage tank's vapor space is routed to it or not." The commenter further explained that any remaining liquid in the truck (i.e., liquid heels or liquid on the truck walls) will quickly come to equilibrium with the air space, so that the truck's air space becomes saturated with HAP vapor even if the storage tank's vapor space is not returned to the truck. For these reasons, the commenter believes that vapor balancing does result in an equivalent emission reduction and cited EPA (AP-42) estimates of control efficiency as high as 90 to 98 percent. The commenter also pointed out that, when vapor balancing is used (i.e., the storage tank vapor space is routed to the truck), the source of pollution is the vapor content of the truck; however, when the storage tank is vented to a control device, there are two sources of pollution: the HAP vapor from the truck and secondary pollutants (such as NO_x) from the control device. (The commenter's facilities all have horizontal tanks, so that the floating roof option is not applicable to storage tanks at any of its facilities [see Section 8.1, above] and emissions from its storage tanks would have to be reduced by routing them to a control device, if vapor balancing is not allowed.) The same commenter (IV-D-20) recommended that the State of New Jersey requirements for vapor control (7:27-16.4 VOC transfer operations, other than gasoline) be incorporated into § 63.1252(b)(2) and (3) as follows:

§ 63.1252(b)(2) The owner of operator ... and procedures in § 63.1253(c) or a vapor balancing system meeting the requirements of paragraphs (b)(2)(I), and (ii) or (iii):

(i) All atmospheric vents positively closed during transfer, and

(ii) A conservation vent adjusted to remain closed during transfer, or

(iii) A hole of 1/4 inch or less in diameter in the cap of the atmospheric vent.

(3) The owner or operator ... of this section or a vapor balancing system meeting the requirements of paragraphs (b)(2)(i), and (ii) or (iii).

Response: The EPA has not specifically allowed the use of vapor balancing systems in the final rule. While such practices may be effective in controlling working losses, there are uncertainties regarding the effectiveness of capture and containment of vapors as well as the control of vapors offsite. Therefore, for the final rule, EPA did not include a provision for vapor balancing as a compliance method.

7.3 EXCLUSIONS/EXEMPTIONS FOR STORAGE TANKS

Comment: One commenter (IV-G-01) suggested two scenarios where the requirements for storage tanks would not be required to be met. These exclusions/exemptions include: (1) a de minimis cutoff below which no additional control would be required (see above comments); and (2) have the rule stipulate that underground storage tanks are only required to control emissions associated with filling (i.e., working losses).

Response: The Agency decided against setting a de minimis value below which storage tanks would be exempt from the standards because it could not be supported by the floor. Regarding underground storage tanks, the only emissions from underground storage tanks should be working losses (during filling), so that adding a requirement that states that only those emissions associated with filling require control is unnecessary.

7.4 STORAGE TANK CONDENSER TEMPERATURE DEFAULTS

Comment: Refer to section 6.1.2--Rule Should Provide a Compliance Alternative for Process Vents and Tanks Based on Condenser Exhaust Temperature.

Response: As stated in the process vent discussion, EPA believes that establishing low-end defaults may be a reasonable alternative for tanks, since emission stream characteristics from both breathing and working losses entering the condenser could be assumed to be at ambient conditions, and therefore, a prediction of temperature required to reduce emissions by 90 or 95 percent could be generated, based on a fairly narrow range of inlet conditions. However, the rule currently requires the owner or operator to use exit gas temperature to demonstrate control

efficiency of condensers--the benefit of allowing prescribed defaults for HAP falling within vapor pressure ranges would be to eliminate the calculation necessary for the compliance determination, which is straightforward. For this reason, EPA has not added defaults to the rule for storage tanks.

8.0 STANDARDS: EQUIPMENT LEAKS

8.1 JUSTIFICATION FOR THE EQUIPMENT LEAKS LDAR PROGRAM

Status at proposal. The pharmaceutical industry entered into the regulatory negotiations in the development of Subpart I of Part 63. The result was that components in chemical synthesis processes in methylene chloride and carbon tetrachloride service are currently required to comply with the LDAR program contained in Subpart H of Part 63. The proposed rule requires that owners and operators implement an LDAR program for components not currently subject to the provisions of Subpart I.

The cost effectiveness associated with the LDAR program included in the proposed rule is approximately $1,000/Mg. The emission reductions for this program were estimated using uncontrolled SOCMI average emission factors to calculate uncontrolled (i.e., baseline) emissions.

Issues.

1. Commenters question EPA's authority to go beyond Subpart I for the industry by including additional controls, and are concerned about having to implement two possibly overlapping LDAR programs.

2. Commenters believe that the proposed rule goes above the MACT floor with an alternative that is not cost effective because the emission reductions are overstated and the program costs are understated.

3. Commenters state that the EPA failed to provide any justification, references, or documentation of the various assumptions made in the cost benefits analysis performed for the LDAR program included in the proposed rule.

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, IV-G-04, and IV-D-04) believe that the EPA is bound by the Subpart I regulatory negotiation and is thus not allowed to expand the LDAR for the industry to additional HAP. The commenters

believe that since the negotiation of Subpart I concluded that LDAR for the industry should only apply to carbon tetrachloride and methylene chloride, the EPA can not expand LDAR to cover additional HAP without violating the negotiated agreement.

Numerous commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, IV-G-04, IV-D-12, IV-D-32, and IV-D-08) believe that requiring a formal LDAR program goes against what is mandated in the Clean Air Act, which requires that the EPA demonstrate that requirements are both environmentally beneficial and cost effective. In order to substantiate this concern one commenter completed a detailed review of the equipment leaks cost analysis conducted by the EPA. During this review a number of issues were raised. These issues include the EPA's revised methodology for calculating uncontrolled emissions for the model process , reducing the number of monitoring instruments included in the analysis from October 1995 to April 1996 , concerns about a number of the assumptions and individual cost elements used in each of the analyses, and the lack of references and documentation provided by the EPA in the docket. Each of these issues are discussed below.

The commenters are concerned about why the EPA revised its methodology for estimating the uncontrolled emissions for the industry. In October 1995, uncontrolled emissions were estimated using site-specific data sent to the EPA by the industry. This data was submitted by facilities subject to the LDAR requirements in the HON and consisted of the first Periodic Reports they submitted. The revised method used to estimate uncontrolled emissions from the industry was included in an April 1996 memorandum. This method used the uncontrolled SOCMI average emission factors included in EPA-453/R-93-026, Table 2-1.

The commenters believe that by rejecting the industry-specific data the EPA is contradicting its own technical advice for determining the program effectiveness of an LDAR program, as presented in Section 5.3 of EPA-453/R-93-026 "... *best way to calculate the effectiveness of an LDAR program is by controlling and analyzing data at the specific process unit.*" Instead, by using the uncontrolled SOCMI average emission factors the EPA has ignored this recommendation. The commenters also note that the uncontrolled SOCMI average emission factors were developed from several studies, *none of which included pharmaceutical manufacturing*. Additionally, the SOCMI process units used to develop the SOCMI average emission factors have quite different physical setups and operational techniques. First, the scale

of components in the pharmaceutical industry is smaller than those used in SOCMI plants. Second, the pharmaceutical industry must meet strict FDA Good Manufacturing Practices that SOCMI plants are not subject to. Third, the variability of the small, nondedicated processes typically employed by the pharmaceutical industry does not lend itself to a high degree of automation as the SOCMI industry does.

The commenters were also concerned about another change in costing methodology made between October 1996 and April 1996 by EPA. In October 1995 the EPA had assumed the purchase of a single monitoring instrument for each process subject to the requirements of the rule. However, the analysis conducted in April 1996 assumed only one instrument per plant. The EPA also dropped all annual maintenance costs ($4,280) associated with the one monitoring instrument. The commenter feels that theses changes make the costs for monitoring instruments unreasonably low. Experience suggests one monitoring instrument for every 8,000 to 10,000 components, and a backup instrument for every three monitors in constant use.

The following other assumptions were identified by the commenters as being problematic:

8.1.1 Assumptions, Data Used, and Uncontrolled Emissions

1. 100 weight percent HAP present in processing lines during an entire batch is unreasonably high due to the intermittent nature of batch operations;

2. The commenter noted that data from several facilities was not included, and only portions of data for other facilities was included in the analysis to estimate initial and subsequent leak frequencies;

3. Some of the data submitted to the EPA was incorrectly used, in that some processes that did not appear in the "Round 1" (initial survey) data were treated as "Round 2" (subsequent monitoring) even though these components may have been part of a nondedicated process and should have been included in "Round 1" data;

4. Connectors included in the "Round 2" data should have been included in "Round 1" data because the report used for "Round 2" was only 6 months after the "Round 1" report and connectors are only monitored annually (i.e., it could not be a "Round 2" monitoring event for connectors);

5. One of the facilities included in the analysis was actually using Phase III leak definitions. However, the EPA disregarded this fact and used the data as Phase I anyway; and

6. The connectors leak definition was incorrectly assumed to be 10,000 ppm, when, in fact the Phase I leak definition for connectors is 500 ppm.

8.1.2 Costs

1. A cost of $6,500 was used for the capital cost of a monitoring instrument. The commenters believe that a more reasonable estimate for a monitor is a TVA which costs approximately $10,300;

2. The EPA did not include any computer and software cost in their analysis. These costs begin at a low end of $15,000 per plant, and some companies have reported $30,000 and more;

3. The EPA did not include any costs for associated LDAR reporting and recordkeeping requirements;

4. PRV's and open-ended lines are not included in the analysis;

5. Setup costs including tagging, data base design, and P&ID markups do not appear in the EPA analysis;

6. No supervisory labor costs are include in the cost analysis. These costs should be assumed to be 20 percent of the base labor costs;

7. No training costs are factored into the labor costs; and

8. The EPA's costs are equivalent to $2.80 per monitoring event and about 5 minutes per monitoring event. This equates to 24,000 monitoring event per year per employee. It is the commentor's experience that a single full-time employee can only accomplish 10,000 monitoring events per year. This equates to 12 minutes per monitoring event and $6.72 in the pharmaceuticals industry.

Response: The Clean Air Act requires that EPA regulate all major sources of HAP. The regulatory negotiations conducted in the development of Subpart I included only a certain fraction of components from the industry because that was the extent of the information that EPA had at the time the negotiations were conducted. The EPA maintains that nothing in the terms of the negotiation precluded further action on the remainder of the components in the industry.

In recent regulatory development efforts involving similar industries, the EPA has generally found equipment leaks to be a significant source of emissions. In general, EPA's approach has been to require industries to identify leaks, and fix them as soon as possible. The EPA is concerned with the recordkeeping burden associated with a LDAR program for this industry and has strived to minimize the number of activities that have to be conducted and documented while still requiring sources to identify and eliminate equipment leaks. In following the HON example compared to earlier rules, the Agency is focusing most of the recordkeeping and reporting burden on those processes and types of equipment that have the most significant, in terms of HAP emissions, leaks. Since the development of the HON, the Agency has been developing a consolidated air regulation (CAR) that is designed to minimize the reporting and recordkeeping burden even further. Although the CAR has not yet been proposed, EPA believes that, in addition to consolidating many LDAR programs, the rule addresses many concerns regarding the burden placed on industry to implement LDAR programs with little environmental benefit. The rule is specifically focused on identifying and fixing leaking components, and leaves out many of the recordkeeping requirements that are focused on nonleakers.

The requirements of the CAR rule include options for identifying groups of equipment, such as valves, that are located within an area or length of pipe without individually listing each component. The CAR rule also allows much less frequent monitoring of components, depending on leak rates identified during an initial survey. For example, for connectors, if the percent leaking components is less than 0.25 percent, monitoring is only required every 8 years (however, at least 50 percent of the connectors must be monitored during the first 4 years and the remainder must be monitored within the next 4 years). For valves, the required monitoring frequency can be as low as every 2 years, if the percentage of leakers for a given group is less than 0.25 percent.

The Agency considered the comments received regarding the justification for an equipment leaks LDAR program. As noted by the commenter, the data that was used in the October 1995 analysis used average leak rate equations to determine the magnitude of uncontrolled emissions from data that was supplied by industry. However, EPA revised the approach for estimating the baseline emissions and the reductions incurred from use of the LDAR program, because EPA was unsure of the leak definitions used in some cases. From the

EPA guidance document entitled, "Protocol for Equipment Leak Emission Estimates," EPA-453/R-95-017, November, 1995, there are four acceptable methods for estimating emissions from leaking components. The protocol identifies acceptable methods depending on the level of data available. These "tiers" of data quality include bagging data, OVA-monitoring data (screening data), leak/no leak data, or no data. The data supplied by industry included component counts and leak frequencies--leak/no leak data. Therefore, EPA used the SOCMI leak/no-leak factors to estimate uncontrolled emissions in later memoranda written prior to proposal.

In response to these concerns, EPA again reviewed its analysis and recalculated the cost effectiveness of several types of LDAR programs. In calculating the impacts of requiring an LDAR program meeting the requirements of the CAR, EPA calculated monitoring costs based on established guidance and recalculated uncontrolled emissions using initial leak frequencies reported from the industry. The details of this analysis are included in the project docket (A-96-03) as Item No. IV-B-5. The EPA, in reassessing industry leak data, addressed many of the concerns of the commenter relative to the inclusion or exclusion of specific data.

Using as a starting point leak data that was confirmed as initial survey data by PhRMA, EPA reviewed the data base and further refined the pool of data. Some data from PhRMA's compilation was revised to reflect reported leak definitions; also, some data was excluded based on the facility's explanation of frequency of monitoring and calculated leak rates and the conclusion that the leak rates reported did not indeed reflect initial monitoring data. The resulting initial leak rate data was 1.45 percent for valves, 6.88 percent for pumps, and 1.5 percent for connectors.

The subsequent leak rate which results from an LDAR program, along with the initial leak rate, determine the overall control effectiveness, and is a critical factor. Limited data were available to determine the leak rates at pharmaceutical manufacturing facilities after the application of an LDAR program. For EPA's analysis, it was assumed that the equipment leak frequency occurrence rate after implementation of LDAR for valves and connectors was equal to the performance levels required in the draft CAR, that repairs were 100 percent effective, and there were no recurrences of leaks. This is similar to the assumptions in the HON, except that the occurrence levels are assumed to be lower than those assumed in the HON analysis. This appears to be a reasonable assumption given the fact that the initial leak frequencies for valves

and connectors were in some cases lower than the performance level specified. In the HON, no performance level for pumps was specified. Therefore it was assumed that the leak occurrence rate after implementation of the rules was equal to 50 percent of the initial leak frequency. This assumption appears reasonable based on the leak frequency reductions that have been achieved by other LDAR programs. Subsequent leak frequencies for the revised EPA analysis were assumed to be 0.25 percent for valves, 3.44 percent for pumps, and 0.25 percent for connectors.

Emission reductions for the program were estimated to be the difference between the uncontrolled emission rate, as calculated using the mass emission rate, in kg/hr-source, calculated from the Average Leak Rate (ALR) equations and initial leak data, and the controlled emission rate, calculated using the ALR equations and the subsequent leak data. The controlled emission rate was calculated assuming one-half of the occurrence rate. This assumption is necessary to account for the average leak frequency over the monitoring cycle. The ALR equations are presented on page 5-46 of the EPA document entitled, "Protocol for Equipment Leak Emission Estimates," EPA-453/R-95-017, November 1995. For the model facility, a reduction of 12 Mg/year was estimated from the implementation of the LDAR program. Based on this revised analysis, the Agency found that the cost effectiveness of the CAR LDAR program was approximately $1,000/Mg HAP.

A review of the HON costing methodology was undertaken as a result of the comments received on the proposed rule. The review indicated that even though some of the cost elements may have changed since the HON costs were developed, the impact of these changes on total annual costs do not appear to be significant. This analysis also indicates that while it is possible for a facility to spend significantly more than the costs estimated using the HON cost methodology, some of the higher costs are not necessary to comply with the LDAR requirements of this rule. A discussion of specific cost elements is provided below. In addition, Table 8-1 presents discussion of some of the specific cost elements cited by PhRMA.

1. Monitoring Instrument Costs. This first cost item specified was that capital cost of a monitoring instrument. As discussed in Table 8-1, the capital cost of the type of monitor used in an LDAR program has increased since the HON cost analysis was performed. However, when total annual cost of the monitor is computed, the HON analysis actually overestimates costs.

2. Data Acquisition and Management Costs. The second area where there were significant cost differences were the cost to manage the data generated by the LDAR program. As shown in Table 8-1, the PhRMA analysis used a computer and software system along with automatic data loggers to acquire data and produce reports. The HON cost analysis assumed a manual system. The EPA believes that the 40 percent factor applied to the annual labor costs for monitoring and repair is adequate to account for these costs. The EPA also believes that the total capital cost shown on the PhRMA analysis for a data management system were overstated based on recent cost information received from vendors.

A second factor to be considered is that the actual number of monitoring events required by the final rule could be as few as 2,030 per year covering 1,747 components for a model plant once the initial monitoring period is complete. The new TVA monitors typically used for LDAR programs now have an internal data logger built into the monitor that can interface with a spreadsheet program. While this data management system would not have all the capabilities for the more expensive system discussed in Table 8-1, it may be adequate for this program. Therefore, the EPA estimated costs for data management system shown in Table 8-1 may themselves be overstated.

In summary, the costs for manual data acquisition and management are incorporated in the costing methodology, and are believed to be adequate based on the requirements of the rule.

3. Setup Costs. The PhRMA analysis stated that setup costs would be $2.80 to $5.60 per component. The HON cost analysis used an initial cost of $0.50 per component to account for increased costs associated with the initial monitoring of each component. Based on more recent information, EPA believes that the HON cost analysis probably does understate this cost. Though the rule does not require that all components be tagged, this is necessary to efficiently monitor components. In the long run, the monitoring labor savings achieved by tagging or logging all components in the LDAR program is greater than the cost of logging and tagging.

For the final Pharmaceutical NESHAP, costs to identify and log or tag all components would be approximately $10,000 based on the EPA developed costs in Table 8-1. The annualized cost (using a capital recovery factor of 0.14) would be $1,400 a year. It should be noted that this cost does not include any cost to update piping and instrumentation diagrams. It is assumed that a facility will periodically update these to reflect the current situation. While the

requirement to properly identify components for an LDAR program may require that the diagrams be updated sooner rather than later, this is an activity that would be performed regardless of an equipment leak rule.

4. Monitoring Event Costs. The PhRMA analysis stated that it would require 12 minutes per monitoring event, compared to the 5 minutes per event they estimated was used in the EPA analysis. The actual cost in the EPA analysis for monitoring labor is $2.00 per event. This value was based on costs typically charged by contractors who monitor equipment for leaks as a service. It is assumed in this analysis that if the facility costs are higher than the cost to hire a contractor, then a contractor could be used.

It should be noted that the 12 minutes stated in the PhRMA analysis includes time to calibrate the equipment. In the EPA costs analysis, this cost is included in the cost of annual repair and maintenance of the monitor. Also, based on discussions with monitoring contractors and equipment vendors, one person can typically monitor 300 to 400 components per day.[5-7] Based on the PhRMA analysis, one person could monitor 40 components a day. For a labor cost of $33.60 an hour (the cost used in the PhRMA analysis), a monitoring cost of $2.00 an event (the value used in the EPA cost analysis) would require that one person be able to monitor 134 components in an 8-hour day. Even with the assumption that the nature of batch processes makes monitoring more difficult than continuous processes, the assumption that one person can achieve a monitoring rate of less than half of the rate typically seen with continuous processes seems reasonable.

5. Training and Supervisory Labor Costs. The other costs mentioned in the PhRMA analysis were training costs and supervisory labor costs. The initial LDAR monitoring includes a $0.50 per component cost. In the EPA cost analysis this additional $0.50 cost is also multiplied by the 40 percent factor previously mentioned. This is assumed to account for training costs. Supervisory costs are included as part of the recording and record keeping costs previously mentioned.

In response to commenter's concern relative to documentation of cost assumptions, two memorandums on the equipment leaks cost analysis were included in Air Docket No. A-96-03. The memorandum documenting the costs of this latest analysis is dated April 13, 1998 and is Item No. IV-B-5.

TABLE 8-1. COMPARISON OF PhRMA AND EPA COST ELEMENTS

Cost item	PhRMA cost	EPA cost	Comments
Monitor	TVA monitor- $10,300 each	$6,936 (1995$)	The OVA monitors originally used in the EPA HON cost analysis are no longer manufactured. A facility required to purchase a monitor would have to purchase a TVA. The $10,300 price quoted by PhRMA is correct. However, the new TVA instruments result in improved maintenance and calibration costs. An extended 5 year warranty for a TVA costs $3,300.[1] The total cost of ownership, including calibration an maintenance is estimated to be $1,000-$1,500 a year.[2] Added to the annualized capital cost of $2,369, total annual costs for the monitor would be $3,869 The total annualized cost (capital and maintenance) in the EPA cost analysis is $6,243. Therefore, the EPA cost analysis actually overstated annualized monitor costs.
Monitor annual maintenance cost	$4,280	$4,280	
Computer and data logger	$15,000	None	The EPA HON costing methodology is based on the assumption that a manual data logging and recordkeeping system is used. For this reason, there are no costs included for a computerized data system. It should be noted that for a HON program applied to the model facility, the annual costs that would be calculated for recording and record keeping would be approximately $7,700 per year for the 8,740 components. The actual capital cost of a complete LeakTracker data management system and a computer for the model facility would be approximately $20,000.[1] This includes a data logger, LDAR management software, and all necessary peripherals. The annualized capital cost would be $4,600 based on the capital recovery factor used in the PhRMA analysis. It is assumed that if a company chooses to use an automated data management system it is because that option is less expensive overall than a manual system. The rule does not require that a computerized system be used
Software purchase, debugging, and installation	up to $30,000 or more	None	
Computer and software annual maintenance	$4,280	None	
Record keeping and Field Inspection terminals	$10,000 per monitor	None	
Setup costs (tagging, database building, piping and instrumentation diagram markups)	$2.80 to $5.60 per component	$0.50 per component	The HON cost analysis incorporates an additional $0.50 per component costs to account for the increased costs associated with the initial monitoring. Costs for component tagging and P&ID markups were not included because these activities were not required by the rule In reality, in order to have an efficient program it will be necessary to tag components (It is not necessary to tag all components. For example, the connectors at either end of valve 100 can be logged as connectors 100 1 and 100.2).[3] Costs to perform this activity are estimated to be $2.15 for tagged components.[4] If the component is only logged into the data base, the cost is estimated to be $0.50 (the cost to enter data in the data base) for the model plant, the initial cost to locate and tag would be approximately $10,000. this assumes one tag for every 2.5 components.[3] The annualized cost would be $2,300.

TABLE 8-1. (CONTINUED)

Cost item	PhRMA cost	EPA cost	Comments
Labor cost per monitoring event	$6.72	$2.00 (in 1989 dollars)	PhRMA indicated that it would require 12 minutes on average to monitor a component. This included daily calibration time. This would mean that a single person could only do 40 components in an 8-hour work day. The EPA analysis assumes $2.00 per monitoring event. This cost is based on having a contractor do the monitoring It is assumed that if the facility cannot perform their own monitoring at this cost or less, they can hire a contractor to perform periodic monitoring

In summary, EPA believes that the final rule, which incorporates the requirements of the CAR rule in Appendix GGGA, is reasonable for this industry. In addition, the Agency has also allowed, in the final rule, owners and operators to consolidate the two LDAR programs (the Subpart I LDAR program and Appendix GGGA program) into one program (the Appendix GGGA program).

8.2 CHANGES NECESSARY IF THE EPA CAN JUSTIFY THE LDAR PROGRAM

Comment: One commenter (IV-D-10) suggested that, because a number of facilities subject to this rule will be co-located at facilities subject to the HON, it is unrealistic to have two different LDAR programs for a single plant site (no matter how different). Therefore, the requirements for equipment leaks should simply reference Subpart H. Another commenter (IV-D-29) suggested that Appendix GGGA be removed from the rule and cross-references to Subpart H be added.

Response: The final rule consolidates the two LDAR programs.

Comment: Two commenters (IV-D-28 and IV-D-23) objected to the requirement of annual monitoring of difficult- and unsafe-to-monitor components which require monitoring personnel to be elevated to a significant height on unstable or sloping ground.

Response: The annual monitoring requirements reflect the need for some type of regular monitoring of components, including those that may be difficult or unsafe to monitor.

Comment: One commenter (IV-D-23) suggested that, in addition to batch processes, the rule allow for pressure testing of semicontinuous and continuous processes that can be shutdown on the required quarterly basis. This option should be available when the HAP can not be monitored (excessive response time) by commercially available monitoring instruments.

Response: The EPA agrees that pressure testing of semicontinuous and continuous processes and equipment, such as supply lines, is reasonable and has allowed the use of pressure testing of these sources in the final rule.

Comment: One commenter (IV-D-16) commented that the leak detection and repair provisions require more effort to keep records than to conduct monitoring. The commenter also favors quarterly monitoring of pumps and agitators coupled with weekly visual inspections.

Response: As described earlier, the EPA believes that the requirements contained in the final rule, which are patterned after the CAR rule, will greatly reduce the administrative burden associated with LDAR recordkeeping. Additionally, EPA has retained the quarterly monitoring requirements for pumps and agitators, as proposed.

8.3 REFERENCES

1. Facsimile transmission from D. Maldonado, Tracker Technologies, Inc., to K. Barnett, U. S. Environmental Protection Agency. March 10, 1998.

2. Telecon. K. Barnett, U. S. Environmental Protection Agency, with T. Bloomer, Foxboro. March 24, 1998.

3. Telecon. K. Barnett, U. S. Environmental Protection Agency, with G. Eeaves, Team Environmental. March 19, 1998.

4. Memorandum. R. Oommen, Radian Corporation, to J. Durham, U. S. Environmental Protection Agency. "Methodology for Estimating National Impacts of Controlling Leaking Refinery Equipment." June 27, 1994.

5. Telecon. K. Barnett, U. S. Environmental Protection Agency, with G. Harris, Radian International L.L.C. February 27, 1998.
6. Telecon. K. Barnett, U. S. Environmental Protection Agency, with G. Mcphee, Tracker Technologies, Inc. March 9, 1998.

7. Telecon. K. Barnett, U. S. Environmental Protection Agency, with B. Serres, Environmental Analytical. December 9, 1997.

9.0 STANDARDS: POLLUTION PREVENTION

Commenters raised several issues related to the Pollution Prevention (P2) standard included in the proposed rule. These comments were submitted by numerous commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04, IV-D-08, IV-D-16, IV-D-26, , IV-D-29, IV-D-22, IV-D-14, IV-D-04, IV-G-02, IV-D-27, IV-D-40, IV-G-06). The individual comments are summarized below.

9.1 GENERAL COMMENTS

Comment: One commenter (IV-D-26) noted that the P2 alternative only works for solvent using processes, which, according to the commenter could be unfair.

Response: Because the majority of HAP emissions occur as a result of solvent usage, the EPA considers the P2 alternative to be appropriate for the industry. In addition, the final rule retains the flexibility provided in the proposed rule which provides alternative formats for achieving the standards. For example, affected sources complying with the process vent standards can meet either a mass emission limit or a percent reduction value. Therefore, the owner or operator has the flexibility to achieve compliance by either implementing process changes (e.g., pollution prevention techniques) or by adding end-of-pipe controls.

9.2 CLARIFICATION OF P2 ALTERNATIVE

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) suggested clarifications in the rule at § 63.1252(h)(3) that would better convey the EPA's intent to provide a second option under the P2 alternative that is equivalent to a 75 percent reduction in the HAP production-based consumption factor when a *minimum* of 50 percent is achieved via P2 and the difference towards the minimum 75 percent reduction is achieved by a control or recovery device. One commenter (IV-D-29) expressed specific concern that, as currently written, § 63.1252(h)(3) could be interpreted to mean that no credit would be given for production-indexed HAP reductions over 50 percent.

The following changes to the proposed rule were suggested by the commenters: § 63.1252 (h)(3)(i) and (ii):

(i) The production-indexed consumption factor (kg HAP consumed/kg produced) shall be reduced by at least 50 percent from an ...

(ii) The total process HAP emissions shall be reduced from an uncontrolled baseline by an amount, in kg/yr, that when divided by the annual production rate in kg, and then summed with the production-indexed HAP consumption value from § 63.1252 (h)(3)(i) above, will yield a value of a least 75 percent of the average baseline HAP production-indexed consumption factor. The annual reduction in HAP air emissions must be due to the use of the following control devices ...

Response: The EPA agrees with the commenter and the final rule clarifies the intent of the P2 alternative, as suggested.

Comment: One commenter (IV-D-23) noted that, as currently written, the last sentence of the rule in § 63.1252(h)(2) states that "no increase in the production-indexed VOC consumption factor for the applicable period of demonstration shall occur," but that the "period of demonstration" is not defined in the rule. The commenter stated that the "period of demonstration" should be the annual reporting period. The commenter further stated that "as long as the annual production-indexed HAP consumption factor is less than 25 percent of the baseline year, and the VOC consumption factor did not increase over the base year, the pollution prevention alternative should apply." The commenter was concerned that variations in recovery yield could cause a short-term negative effect in either the HAP or VOC consumption factors; and therefore, the period of demonstration over which there is no increase should not be from year to year each year between the baseline year and the present.

The commenter gave an example where the production-indexed HAP consumption factor increased slightly from 1991 to 1992, but based on the production-indexed HAP consumption factor determined in 1990, the process would still be in compliance with the P2 alternative.

Response: The EPA agrees with the commenter, and the meaning of "period of demonstration" is clarified as an annual period of time in the final rule. Additionally, the final rule requires that the baseline production-indexed HAP and VOC consumption factors be determined based on consumption and production values that are averaged over the time period

from startup of the process until the present time (assuming the process has been in operation at least 1 full year), or the first 3 years of operation, whichever is the lesser time period. The changes to the baseline averaging period were made to ensure the baseline production indexed HAP consumption factor reflected normal production.

Comment: Three commenters (IV-D-22, IV-D-27, IV-G-02) do not believe that facilities complying with the P2 alternative should be exempt from the storage tank requirements included in the proposed rule. Because storage tanks are not included in the definition of "process" the emissions associated with these sources may not be affected by the P2 alternative instituted by a facility. Therefore, these emissions would not be reduced.

Response: The Agency intended that emissions from storage tanks would be included in any P2 alternative. To clarify the pollution prevention provisions of the rule, the final rule refers to "PMPU's" as opposed to "processes" under the pollution prevention alternative, and the definition of PMPU was revised in the final rule to include storage tanks. (See also, Section 1.2, Definition of Pharmaceutical Manufacturing Operations, Pharmaceutical Manufacturing Process Units, and General Applicability.)

9.3 BASELINE YEAR FOR P2 ALTERNATIVE

Comment: A number of commenters (IV-D-04, IV-D-22, IV-D-27, IV-D-14) stated that the base year for the P2 alternative should be moved up from 1987 to 1990. One of the commenters (IV-D-27) stated that the proposed baseline year of 1987 allows too much credit for reductions already achieved as part of other programs or requirements. However, the commenter stated that use of an earlier baseline year (i.e., pre-1990) may be warranted in cases where a product was not produced in every calendar year. Another commenter (IV-D-22) stated that the quality of the data used to substantiate the baseline consumption factors was more important than the baseline year; however, the commenter recommended a base year of 1990 because 1987 was the first year that in-depth facility-wide environmental release reporting was required under the Toxics Release Inventory (TRI), and data from the initial reporting years is often flawed and not quality assured.

Another commenter (IV-G-02) also noted the importance of data quality, and stated that the proposed baseline year of 1987 would be acceptable if the facility has adequate and verifiable HAP-specific data at the process level.

One commenter (IV-D-15) stated that the 1987 base year is appropriate and need not be moved to a later year.

Response: At proposal, baseline production indexed consumption factors were determined based on the average values in 1987 or for the first full year of operation (or the first year for which data are available). The EPA considered 1987 to be the earliest year in which data would be acceptable, citing that 1987 was the first year in which SARA/TRI reports were required. However, EPA recognizes the importance of data quality with regard to the calculation of HAP and VOC indexed consumption factors. The final rule accounts for sensitivity in data quality by requiring that the baseline production-indexed HAP and VOC consumption factors be determined based on consumption and production values that are averaged over the time period from startup of the process until the present time (assuming the process has been in operation at least 1 full year), or the first 3 years of operation, whichever is the lesser time period. The changes to the baseline averaging period were made to ensure the baseline production indexed HAP consumption factor reflected normal production.

9.4 SUGGESTED CHANGES TO REDUCE RESTRICTIONS ON USE OF P2 STANDARD

9.4.1 Processes that Generate HAP

Status at proposal. At proposal, processes emitting HAP that are generated in the process were prohibited from using the pollution prevention alternative.

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04, IV-D-08) would like for processes that generate HAP to still be allowed to use the P2 alternative as long as these quantities were included in the analysis. These commenters believe that the rule should provide a de minimis HAP generation cutoff below which facilities may opt for under the P2 alternative. The example cited by many of the commenters is the generation of HCl as a reaction by-product.

Response: The Agency agrees with the commenter that sources that generate HAP emissions should be eligible for the P2 standard, provided the HAP emissions generated by the source are included in the analysis. The final rule allows processes that generate HAP that are not part of the production-indexed consumption factor (e.g., the HAPs generated are different than the HAPs brought into the process) to use the P2 alternative, provided that the HAP emissions generated in the process are controlled to the levels required by the applicable

provisions for storage tanks, process vents, wastewater and equipment and the remaining requirements of the P2 standards are met. For HAPs that are generated in the process, as well as brought into the process (e.g., considered as part of the production-indexed consumption factor), the definition of consumption was revised to consider generated HAP.

9.4.2 Increases in Production-Indexed VOC Consumption Factor

Status at proposal. At proposal, no increase in the production-indexed VOC consumption factor was allowed as the result of compliance with the P2 alternative.

Comment: One commenter (IV-D-20) believes that the stipulation in the P2 alternative that does not allow for an increase in the VOC consumption factor as a result of a decrease in use of HAP is unfair. According to the commenter, this will eliminate many solvent replacement projects. The example that the commenter used was a 100 percent reduction of methylene chloride (a non-VOC HAP), and the replacement of this solvent with a water-based solvent that contains trace amounts of some VOC. This trace amount of VOC would result in an increase in the VOC consumption factor. The commenter further explained that HAP solvents generally tend to have more aggressive solvent properties than non-HAP, and thus, when replacing a HAP solvent with a non-HAP solvent, the result is generally lower yields, more extensive processing, or higher quantities of solvents used. The commenter also made two additional points in anticipation of EPA concerns with increases in VOC emissions: (1) any increase in solvent usage that would result from solvent substitution would be limited due to existing equipment capacities, and (2) any physical or operational change that resulted in an increase in VOC emissions would have to undergo major or minor New Source Review. As a compromise, the commenter suggested that an upper limit could be set on the increase in VOC consumption, and gave a "conservative" limit of two times the baseline production-indexed VOC consumption factor.

Response: When evaluating MACT options, the Agency estimates the environmental impacts associated with each candidate MACT option, as well as the effectiveness and costs of these options. Adverse environmental impacts are considered when selecting MACT for each source. In some instances (e.g., the use of incineration-based add-on controls) the installation of MACT-based controls can result in increases in emissions of non-HAP, such as nitrogen oxides. Because VOC emissions contribute to tropospheric ozone formation, the Agency must balance

the benefits of reducing HAP emissions with the adverse impacts associated with an increase in VOC emissions. In many cases where solvent substitution is an option for meeting a particular standard (e.g., in some of the surface coating NESHAP), the HAP in question are also VOC's, such that reducing the HAP content of the solvent reduces the VOC content of the solvent, and subsequently, emissions of both HAP and VOC's are reduced. In the example provided by the commenter, the solvent is 100 percent methylene chloride (a non-VOC HAP), and therefore, a switch from methylene chloride to any VOC-containing solvent would result in an increase in VOC emissions. The EPA realized that the proposed rule gave un unfair advantage to sources using VOC-HAP solvents as opposed to non-HAP solvents because the rule did not allow affected sources using non-VOC HAP solvents to switch to VOC solvents and still qualify under the pollution prevention alternative. After consideration of this concern, EPA has changed the final rule to require an equivalent reduction in the production-indexed VOC consumption factor, if the reduction in the production-indexed HAP consumption factor is achieved by reducing a HAP that is also a VOC. If the reduction in the production-indexed HAP consumption factor is achieved by reducing a HAP that is not a VOC, the consumption-indexed VOC factor may not be increased. In making these changes to the final rule, EPA has essentially eliminated the possibility of receiving credit, through the pollution prevention alternative, for switching from HAP to VOC in either circumstance. Note also, that the decrease in the VOC consumption factor required if the reduction is achieved by reducing a HAP that is also a VOC is in terms of kg/kg, and not as a percentage of kg/kg. For example, an owner or operator may have a HAP baseline consumption factor of 100 kg/kg and a VOC baseline consumption factor of 500 kg/kg. If complying with the pollution prevention alternative requiring 75 percent reduction in the baseline HAP consumption factor, the owner or operator would also be required to reduce the VOC consumption factor by 75 kg/kg, so that the VOC consumption factor after implementing the changes would be 425 kg/kg.

In response to the commenters request that a switch from a HAP to a low-VOC material should be allowed through the pollution prevention alternative, EPA's response is that, in this situation, the process would likely not be covered under the MACT standard because there would be no HAP used or processed in the process (although if HAP were generated in the process, it would still be covered--see applicability).

9.4.3 Facility-Wide Averaging Allowance

Comment: One commenter (IV-D-29) believes that the P2 alternative should allow a facility-wide averaging allowance.

Response: The Agency disagrees with the commenter because of the difficulty in implementing a standard for the pharmaceutical industry based on facility-wide control. The pharmaceutical industry predominantly uses batch processes to manufacture pharmaceutical products, and facilities typically run multiple processes, such that at any one time, one process may be ending, another starting, and still others continuing to run. Therefore, the application of a facility-wide standard would require an enormous amount of effort to track site-wide uncontrolled and controlled emissions to ensure that a single control level would be met over the entire plant site on a yearly basis, and facility operators may not know that they are out of compliance until a year has passed. In addition, the form of the P2 standard (i.e., kg HAP per kg product) presents an additional complication to any facility-wide averaging scheme because there is no standard way to combine various products manufactured at one facility into one common denominator.

9.4.4 Solvent Recycling

Status at proposal. At proposal, control devices that allowed for recycling of material back to the process were excluded from the P2 alternative.

Comment: A number of commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04, IV-D-08, and IV-D-40) do not believe that the P2 alternative, as it is currently written, will be used for multiproduct (nondedicated) processes due to strict FDA and QC restrictions on cross-contamination. These restrictions will oppose attempts to reduce the amount of solvent per kilogram of product. For this reason, the commenters have suggested that the P2 alternative be modified such that multiple-product facilities may have a greater opportunity to make use of this alternative. The specific modification suggested by the commenters includes allowing solvent that is "returned to the economy" to be considered as an alternative for multi-product processes. The commenters noted that, for implementation purposes, the interested party (first user of the solvent) would need to demonstrate that the required fraction of solvent was transferred to another (second) user *as a raw material*, to be used

as is, so that the second user will purchase that much less solvent. Under this approach, the consumption of HAP would be equivalent to the amount purchased minus the amount sold.

A similar comment submitted by two commenters (IV-D-24, IV-D-28) suggests that the P2 alternative should be revised to allow credit for in-process recycling in the calculation of HAP reduction from a process. The proposed rule specifically prohibits the use of a control device that would allow for recycling of material back to the process.

Response: Although the Agency recognizes that multiple-product facilities may not be able to take advantage of the pollution prevention alternative, the type of program whereby one entity certifies the nature and amount of the recovered solvent usage by another entity would be difficult and burdensome to implement, and would require tracking and verifying the usage of the recovered solvent at the second entity. Also, when the recovered solvent is sold to the second entity, the first entity does not achieve any real emission reduction (i.e., reduction in solvent usage), but instead, takes credit for the assumed emission reduction that would occur at the second entity. Also, the second entity may not be a pharmaceutical manufacturing facility which would result in emission reductions being moved across source categories entirely. For these reasons, the final rule does not allow credit for sale of recovered solvents in the P2 standard.

The Agency disagrees with the commenters that suggest credits be given for in-process recycling because giving a source "credit" for in-process recycling would result in "double-counting" of the emission reduction. By recycling solvents, the owner or operator already has reduced the amount of solvent entering the process (i.e., the more that is recycled, the less that is purchased), so further credits due to recycling are not necessary.

9.4.5 Re-engineering of an Existing Process

Comment: One commenter (IV-D-38) believes that if a process is re-engineered in such a way that results in an overall reduction in HAP consumption, and the product remains the same, then the process should be eligible for the P2 alternative. The commenter gave an example in which a process uses catalytic reactions to produce the same product formerly produced by HAP driven chemical synthesis. The commenter further stated that any new HAP emissions generated in the new process should be permissible provided that these emissions are accounted for in the P2 alternative.

Response: The EPA agrees with the commenter but stresses that the product produced using the new process must be produced at the same facility where the product was produced using the "old" process. The EPA believes this restriction is necessary to avoid the difficulties that would be associated with "transfer" of baseline HAP consumption factors between different facilities.

9.5 INCLUSION OF CLINICAL TRIAL PERIODS IN BASELINE HAP CONSUMPTION FACTOR DETERMINATIONS

Comment: One commenter (IV-D-23) suggested that the baseline HAP consumption factor be allowed to include the clinical trial manufacturing period because this would encourage facilities to reduce or eliminate the consumption of HAP during process development. The commenter stated that "most of the pollution prevention activities occur during process development, either by changes in the chemistry or synthetic route, or by changes in process materials such as solvents." The commenter suggested that EPA set the baseline date as the date of submittal of the Investigational New Drug (IND) application, which requests FDA approval for the start of the clinical trials. Following the clinical trials, the facility submits the New Drug Application, and after that point, any process changes would require FDA approval.

Response: Because solvent usage is not a primary concern during the clinical trial period, the difference between the initial quantities used during the clinical trial period (which may be excessive) and the quantities used during commercial production may not represent true pollution prevention measures as much as normal process optimization/cost reduction measures. Also, the implementing agencies would have to determine if the baseline HAP consumption factor determined during the clinical trial period was "reasonable" or artificially high. Because each product is unique, the Agency could offer no guidance in this area, and therefore, the final rule does not allow the clinical trial periods to be included in determining the baseline HAP consumption factor for the P2 standard.

9.6 75 PERCENT REDUCTION AND MASS BALANCE ISSUES

Comment: Two commenters (IV-D-08 and IV-D-20) believe that the 75 percent reduction included in the P2 alternative is too high. One of the commenters (IV-D-08) stated that the 75 percent reduction in the production-indexed HAP consumption factor does not take into account the technical difficulties associated with obtaining an accurate mass balance. The

commenter provided an example where a mass balance around one process could account for only 90 to 95 percent of the total material used, despite a 5-year effort to close the balance, use of outside consultants, and implementation of an LDAR program. Therefore, the commenter suggested that EPA allow a correction factor of up to 5 percent to be applied to the production-indexed HAP consumption factor. The commenter also suggested that EPA consider including a "material usage efficiency" (also referred to as the recycling or recovery efficiency) concept as part of the P2 alternative; under this concept, the required production-indexed HAP reduction would be adjusted according to the initial material usage efficiency.

The other commenter (IV-D-20) took issue with the selection of a 50 percent reduction in the HAP consumption rate in the second option of the P2 alternative. The commenter stated that a 50 percent reduction in HAP consumption is too aggressive, especially considering that "pharmaceutical processes are usually installed as extensively optimized operations." The commenter also recommended that EPA "allow a reduction in the HAP consumption factor by any amount less than 75 percent, with the remaining amount reduced by add-on controls." To incorporate this suggestion into the rule, the commenter provided the following changes in the equation used to calculate the HAP reduction required by controls in § 63.1253(f)(2)(ii):

$[kg/kg]_b * 0.25 * [kg\ produced]_a = [kg\ reduced]_a$

(proposed rule)

becomes:

$([kg/kg]_a - 0.25 * [kg/kg]_b) * [kg\ produced]_a = [kg\ reduced]_a$

<u>Response</u>: The P2 alternative is an alternative to the standards in the MACT rule. As such, the Agency developed a P2 alternative that was approximately equivalent to the reductions achieved from imposing the standards on an uncontrolled industry. By requiring, in the second P2 alternative, at least a 50 percent reduction due to P2, the EPA is requiring that a significant portion of the reductions are to be achieved using P2 techniques, not add-on controls. Generally, the standards require that some level of control be achieved by add-on devices. Therefore, if the commenters wish to use add-on devices to significantly reduce emissions from the processes, they must achieve the reductions required by the standards. Therefore, the Agency sees no reason at this time to change the targeted reductions in the P2 alternative from what was proposed.

Regarding the addition of a 5 percent correction factor, EPA has not provided for such a confidence margin in the final rule. However, EPA recognizes that the overall significance of the numbers used in complying with the standards is an important aspect of compliance and believes that a facility may establish both baseline and annual factors considering standard statistical procedures.

9.7 COMPLIANCE PROCEDURES FOR P2 ALTERNATIVE

Comment: Three commenters (IV-D-29, IV-D-28, IV-D-14) believe that the P2 provision that requires demonstrating compliance every 10 batches (for batch operations) would be excessive for batch processes with very short cycle durations. One commenter (IV-D-29) noted that for continuous processes, the annual factor for demonstrating compliance is every 30 days and suggested that the standard be changed such that batch processes should demonstrate compliance every 10 batches or monthly.

Response: The EPA agrees with the commenters and the final rule allows owners or operators complying with the P2 standard to demonstrate compliance either every 10 batches or on a monthly basis.

9.8 REPORTING AND RECORDKEEPING REQUIREMENTS FOR ALTERNATIVE P2 STANDARD

Status at proposal. The proposed rule in Section 63.1255(a)(4) requires sources that comply with the P2 alternative to maintain records of rolling average values of kg HAP/kg production and kg VOC/kg production. The proposed rule specifies how production- indexed HAP and VOC consumption factors should be calculated (i.e., by dividing annual consumption of total HAP or VOC by the annual production rate, per process) but does not require the owner or operator to explain how the reductions in product-indexed HAP consumption factors are achieved.

Comment: Several commenters (IV-D-22, IV-G-02, and IV-D-27) stated that EPA should develop data requirements necessary to substantiate compliance with the pollution prevention alternative. Two commenters (IV-D-27 and IV-G-02) suggested that the final rule require facilities to submit a "P2 Demonstration Summary" that briefly describes the pollution prevention methods that were used to achieve the reduction in HAP consumption. The commenters stated that information on the facility's P2 activities was necessary to verify that

(1) the HAP consumption data is directly related, on a per process basis, to each process that is complying with the P2 alternative; and (2) the reduction in HAP consumption was achieved via pollution prevention methods that meet the Agency's definition of pollution prevention. These commenters also noted that, "in order to provide adequate incentive for facilities to choose the pollution prevention alternative, the EPA should ensure that data requirements are reasonable and protect confidential chemical formulation data." Another commenter (IV-D-16) suggested that the monthly rolling average values of the production-indexed HAP and VOC consumption factors be entered into an Inventory Tracking System and suggested that EPA provide a standard reporting format and an option for electronic reporting.

Another commenter (IV-G-02) proposed an alternative approach to reporting under the P2 alternative. This commenter suggested that if a facility would provide consumption data (including purchase data) from a baseline year and a current year, and show a reduction, then, as a streamlining measure, the EPA would not require the facility to provide details of how this reduction was accomplished. The commenter feels that this would reduce some of the potentially burdensome aspects of the P2 alternative.

Response: The Agency agrees with the commenters that specific information on pollution prevention alternatives implemented by pharmaceutical manufacturers is necessary to ensure compliance with these standards. The Agency also agrees with the commenters that the reporting burden associated with the P2 alternative must be minimized to encourage pollution prevention as a means of complying with the standards. Therefore, the rule has been revised to require sources seeking to comply with the P2 alternative to submit a P2 demonstration summary, as part of the Precompliance Report, which describes how the P2 alternative will be applied at their facilities. The data requirements of the P2 Demonstration Summary include descriptions of how each facility measures and records HAP consumption and pharmaceutical product production on a daily, monthly, and annual basis, and appropriate documentation such as operator log sheets, copies of daily, monthly, and annual inventories of materials and products, shipment and purchase records, tank-specific charts for converting tank-level measurements to volume (e.g., gallons) of HAP or product, and temperature/density charts for converting tank volume measurements into weight measurements. Also, if a facility complying with the P2 standard uses the same HAP in more than one process, the owner or operator will be required to

modify existing methods of tracking HAP consumption at the plant, if necessary, to ensure that HAP consumption can be measured for each PMPU, as opposed to facility-wide.

9.9 GUIDANCE ON P2 ALTERNATIVE

Comment: One commenter (IV-D-27) suggested that the EPA develop guidance and recommendations for the P2 alternative that document the P2 methods used to reduce HAP consumption and the data requirements that are necessary in order to comply with the P2 alternative. Specifically, it would be used to develop case studies of those facilities that use the P2 alternative to help evaluate this regulatory approach, so that it may be used as a model in other regulations.

Response: The Agency plans to issue a guidance document for implementation of the pharmaceutical NESHAP. Specific guidance on P2 alternatives will be included in this guidance/implementation document.

10.0 EMISSIONS AVERAGING

10.1 RESTRICTIONS ON EMISSIONS AVERAGING

Comment: Numerous commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04, IV-D-08, [illegible] -D-29) stated that the restriction in 63.1252(j)(4) to not allow averaging of emissions reductions for controls in place prior to November 15, 1990 should be deleted from the rule. In general, the commenters believe that sources should not be penalized for an environmentally proactive position of voluntarily controlling emissions. Commenter (IV-D-27), however, approves of said restrictions.

Response: The Agency's policy on not allowing averaging of emission reductions for controls in place prior to passage of the 1990 CAA amendments (i.e., November 15, 1990) was explained in a previous rulemaking (citation: preamble to the proposed HON). Emission reductions achieved by controls that were in place prior to November 15, 1990 would have occurred regardless of whether or not the CAA was amended. If EPA allowed sources to take credit for these pre-existing emission reductions, those sources could increase their emissions above 1990 baseline levels. Emissions averaging is a method for complying with the pharmaceutical NESHAP and should not result in more emissions than other compliance options.

Comment: Two commenters (IV-D-04 and IV-D-27) stated that emissions averaging should not be included in this regulation. Both commenters cite concerns with the acceptance of interpollutant trading. Furthermore, both commenters approve of provisions that allow individual state and local agencies to prohibit emissions averaging. Two commenters (IV-D-14 and IV-D-27) also object to the automatic approval provisions of 63.1253(h)(1) and (i)(1) that call for EPA to grant automatic approval of emissions averaging plans for storage tanks and process vents if the agency fails to provide notification of approval or disapproval within 60 days. One of the commenters (IV-D-14) further explained that (1) a preset time limit (i.e., 60 days) does not allow not address extenuating circumstances that may alter the review process

(such as resources and workload) and (2) there is no incentive for affected sources to submit good plans if they receive automatic approval after 60 days. The commenter (IV-D-14) requested that EPA include the following language in the emissions averaging provisions:

"Upon receipt of the Implementation Plan, the review authority shall notify the owner or operator in writing of its completeness. Once the review authority has approved a plan, including any modifications deemed necessary, the owner or operator will be notified in writing of the approval."

Another commenter (IV-D-23) believes that the proposed averaging provisions are relatively simple, especially because there is no cross-plank averaging. Therefore, the commenter does not believe that allowing states to restrict or prohibit the use of emissions averaging is appropriate in this situation.

Response: In the case of the process vent standards, averaging is already implicit in the standards; therefore, the averaging of multiple contaminants (i.e., "interpollutant trading") is already allowed by the standards with or without the emissions averaging provisions. Secondly, automatic approval of emissions averaging plans only arises as a result of no disapproval notification from the State within 60 days. The Agency believes that 60 days provides sufficient time to evaluate the emissions averaging proposals, considering the number of sources that can be averaged and the relative simplicity of the provisions. In addition, the EPA maintains that States should retain the authority to disallow emissions averaging and has provided a rationale for this policy in previous rulemakings (59 FR 19402). Some of the reasons cited by the Agency include the increased administrative burden associated with emissions averaging and potential conflicts with existing State air toxics rules.

10.2 INCORPORATION OF EMISSIONS AVERAGING INTO THE GENERAL PROVISIONS

Comment: Commenter (IV-D-16) stated that emissions averaging provisions should be located in the General Provisions to Part 63, not in individual MACT standards.

Response: To respond to comments on the proposed rule that criticized the amount of cross-referencing in the rule and requests from these commenters that portions of the General Provisions be incorporated directly into the final rule, EPA has limited references to other rules. where practical. Therefore, keeping the emissions averaging provisions within the

pharmaceutical NESHAP appears to be in line with the wishes of the majority of commenters. Also, the emissions averaging provisions for the pharmaceutical NESHAP are customized for this industry, only apply to process vents and tanks, and thus would not be appropriate for inclusion in the General Provisions.

10.3 GENERAL COMMENTS ON AVERAGING PROVISIONS

Comment: Commenters (IV-D-28 and IV-D-23) have recommended that more than 20 sources be allowed to be included in the process vent and storage tank averaging provisions. Commenter (IV-D-23) stated that the limit of 20 storage tanks seems inconsistently restrictive, when compared to an averaging group of 20 processes that might easily contain 100 pieces of equipment. At a minimum, the commenter believes that at least 100 storage tanks should be included in the averaging group. Commenter (IV-D-28) stated that the number of sources should not be limited to a fixed number, but rather to the number of components that are connected to a common control system.

Response: The limited number of sources in the emissions averaging provisions was intended to reduce the complexity associated with implementing the program across the facility and is consistent with other EPA regulations (see the HON). While the Agency agrees that the process-based format of the standard could also lead to averaging of numerous emission sources, in excess of 20, the use of emissions averaging on top of process averaging is an additional complexity. Therefore, the Agency has retained in the final rule a limit on sources.

Comment: Commenter (IV-D-28) suggested that the averaging provisions should not bear a 10 percent penalty.

Response: The 10 percent discount factor is also consistent with other EPA regulations (see the HON). In supporting the discount factor in other rules, EPA argued that cost savings could result from implementation of emissions averaging measures, and that the environment should benefit from that cost savings. One way to provide for such a benefit to the environment would be to apply a discount factor to reduce the value of credits in the emissions average by a percentage before the credits are compared to the debits.

Comment: Commenter (IV-D-20) stated that the provision in 63.1255(f)(2) requiring a hazard or risk equivalency demonstration be made "to the satisfaction of the operating permit authority; in accordance to any guidance the Administrator makes available or any other

technically sound information or methods; and to meet any requirements set by the Administrator for such demonstrations" is extremely ambiguous. Although the averaging plan will not be approved without an adequate demonstration, the rule does not provide any indication of what is "adequate."

Response: The adequacy of such a demonstration is envisioned to be made on a case by case basis. Because both hazard and risk assessment methodologies carry with them some uncertainty, the EPA intends that States should have discretion in structuring these determinations and notes that many States already use hazard or risk assessments to evaluate HAP control.

11.0 TESTING PROVISIONS AND COMPLIANCE DEMONSTRATIONS

11.1 WORST-CASE TESTING

Status at proposal. The proposed rule states that devices used to control greater than 10 tons/yr of HAP emissions are required to conduct a performance test to determine efficiency around the device. The conditions under which the performance tests are to be performed are stipulated in the regulation as the following options:

Absolute worst-case conditions for all control devices, where absolute worst case is defined as: (1) the period in which the inlet to the control device will contain at least 50 percent of the maximum HAP load capable of being vented to the device over any 8 hour period, or (2) a 1-hour period of time in which the inlet to the control device will contain the highest HAP mass loading rate, in lb/hr, capable of being vented to the control device.

Hypothetical worst-case for all control devices is a simulated condition in which the test conditions contain, at a minimum, the highest hourly HAP load of emissions that would be predicted to be vented to the control device.

Representative worst-case for incinerators, where representative is defined as the 1-hour period of time that contains the highest HAP mass loading rate from a single process.

Normal conditions for all devices, where normal was not defined, but describes a routine condition during which testing is conducted. If the device is tested under normal conditions, the owner or operator is required to operate within these conditions (e.g., a higher HAP load in the control device inlet that exceeds the HAP load of the stream entering the device during testing would not be valid and operating under such conditions would be a violation of the standard).

Absolute and hypothetical worst-case are not workable.

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) believe that the provisions for absolute or hypothetical worst-case testing are not workable, especially in batch facilities where multiple streams are routed to common control

devices. In such cases, they believe that a facility might have to cease production in order to simulate a hypothetical worst-case test for the device, or would have to artificially change its production in order to align emission events for testing that would meet absolute worst-case conditions. In both situations, there are safety concerns associated with generating such conditions, as well as practical concerns.

Commenter IV-D-20 states that "the [absolute worst-case] test conditions require that maximum hourly HAP emissions from all process(es) that can be routed to a control device be tested, and that, in an example process with four unit operations, if each operation has one emission episode that represents the highest hourly HAP loading to the control device, absolute worst-case requires three 1 hour test runs be conducted when all four unit operations have the maximum emission episode occurring." The commenter stated that calculating the potential maximum inlet loading scenario for a control device used to control emissions from multiple batch processing vessels is a difficult but manageable task. This statement is consistent with commenter IV-D-28 who stated that industry's perceived inability to predict worst-case should not be generalized because it may not represent the view of the majority of the industry. Since it appears that industry can predict what the worst-case load could be for a device, the problem actually lies with predicting the exact instant that the worst case will occur. Along the same lines, one commenter (IV-D-02) stated that a facility could not prove that it accounted for absolute worst-case to an inspector and that it was operating at less challenging conditions than those used during a compliance inspection.

Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) suggested that fluctuations related to processing, including sudden changes in temperatures or operator, could shift the timing of emission events and render any predictions about the timing of specific events invalid. The commenters believe that, for devices controlling multiple streams from moderately complex facilities, absolute worst-case test conditions might never occur within the life of the facility, nor could they reasonably be predicted.

An additional concern related to both absolute and hypothetical worst-case testing is that the manifold systems designed to carry emission streams to control devices may not be sized to handle the absolute worst-case situation, which could lead to potentially explosive situations during absolute and hypothetical worst-case testing. Many commenters (IV-D-17/13/15/19/20/

21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that sources often design and install manifold systems at a lower capacity than that of the control device itself to prevent such explosion potential.

Per commenter IV-D-20, the problem with hypothetical worst-case conditions is that testing will not be able to be performed while an actual batch is being produced. Based on past experiences, testing in some cases could result in a process shutdown for 2 weeks, resulting in serious production losses. Many other commenters IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) echo these concerns.

Suggested revisions to normal and representative worst-case.

Comment: Commenter IV-D-20 also states that representative worst case will **also** result in timing uncertainties similar to those of the absolute worst-case situation, especially when the device is controlling a single process with numerous emission episodes. In the example cited above, the representative worst-case would be the same as the absolute worst-case.

For normal testing conditions, commenters (IV-D-15, and IV-D-20) believe that the restriction to operate within conditions that existed during the test should be dropped. The commenters believe that because the standard is on an annual compliance period, the control device will constantly see variably challenging conditions and therefore, should be allowed to operate under conditions that are outside the range of conditions encountered during testing. In order to alleviate the EPA's concerns that a test under normal conditions may not indicate a control device's performance under more challenging conditions, commenter IV-D-20 suggested that an additional requirement to provide a design evaluation under more challenging conditions be added. Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) also suggested that representative worst case should be revised to include all control devices, and should not be restricted to "the level for which it was designed." Additionally, commenter IV-D-15 believes that EPA did not mean to impose this limit on representative testing conditions and would like EPA to make the appropriate language changes to reflect their intent.

Lastly, several commenters (IV-D-27, IV-D-16, and IV-D-07) expressed approval of testing under worst-case conditions, but would like the conditions to be more clearly defined.

Response: The intent of compliance testing under worst case conditions is to document the reduction efficiency of the control device under its most challenging conditions. Subsequent to the initial compliance test, continuous monitoring of operating parameters established during the test is a reasonable measure of continuous compliance with the efficiency requirement under all conditions. Presumably, the control device should function as well or better under conditions that are not as challenging.

Many of the comments regarding worst-case testing conditions are related to the restrictive language defining the worst case challenge and the difficulty associated with developing a time-dependent emissions profile to identify the appropriate test period. In an effort to provide more flexibility to owners and operators regarding the identification of the proper testing conditions, EPA has redefined the worst case "challenge" to include challenging conditions that are not based on high HAP load. These conditions include cases where efficiencies are dependent on other characteristics of emission streams, including the characteristics of components and the operating principles of the devices. For example, solubilities of emission stream components in scrubbing media, or emission stream component affinity in carbon adsorption systems can also define the worst-case challenge for a particular control device.

For worst case challenges that are based on loading of HAP, EPA has also expanded the language describing the development of the emission profile. The emissions profile can be developed based on the actual processing conditions at the facility, as proposed, in which all emission events that can contribute to the control device are identified and considered to determine the highest hourly HAP load from all events that can occur at the same time. However, in the final rule, other options for the emissions profile have been developed that consider the facility's limitations based on equipment or conveyance and capture systems. Owners and operators can develop emission profiles based on equipment, in which the highest hourly HAP-producing emission streams that possibly could enter the control device, considering the facility's available equipment and HAP materials, are identified as appropriate testing conditions. Also, owners and operators have the option to develop emission profiles based on limitations of the control device or conveyance system. For example, many manifolds are

limited in flows and concentration limits by fans and LEL monitors. Conducting performance tests based on conditions approaching these limits is also an option provided in the rule.

The expanded language on emission profiles eliminates the need for allowing owners and operators to test at conditions that are less than the worst-case challenge. Therefore, language referring to testing under "representative" and "normal" conditions was deleted from the batch testing provisions.

11.2 TEST METHODS AND PROCEDURES

11.2.1 Expedited Approval for Alternative Methods

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that the test methods referenced in 63.1253(b)(1) through (6) will require modification, since the methods were developed for continuous processes. Based on past experience, obtaining approval for modifications to test methods often takes 6 to 12 months. Therefore, the industry would like for EPA to consider adding explicit language in the rule allowing for the use of alternative test methods and providing some mechanism for expedited approval. Commenter (IV-D-14) appeared to concur with this suggestion and recommended that additional test methods be included in the rule.

Specific suggestions from the above commenters for expediting approval are:

1. For significant modifications to test methods, allow an analysis that incorporates the intent of Method 301 (Validation Method), without its burdensome requirements. The requests for alternative approvals would be included in the site-specific test plans or within thirty days of their submittal and would require that the Administrator disapprove of such procedures within a 30-day time frame. The commenters also suggest that if a site-specific test plan is not submitted, the o/o could submit the request for an alternative test method 60 days prior to the scheduled test.

2. Explicitly state that approval of minor modifications to existing test methods (such as relocation of sampling probes or equipment configurations) does not require Method 301 validation or the less-burdensome approach described above.

3. Explicitly provide that approval of alternative test methods does not trigger the need for a Title V permit revision, contrary to EPA's latest update on the proposed changes to the Title V permit rule, which includes "significant monitoring and testing changes."

Response: The Agency believes that the provisions in the final rule that require a site-specific test plan be submitted prior to any testing suffice in providing a mechanism for the presentation of, and approval of, proposed modifications to EPA test methods. In general, Method 301 should be used as a validation method for completely new and different testing procedures and instruments that have not previously been reviewed by EPA. It is not the Agency's intent to require the use of Method 301 for minor modifications to test methods such as the relocation of sampling probes. Regarding the approval mechanism for alternative test methods, Section 63.7(c)(3)(ii)(B) and (f) address the mechanism for Agency approval of alternative test methods. Based on this language, EPA rejects the notion that alternative test methods should be automatically approved after a set period of review if no objection is registered by the Agency and refers the commenter to the referenced language. In this regard, the pharmaceutical industry is no different than any other industry. Lastly, the flexible permitting strategy includes provisions for addressing anticipated methods changes through the permit application process.

11.2.2 Method 25A

Comment: Commenter (IV-D-14) stated that Method 25A should be used only after an accurate response factor has been determined.

Response: The final rule specifies the following test methods:

1. Method 18 for control efficiency in all situations.
2. Method 25 for control efficiency determination in combustion devices.
3. Method 25A for the 20 ppmv outlet TOC concentration standard.
4. Method 25A in control efficiency determinations in the situations described in the introductory paragraphs of Part 60, Appendix A, Method 25 (when direct measurement by FID is appropriate).

The importance of calibrating an FID reading obtained using Method 25A with respect to a certain compound (adjustment by response factor) depends on how the method will be used to demonstrate compliance with the standard. In general, the EPA believes that an accurate response factor is necessary in cases where Method 25A is used to demonstrate control efficiency across a device where the composition of the stream may change, or in situations where multiple components, including non-HAP VOC's are present. Because the relative proportion of organic

compounds may change across the control device, appropriate response factors are needed to accurately quantify TOC at the inlet and outlet of a control device.

In addition, the final rule allows owners and operators the opportunity to demonstrate compliance at the outlet of a control device by measuring 20 ppmv TOC or less during controlled episodes. The EPA has allowed owners and operators to use Method 25A and to calibrate the FID using methane or the predominant HAP expected in the emission stream. The use of methane as a calibration gas for the 20 ppmv TOC alternative standard is based on the response factor of methane that is similar to response factors of HAP that are predominant in this industry, such as methylene chloride and methanol. The EPA intends with this requirement to minimize the burden of recalibration for various HAP constituents that may actually change over a given period of time.

11.2.3 Flowrate Sampling

Comment: Commenter (IV-D-28) suggested that the requirement for proportional testing of batch process vents should be eliminated. Commenter (IV-D-14) stated that integrated sampling should be used, and that the grab sample option should be deleted, since grab samples can be grossly biased either high or low. The commenter stated that the use of integrated samples does not require a proportional adjustment of sampling rate, if an average flow rate is also used. Commenter (IV-D-32) stated that many batch processes have such variation in flow rates that it is not possible to obtain a proper sample following EPA Method 2 series.

Response: Proportional sampling is required if an integrated sample is collected. Because the flow rate for batch processes can be variable the sampling rate must be adjusted proportionally to reflect variations in the flow rate. When collecting an integrated sample proportional adjustment of flow rate is required to minimize bias, even when the average flow rate is used in calculating results. Use of proportional sampling will result in a "weighted" average concentration to be used in conjunction with the average flow rate. The EPA notes that the commenter's suggestion to delete grab sampling as an option because of potential biases actually highlights the need for proportional sampling when integrated sampling is applied.

Each sampling situation is different; the use of grab samples is an appropriate option in certain circumstances (e.g., when emissions are relatively constant over a period of time, or if a number of grab samples are used). Therefore, the option of using grab samples has been

retained. Ultimately, the sampling protocol selected has to be appropriate for the particular emission measurement situation.

Measurement of flows from batch processes can be problematic in some cases. In general, Method 2 series measurements should be used; on a case-by-case basis, modifications to the Method 2 procedures may be necessary. For situations of low flow in small ducts, the EPA Method 2 series does include procedures for measuring the total flow (Method 2 A and 2 D). For situations where the flow varies significantly over a short period of time and the methods for measuring total flow are not applicable, some modification to the standard procedures for traversing with a pitot tube may be required to obtain the flow measurement. For example, a multiple point pitot array with an electronic device to continuously record the flow measurement could be used so that a traverse does not need to be attempted during a period of unsteady flow. Any modifications to the standard methods for flow measurement should be proposed as a part of the sampling protocol (test plan).

11.2.4 Test Durations

Comment: One commenter (IV-D-28) stated that the requirements for test durations (three 1-hr runs and the requirements to test for over 1-hr) are too burdensome and should be revised.

However, many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that, for test durations in excess of 1 hour, three test runs should also be required. Another commenter (IV-D-16) stated that the hypothetical worst-case test should not be conducted over 8 hours. Commenter (IV-D-32) stated that the 8 hour test is not appropriate for some organic species. Tedlar bags are normally used to collect the gas sample, and samples collected must be analyzed within an hour because of problems with permeation and wall losses. Therefore, samples collected in Tedlar over 8 hours will not meet quality assurance requirements.

Response: The commenter is correct that samples in Tedlar bags may be lost through adherence to the walls or other losses; however, Method 18 includes self-validating quality control criteria that addresses whether the use of Tedlar bags for integrated sampling is appropriate. Additionally, EPA stresses that the standard does not require 8 hours of testing in any case, but maximizes the length of a test run to 8 hours. The EPA has evaluated the proposed test requirements and has concluded that three test runs are, indeed, necessary for obtaining a

representative estimate of emissions. Therefore, EPA included in the final rule, requirements to conduct three runs, even for performance tests conducted over batch or intermittent sources. To minimize the test burden and the resources necessary to conduct three runs of testing, EPA has required that each run take a minimum of 1 hour and a maximum of 8 hours.

11.2.5 Guidance Regarding Testing of Multiple Control Devices

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) suggested that, in situations where multiple control devices exist in series the rule should provide specific guidance regarding how to determine the test requirements that apply. The commenters requested that language be added to the preamble.

Response: Multiple control devices that are actually part of the same control system that were installed as a single unit can be treated as such for the purposes of evaluating compliance. The final rule incorporates this idea in the definition of air pollution control device.

11.2.6 Condenser Exit Gas Temperature

Comment: Many commenters (IV-D-17) support the concept behind using a direct measurement of condenser exit gas temperature during the 1 hour period when the condenser requires the maximum heat removal capacity; however, the commenters suggested that a direct measurement of condenser exit gas temperature alone may not yield valid data. Therefore, the rule should provide that the measurement of exit gas temperature should occur during periods when there is flow to the device.

Response: The EPA agrees with the commenter that the measurement of exhaust gas temperature is appropriate for determining the effectiveness of a condenser, and recognizes that this measurement data done may yield inaccurate results, particularly when the flow through the condenser has been interrupted. Therefore, language was added to the final rule stating that monitoring readings taken during periods of no flow to control devices should not be considered in evaluating compliance with the rule. These periods of no flow are expected to be measured using continuous flow indicators. Also, EPA has clarified that exit gas temperature should be measured during all episodes that the owner or operator seeks to control as part of compliance with the standards, thereby eliminating the 1-hour compliance demonstration under worst-case conditions.

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) believe that the testing requirements for storage tanks using condensers are more stringent than the requirements for process tanks using condensers because the proposed rule requires in § 63.1253(c)(2) that sources conduct a design evaluation for storage tanks controlled by condensers, whereas § 63.1253(b)(7)(ii)(A)(3) and (B)(2) allow for direct measurement of exit gas temperature in lieu of performance testing for process tanks using condensers. The commenters recommend that EPA allow for the use of direct measurements of exit gas temperature OR design evaluations to determine compliance with the storage tank percent reduction requirement. The commenters pointed out that the Resource Conservation and Recovery Act (RCRA) air emission standards for tanks, surface impoundments, and containers (40 CFR 264, Subpart CC) clearly allow the use of both design evaluations and tests (i.e., measurements of exit gas temperatures) for tanks. The commenters further requested that sources be given the option of either using exit gas temperature measurements or design evaluations to assess initial compliance with the process vent standards, when condensers are used for emissions control.

Response: As stated above, the EPA believes that the exhaust gas temperature of a condenser is a critical parameter that must be considered in evaluating the efficiency of a condenser system. Therefore, EPA has clarified in the final rule that, for a condenser, the temperature of the stream exiting the condenser must be used as part of a design evaluation to determine control efficiency. This requirement is in effect for all condensers controlling >1 ton/yr of HAP, regardless of whether they are controlling streams from tanks or process vents.

11.2.7 Emission Profiles

Comment: Many commenters (IV-D-12, IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, IV-G-04 IV-D-08, and IV-D-14) requested clarification of the methodology for developing an emissions profile, which is contained in Section 63.1253(b)(iii). Commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that the definition of emissions profile implies that sources must prepare a graph of HAP emissions versus time. However, because EPA included the language "the average hourly HAP loading rate may be calculated by first dividing the HAP emissions from each episode by the duration of each episode, in hours, and selecting the highest average hourly block average," EPA's intent was not

to profile emissions versus time, but rather to simply list each batch episode and the average hourly HAP emissions loading from each episode. Commenter IV-D-12 stated that the emission profile method seemed very complicated, and that personnel with operating experience can quickly determine the worst-case conditions for a control device without producing the extensive information required by the emissions profile. Commenter IV-G-01 stated that, while developing the profile might be relatively simple for devices controlling one vent, the task becomes increasingly difficult as the number of vents controlled by the devices is increased. The commenter suggested changing the language of Section 63.1253(b)(7)(iii) (A) by eliminating the phase "must include," so that sources can have the option of discussing an alternative means of determining appropriate test conditions with the permitting authority. Commenter (IV-D-14) also stated that the simulated (hypothetical) tests based on the selection of the 'worst-case" conditions should be justified based on appropriate calculations which are recommended and approved by the reviewing agency. Commenter (IV-D-08) stated that the emission profile might yield an instantaneous HAP emission rate, as expressed in pounds of HAP emissions per hour; the method would not yield representative worst-case emissions estimates for the hour long period.

Response: The intent of developing the emissions profile is to determine the maximum HAP loading to a control device over time. Therefore, EPA's intent was not to simply list the emission events and select the highest loading event from any single episode, as interpreted by the commenters, but rather to consider the net effect of having numerous emission points discharging to the control device at any given time. The EPA has not, in the final rule, changed the requirements for developing the emissions profile, although EPA has clarified the language in the final rule to address the commenter's concerns about the clarity of the requirement. The EPA has also added several other methods for developing the emissions profile as discussed in the response to 11.1 of this chapter.

11.2.8 Clarifications to Testing and Monitoring

Several commenters requested specific clarifications to the testing provisions contained in the proposed rule. These specific comments are contained below:

11.2.8.1 Language Should Specify "HAP Emissions," Not "Emissions"

Comment: Two commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that references to "emissions" should be amended to clarify that the rule pertains

to "HAP emissions" only. For example, Section 63.1253(b) specifies that devices controlling 10 tons/yr or more of "total emissions" must conduct performance tests. This language should be changed to "total HAP emissions."

Response: The EPA agrees with this comment. The final rule reflects these changes.

11.2.8.2 Thermal Oxidizer Efficiency Determination Does Not Require O_2 Correction

Comment: Commenter (IV-D-23) stated that the correction to 3 percent O_2 is not necessary when determining thermal oxidizer efficiency.

Response: The EPA agrees that, in determining control device combustion efficiency, no correction for dilution from excess combustion air is necessary. However, the final rule contains provisions that allow owners and operators to demonstrate compliance by achieving an outlet concentration (e.g., 20 ppmv TOC). If supplemental combustion air is used, the Agency believes that there exists a possibility for owners and operators to dilute the exhaust to achieve the standard. Therefore, the Agency has revised the rule to require a correction for oxygen only when supplemental (e.g., nonprocess, nonaffected steam) combustion air is used.

11.3 EXEMPTIONS FROM TESTING

11.3.1 Use of Control Device Models

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) recommended an option to develop a model which predicts control device efficiency to use as an acceptable substitute for testing when a source has actual test data from a similar device. These test data would be used to validate the control device models. Commenter (IV-D-23) also supplied data on testing costs for two scrubbers.

Response: The EPA disagrees with this comment. The final rule requires testing of all devices controlling greater than 10 tons per year of HAP emissions. The EPA believes that the application of this cutoff, as well as the allowances for direct measurement of condenser exhaust gas temperature, have decreased the testing burden associated with the rule and contends that such large control devices should be tested.

11.3.2 Exemptions for Unsafe Conditions

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, IV-G-04, and IV-D-33) have expressed concern regarding the proposed rule's requirement to test at both the inlet and outlet of the control device. Specifically, the commenters believe that

breaking the inlet line to the device could result in HAP concentrations that exceed the Immediately Dangerous to Life and Health (IDLH) levels established by the Occupational Safety and Health Act (OSHA). Further, they stated that many devices operate continuously when controlling multiple pieces of equipment, and it may not be possible to shut down the processes to insert probes or other instruments to conduct the tests. They recommended that the rule provide for the use of emissions calculations or mass balance data as an alternative to emissions testing for uncontrolled HAP emissions streams that cannot be safely tested.

Response: The problem of breaking the seal on an inlet line to the control device to obtain access for sampling is not unique to this industry. Permanent sampling ports should be installed at the inlet to the control device during a period when it is most convenient (or least disruptive) to shut the process down (e.g., scheduled maintenance outage). In cases where it is imperative to limit any leakage of emissions into the work atmosphere, a sampling port with a double seal should be installed so that the probe can be inserted and removed without any leakage of exhaust gas into the work atmosphere. Typically, this type of port consists of a valve in the port nipple that seals the port nipple from the exhaust stream while the probe is being inserted into the nipple. The probe is inserted through a special port cap that seals around the probe; once the probe seal is secured, the valve in the port is opened and the probe is inserted into the exhaust stream.

11.3.3 Revising Testing Cutoff

Comment: Commenter (IV-D-20) suggested that EPA revise the requirement for when sources should test control devices to greater than 10 tons per year, after control. The commenter also stated that EPA should not require testing of uncontrolled vents, or testing of processes complying with the 2,000 lb/yr alternative.

Response: Although it may not have been clearly stated in the rule, testing is not required for uncontrolled vents. Language was added to the final rule to clarify that for the purposes of uncontrolled vents, calculations are sufficient to determine uncontrolled emissions and no performance tests are required.

The EPA stresses that testing is required only for devices handling 10 tons per year or more before control. The 2,000 lb/yr level is intended as an alternative level of compliance. To demonstrate compliance with this alternative, facilities with devices controlling over 10 tons/yr

HAP emissions prior to control, must test to show that the reduction efficiency of the control device is sufficient to control emissions from the process to a level at or below 2,000 lb/yr. Control devices receiving less than 10 tons/yr HAP emissions prior to control are not required to be tested; owners and operators may use calculations to demonstrate compliance with the 2,000 lb/yr limit in these cases.

11.3.4 Testing of Incinerators

Comment: Commenter IV-D-20 suggested that EPA should not require performance tests for certain control technologies. The commenter stated that the proposed rule provides that storage tanks vented to an incinerator with 0.5 seconds residence time and a minimum temperature of 760°C are assumed to meet the control efficiency requirements for tanks of 90 and 95 percent. The commenter stated that if EPA has information indicating that a control device is capable of complying with required reduction efficiencies, the use of such a device should be offered as a presumptive control alternative. However, commenter (IV-D-14) stated that incinerators should be required to be tested during the initial compliance demonstration.

Response: The EPA agrees with the statement made by commenter IV-D-14. Testing is important to ensure that a control device can achieve the required control level and to establish operating parameters that are indicative of proper operation and maintenance.

The EPA's basic reference for incinerator performance is an EPA June 1980 memo from David C. Mascone to Jack R. Farmer, titled "Thermal Incinerator Performance for NSPS" (Docket Item No.IV-B-6). According to that memo, "mixing is a critical factor in efficiency, a factor of equal or greater importance than other factors such as temperature." The best way to determine the effect of the combination of factors that affect incinerator efficiency is through emission testing. Therefore, EPA standards generally require performance testing when incinerators are among the candidate control devices to meet the rule (e.g., HON, SOCMI NSPS). This is the most ideal situation. The only times when EPA has not required testing is when it is impossible or extremely difficult (e.g., storage vessels) or to reduce testing burden for smaller streams. In these cases, specifications like the commenter mentioned have been used. Consistent with this approach, in this rule EPA has exempted smaller streams less than 10 tons per year of HAP from testing and has established performance specifications these streams can meet. The only purpose of this allowance is to reduce the testing burden on the pharmaceutical

industry because they typically have many processes and vents. The EPA believes it is important to retain the testing requirements for the larger emission streams to ensure the performance of all factors that affect efficiency.

11.3.5 Testing of Batch Emissions

Comment: Commenter (IV-D-32) stated that the requirement to test emissions from batch processes using the referenced test methods is unreasonable and impractical.

Response: Although testing batch emissions may be more difficult than testing emissions from continuous sources, it is not unreasonable to require emissions testing. The EPA again notes that the control devices required to be tested will be large devices that control at least 10 tons per year or more HAP.

11.3.6 Exemptions for RCRA- Permitted Equipment and Equipment Previously Tested

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) support the exemptions from performance testing of process vents contained in Section 63.1253(d)(4). However, many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) requested that EPA include the exemption afforded by Section 63.116(b)(5) (as amended on January 17, 1997) which also exempts hazardous waste incinerators for which the owner or operator has been issued a final permit under 40 CFR Part 270 and complies with the requirements of 40 CFR Part 264, Subpart O, or has certified compliance with the interim status requirements of 40 CFR Part 265, Subpart O. Also, commenter (IV-D-23) suggested that provisions should also be added to allow test results from "substantially similar" test methods.

Response: The EPA has added the specified language from § 63.116(b)(5) to the final rule. However, in the final rule, EPA has not provided language allowing test results from "substantially similar test methods," as requested. Such a determination must be approved by the Agency on a case-specific basis.

11.4 GENERAL COMPLIANCE DETERMINATION

11.4.1 Mass Balances and Process Condenser Efficiency

Issue. As discussed in the preamble, some states have raised questions concerning assumptions about process condenser efficiencies. In particular, they are concerned about how

the uncontrolled emission estimates can be significantly underestimated if the condensers don't function properly. Comments were solicited on this issue.

Comment: Commenter IV-G-01 stated that, at one of their sites, a mass balance was used to determine how well the process condensers were operating. Results indicated that condensers across the board performed at between 99 percent and 100 percent efficiencies. However, the commenter stated that owners and operators with data concerning the efficiencies of their condensers should be allowed to use this information to correctly demonstrate their uncontrolled emissions as well as their resulting control efficiencies.

Commenter IV-D-24 stated that, in their experience, process condensers do not routinely achieve efficiencies on the order of 100 percent. It is for this reason that, historically, control devices have been added to these vents to reduce emissions. The commenter adds that further investigation into this issue is warranted before the Agency requires additional burdens on industry by requiring monitoring of process condensers. Commenter IV-D-15 concurred, saying that EPA should not mandate monitoring of process equipment. Commenter IV-G-04 added that owners and operators should be allowed to take the process condenser's efficiency and the control condenser efficiency in series to get the required reductions.

Two commenters (IV-D-07 and IV-D-27) recommended using mass balance results to predict the efficiencies of process condensers. Additionally, commenter IV-D-27 stated that it is appropriate to incorporate some system for monitoring the level of emissions from a condenser, especially facility mass balances that indicate potentially large losses.

Response: Based on the above comments, EPA agrees that there is sufficient concern about the adequacy of process condensers in this industry to merit some demonstration of their performance. Therefore, EPA has specifically stated, in the final rule, that vessels are to be equipped with a properly operating process condenser while boiling materials. To demonstrate that a process condenser is properly operated, an owner or operator must either measure the temperature of the exhaust gas and show that it is less than the boiling point of the substance(s) in the vessel, or perform a material balance around the vessel and condenser to show that at least 99 percent of the material vaporized while boiling is condensed. This requirement will ensure that owners and operators are accurately characterizing processing conditions.

Regarding the commenter's (IV-G-04) suggestion that the owner or operator be allowed to take the efficiency of both the process condenser and the air pollution control condenser (APC) into account in demonstrating compliance, EPA notes that the percent reduction format of one of the control requirements is sensitive to this interpretation because of the nature of distillation, in which the condensation of boiling materials will drive the magnitude of reductions around a process condenser and air pollution control device. For this reason, EPA and the PMACT workgroup verified that the data used to set the MACT floor reflected emissions after the process condenser. Therefore, the control level required reflects a baseline after the process condenser.

11.4.2 Exemptions from Calculation of Uncontrolled Emissions

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that sources should be able to stipulate the applicability of provisions that depend on the source's level of uncontrolled emissions rather than incurring the burden and expense of having to conduct emission calculations and analyses.

Response: The final rule has only two provisions that depend on a "source's" uncontrolled emissions; one provision is the cutoff for process vent new source MACT. In this situation, the cutoff is 400 lb/yr, uncontrolled. The second is an exemption from control of all processes whose process vents have the potential to emit less than 100 lb/d, on an uncontrolled basis. The EPA maintains that the owners and operators need to document their emissions with regard to these thresholds using the methods provided in the rule.

12.0 EQUATIONS TO CALCULATE EMISSIONS FROM PROCESS VENTS

Status at proposal. The proposed rule would require that owners and operators estimate uncontrolled emissions from each individual process vent. The proposed rule provided equations to use if the emissions occurred from five types of operations (vapor displacement, purging, heating, depressurization, and vacuum systems). If emissions occurred from other types of operations, the owner or operator would be required to conduct an engineering assessment to estimate emissions. The owner or operator could also conduct an engineering assessment to estimate emissions from any of the five types of operations covered by equations in the regulation if the owner or operator believes another approach would give a better estimate of emissions. Permitting authorities must approve procedures proposed in engineering assessments.

The proposed rule also would require the owner or operator to determine controlled emissions. If the emissions were controlled using a device that controls more than 10 tons/yr, an emission test would be required to determine the control efficiency, and the control efficiency would be multiplied by the uncontrolled emissions to determine the controlled emissions. If the process vent emissions were controlled using a device that controls less than 10 tons/yr, the owner or operator would be required to determine the control efficiency of the device for emissions from each vent manifolded to the control device using either specified procedures for a design evaluation or by using the same equations used to estimate uncontrolled emissions, whichever was most appropriate.

12.1 ALTERNATIVES TO THE EQUATIONS PROVIDED IN THE REGULATION

Comment: Several commenters (IV-D-15, IV-D-17, IV-D-20, IV-D-23, IV-D-28, IV-D-31, IV-D-35, IV-D-38, and IV-G-01) stated that the final rule should provide for the use of the emission estimation procedures in the 1978 *Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products* (1978 CTG) in addition to the procedures in the rule. Commenter (IV-D-23) also stated that rule should allow for the use of any

procedures, provided they are reported to, and approved by, the implementing authority. The commenters indicated that procedures in the proposed rule and the 1978 CTG give different results, but they are generally comparable, and either method provides adequate emission estimates (i.e., both procedures are based on the same fundamental principles, and neither gives better results). Furthermore, Commenter IV-D-23 stated that neither approach would produce consistent results among facilities because engineering judgement still must be used to determine how to apply the equations to the multitude of scenarios that fall under the broad categories of operations covered by the equations.

The commenters stated four reasons to allow use of the 1978 CTG equations. First, the MACT floor was based on data from the industry, which were estimated using the procedures in the 1978 CTG. Second, sources would incur significant costs to invest in a programs and data systems to develop and maintain a second method for estimating emissions. Third, the emission estimation equations are based on the 1994 *Control of VOC Emissions from Batch Processes-Alternative Control Techniques Document* (1994 ACT), which has not undergone final public review and comment. Fourth, facilities would have to maintain two sets of emissions estimates because the procedures in the 1978 CTG are, and the commenters believe will continue to be, required by States to demonstrate compliance with other regulatory requirements (e.g., RACT and major and minor new source review determinations); facilities also use the 1978 CTG procedures to estimate emissions for Title V permit applications. Having two sets of emissions estimates would make State review and compliance efforts complex and confusing, and, according to Commenter IV-D-31, could lead to compliance actions for perceived violations for one estimate but not the other. Other problems the commenters foresee are: coordinating implementation of the final rule with other programs such as RACT and Title V will be unnecessarily complicated, there could be reporting inconsistencies under the different statutory authorities, and States would have two values on which to base Title V bills.

Response: The EPA reevaluated the procedures for calculating uncontrolled emissions and determined that, except for two situations, the procedures in the 1978 CTG provide reasonable estimates of uncontrolled emissions. The two situations for which emissions estimation procedures in the 1978 CTG are not acceptable are (1) purging with streams that have large flow rates and (2) heating when the final temperature approaches the boiling point.

Rationale for these exceptions is provided in responses to comments in sections 12.1.1 and 12.1.2. All other emissions estimation procedures from the 1978 CTG are allowed in the final rule. The EPA believes this change mitigates the commenters concerns because the two situations where the 1978 CTG procedures are not allowed affect a small number of emissions streams.

As written, the equations in the final rule look slightly different than the equations in the 1978 CTG, but they reduce to the same equations. For example, the equation for vapor displacement in the final rule uses a term for the HAP partial pressure. However, the rule also indicates that Raoult's law may be used to calculate the partial pressure, which is consistent with the approach in the 1978 CTG. Another difference is that the 1978 CTG calculates VOC emissions, not HAP emissions. If the VOC's in an emission stream are not all HAP, the terms for VOC partial pressures (or mole fractions) in ratios of condensables to noncondensables or total volume to noncondensable volume the 1978 CTG equations cannot be replaced with HAP partial pressures. A third difference is the equations in the final rule are used to calculate the total emissions for an emissions event, whereas the equations in the 198 CTG calculate an emissions rate. However, simply multiplying the results of the equation in the 1978 CTG by the time of the emissions event give the result that would be obtained with the equation in the final rule.

Comment: One commenter (IV-D-20) noted that the emission estimation equations for purging and heating differ between the 1994 ACT and the proposed rule. The commenter urged EPA to change the equations in the final rule to be consistent with the equations in the 1994 ACT. Otherwise, a facility would face the same problems associated with maintaining two sets of emissions estimates (as noted in the comment above) if a State changed its requirements to be based on the procedures in the 1994 ACT instead of the procedures in the 1978 CTG.

Response: The final rule and the 1994 ACT have the same equation for purging, but not for heating. Rationale for the changes is provided in sections 12.1.1 and 12.1.2.

Comment: If the final rule does not allow for the use of the 1978 CTG emission estimation procedures, several commenters (IV-D-15, IV-D-17, IV-D-20, and IV-D-35) urged EPA to address the other methods used for other air compliance activities. One commenter (IV-D-20) also recommended that EPA provide language in the final rule that would protect

facilities from enforcement actions and citizen suits initiated because the facility is required to develop two different emissions estimates for the same process; the commenter suggested that enforcement actions and citizen suits might be brought against a facility under the credible evidence rule.

Response: As noted in the response to a comment above, the final rule allows facilities to use the 1978 CTG equations in most situations. States may adopt the equations for purging and heating in the final rule.

Comment: One commenter (IV-D-39) derived algorithms for estimating emissions from depressurization and heating. The commenter asserts that the algorithms are more accurate than the procedures in the rule, especially when the vessel contents are close to their boiling point. Therefore, the commenter recommended replacing the procedures in the rule with these algorithms.

Response: The EPA agrees with the commenter that the algorithms give good estimates when the vessel contents are close to their boiling point. The EPA decided not to replace the procedures in the rule with these algorithms because, as noted in responses to comments above, the procedures in the 1978 CTG and 1994 ACT were determined to be acceptable. However, the algorithms are included in the final rule as an option that an owner or operator may elect to use.

12.1.1 Equations for Purging

Comment: Two commenters (IV-D-15 and IV-D-17) noted the equations in the proposed rule and the 1978 CTG give different estimates of emissions for purging. Another commenter (IV-D-31) stated the equations in the 1978 CTG and the 1994 ACT are different. Commenter IV-D-31 also believes the assumption that the vapor phase is 25 percent saturated instead of 100 percent saturated for purge streams greater than 100 scfm is merely a different assumption and is not based on better information. According to Commenter IV-D-31, assuming 100 percent saturation, as is done for all purge rates in the 1978 CTG, is more conservative because it will overestimate emissions, whereas the 25 percent assumption will sometimes result in overestimation and sometimes result in underestimation.

Response: The term that accounts for the increase in flow rate due to the volatilization of HAP was inadvertently left out of the equation in the proposed rule (i.e., the purge flow rate

needs to be multiplied by the ratio of total flow to noncondensables at saturation). The equation in the final rule reads as follows:

$$E = \sum_{i=1}^{n} P_i MW_i \times \frac{(V)(t)}{(R)(T)} \times \frac{P_T}{P_T - \sum_{j=1}^{m} (P_j)}$$

where:

E = mass of HAP emitted

V = purge flow rate at the temperature and pressure of the vessel vapor space

R = ideal gas law constant

T = temperature of the vessel vapor space; absolute

P_i = partial pressure of the individual HAP

P_j = partial pressure of individual condensable VOC compounds (including HAP)

P_T = pressure of the vessel vapor space

MW_i = molecular weight of the individual HAP

t = time of purge

n = number of HAP compounds in the emission stream

m = number of condensable VOC compounds (including HAP) in the emission stream

The above equation gives the same results as the equation in the 1978 CTG (as long as P_T is equal to 760 mmHg). Commenter IV-D-31 was mistaken; this equation also is identical to the equation in the 1994 ACT.

The assumptions that purge streams with flowrates less than or equal to 100 scfm are 100 percent saturated, and that purge streams with flowrates greater than 100 scfm are 25 percent saturated, are based on modeling analyses that are described in the 1994 ACT. In the 1994 ACT, the mass transfer (of toluene) from the liquid to the purge stream was estimated using various correlations and a range of design and operating parameters. The correlations showed the purge streams, especially purge streams with high flow rates, were well below saturation for all but the most agitated vessels or vessels with very shallow head space. Assuming these large streams are completely saturated would result in significantly overestimated uncontrolled emissions.

Overestimating uncontrolled emissions leads to at least two problems. First, for a condenser, overestimating uncontrolled emissions means the control efficiency of the condenser

will be overstated (and the condenser will operate at a higher temperature than is actually needed to meet the standard). A second problem with overestimating the uncontrolled emissions is that even if the control efficiency is being met (say with an incinerator), the quantity of emissions reductions would also be overestimated, which would result in overestimation of control on a process basis. To mitigate these problems, the EPA reviewed the results of the modeling analyses and selected values that while still conservative greatly reduce the potential amount of overestimation. The correlations showed that under all types of conditions, the degree of saturation declines rapidly with increases in purge flowrate up to about 100 scfm, and then nearly levels off; the "knee" of the curve was at about 100 scfm for every scenario. For all modeled scenarios, purge flowrates greater than 100 scfm were always less than 25 percent of saturation. Based on these results, the EPA believes that assuming purge streams with flowrates greater than 100 scfm are 25 percent saturated rather than 100 percent saturated results in a better estimate of emissions, more accurate operating parameters, and reasonable credits for emissions averaging. Thus, the requirement to assume purge streams with flowrates greater than 100 scfm are 25 percent saturated was retained in the final rule; as noted in the response to comments in Section 12.3, the owner or operator may conduct an engineering assessment to show that another value is more appropriate.

12.1.2 Equations for Heating

Status at proposal. The procedures to estimate emissions from heating under the proposed rule varied depending on the final heatup temperature. If the final temperature was lower than 50 K below the boiling point, the proposed rule would require the owner or operator to use the equation in the 1994 ACT. If the final temperature was higher than 50 K below the boiling point, the proposed rule would require the owner or operator to estimate emissions as the sum of the emissions obtained using the equation in the 1994 ACT over temperature increments. The first increment would be from the initial temperature to the temperature 50 K below the boiling point. Additional estimates would be over 5 K increments from the temperature 50 K below the boiling point to the lower of either the final temperature or the temperature 5 K below the boiling point. This approach would also be required if the vessel contents were heated to boiling but the vessel was operating without a process condenser. If the contents of the vessel were heated to boiling and the vessel operated with a process condenser, the proposed rule would

require the owner or operator to estimate uncontrolled emissions assuming the amount of noncondensable vapor displaced from the vessel was saturated with HAP at the conditions of the receiver.

Comment: Three commenters (IV-D-15, IV-D-17, and IV-D-31) noted that the procedures in § 63.1253(d)(2)(i)(C)(*3*) of the proposed rule were not in the 1994 ACT, but they correct a deficiency in that document. Commenter (IV-D-31) further indicated that these procedures result in negative emissions when a heated vessel has a process condenser.

Response: The EPA agrees with the commenter that the language in § 63.1253(d)(2)(i)(C)(*3*) of the proposed rule is ambiguous. This section of the proposed rule indicates that Equation 2 is to be used to calculate emissions "due to heating the vessel contents to the temperature of the gas exiting the condenser." If the process condenser operates at a temperature below the initial temperature of the vessel, the commenter is correct that using this procedure will estimate negative emissions. To improve clarity and simplify the rule, EPA revised the requirements for estimating emissions when the heated vessel is operating with a process condenser. The final rule clarifies that a condenser is only a process condenser while the contents of the vessel are boiling. When operating under these conditions, the final rule requires the owner or operator to demonstrate that the process condenser is operating properly by either measuring the condenser exhaust gas temperature and showing it is less than the boiling point of the vessel contents or by performing a material balance around the vessel and condenser to show that at least 99 percent of the vaporized material is condensed.

If the vessel contents are not boiling, any condenser is a control device. Requirements for estimating controlled emissions are described in section 12.4.

Comment: One commenter (IV-D-31) indicated that the equations in § 63.1253(d)(2)(i)(C)(*1*) of the proposed rule yield either higher or lower uncontrolled emissions compared with the equation in the 1978 CTG depending on the temperature that is used in the 1978 CTG equation (i.e., initial, final, or somewhere in between). Two other commenters (IV-D-15 and IV-D-17) noted the difference occurs because the procedure in the proposed rule uses the average of the initial and final vessel conditions, whereas the 1978 CTG uses the saturation concentration at the temperature of the receiver. Commenters IV-D-15 and IV-D-17 also indicated that the requirement in § 63.1253(d)(2)(i)(C)(*2*) for calculating emissions over 5 K

temperature increments is an error because it is not part of the approach in the 1994 ACT. Another commenter (IV-D-08) believes the 5 K increments are overly conservative and noted this procedure is not specified in the 1978 CTG.

Response: The equation in the 1978 CTG estimates emissions assuming equilibrium at the temperature of a receiver (i.e., the equation uses a ratio of the condensables partial pressure to the noncondensables partial pressure at equilibrium). This procedure does not specify what equilibrium conditions should be used in the absence of a condenser. As the commenters noted, it underestimates emissions if the initial vessel temperature is used, and it overestimates the emissions if the final temperature is used. The overestimate becomes more significant when the final heatup temperature is close to the boiling point because the partial pressures ratio (condensables to noncondensables) increases exponentially with increasing temperature, and goes to infinity as the temperature approaches the boiling point. The EPA reevaluated the results for several situations and determined that, typically, the overestimate becomes unacceptable when the final heatup temperature is above the temperature 10 K below the boiling point of the material in the vessel. Therefore, if the final heatup temperature is 10 K below the boiling point or lower, the final rule allows the equation in the 1978 CTG to be used with any temperature between the initial and final temperatures; however, an average would give a better estimate than either extreme. If the final heatup temperature is above the temperature 10 K below the boiling point, the final rule requires the owner or operator to use the temperature 10 K below the boiling point in the equation, and the partial pressures must be calculated at that temperature.

The equation in the 1994 ACT uses the average of ratio of the initial and final partial pressures. This approach also overestimates emissions as the final heatup temperature approaches the boiling point. Therefore, the requirements in the final rule for using the 1994 ACT equation are similar to those for the 1978 CTG equation. If the final heatup temperature is 10 K below the boiling point or lower, the final rule allows the 1994 ACT equation to be used without modification. If the final heatup temperature is above the temperature 10 K below the boiling point, the final rule requires the owner or operator to use the temperature 10 K below the boiling point in the equation, and the partial pressures must be calculated at that temperature.

The final rule also includes the approach based on estimating emissions over temperature increments of 5 K, but the starting point was moved from 50 K below the boiling point to 10 K

below the boiling point. Thus, emissions must be calculated over either two increments or one, depending on the initial temperature. If the initial temperature is lower than 10 K below the boiling point, emissions must be calculated over two increments. The first is from the initial temperature to the temperature 10 K below the boiling point, and the second is from the temperature 10 K below the boiling point to the lower of either the final temperature or the temperature 5 K below the boiling point. If the initial temperature is higher than the temperature 10 K below the boiling point, the emissions are estimated over one temperature increment from the initial temperature to the lower of either the final temperature or the temperature 5 K below the boiling point. The EPA believes calculating emissions over the increments results in better emissions estimates than the 1978 CTG or 1994 ACT equations and encourages owners and operators to use this approach (or the algorithm described in a comment above).

Comment: One commenter (IV-D-29) stated that the procedures in § 63.1253(d)(2)(i)(C)(*3*) will underestimate emissions from byproducts produced by reaction, dissociated compounds, and compounds subject to Henry's Law; and they will overestimate emissions from vacuum systems. The commenter noted that the equations appear to be based on nondissociated VOC's and asked for clarification of their application to other HAP.

Response: The equations are not applicable to all emission episodes, and they may not be applicable in the situations listed by the commenter. If an owner or operator believes that the equations are not applicable, they should conduct an engineering assessment to demonstrate how to calculate the emissions.

12.1.3 Equations for Vapor Displacement

Comment: Two commenters (IV-D-15 and IV-D-17) stated that V in Equation 1 in the proposed rule should have units of volume per time.

Response: The equation is designed to calculate the total emissions from a displacement episode. Time is not specified in the equation because an owner or operator may estimate the total volume of gas displaced by any appropriate means. One approach, suggested by the commenters, is to multiply the volumetric flow rate of material transferred to the vessel by the length of time during which the transfer occurs. Another approach might be to determine initial and final levels in the vessel and calculate the change in volume based on vessel dimensions. Other methods would also be acceptable.

12.1.4 Equations for Vacuum Systems

Comment: Two commenters (IV-D-15 and IV-D-17) noted that procedures in the 1978 CTG and the 1994 ACT result in different emissions estimates because they use different air leakage equations.

Response: Equations to estimate air leakage rates were not specified in the proposed rule, and they are not specified in the final rule. Each owner or operator should determine the appropriate approach to estimate air leakage rates on a case-by-case basis.

12.1.5 Equations for Vacuum Drying

Comment: One commenter (IV-D-31) indicated the equations in the proposed rule and the 1978 CTG are identical, but the 1978 CTG limits the emissions to the amount of VOC in the original wet cake, whereas the proposed rule does not.

Response: The 1978 CTG does not limit the emissions to the amount of VOC in the original wet cake. The EPA also decided not to include procedures in the final rule for limiting emissions from vacuum drying. If the exhaust gas is not saturated, the owner or operator may conduct an engineering assessment to demonstrate that calculating emissions using the equation is not appropriate.

12.1.6 Equations for Air Drying and Gas Evolution

Comment: One commenter (IV-D-31) recommended including the equations from the 1978 CTG for air drying and gas evolution in the rule.

Response: The equations in the rule are not meant to cover all possible types of process vent emissions. However, because the rule will allow owners and operators to use the air drying and gas evolution procedures in the 1978 CTG, these procedures also were added to the final rule.

12.1.7 Equations for Depressurization (Evacuation)

Comment: Two commenters (IV-D-15 and IV-D-31) indicated that the equations in the proposed rule and the 1978 CTG give different results; Commenter IV-D-31 indicated the equation in the proposed rule usually gives the higher value. Two other commenters (IV-D-15 and IV-D-17) indicated that the differences are due to different averaging approaches.

Response: The two equations are based on different assumptions, but EPA believes both give acceptable estimates of the emissions from depressurization. Therefore, the final rule contains both equations.

12.2 METHODS TO CALCULATE HAP EMISSIONS FROM MULTICOMPONENT SYSTEMS

Comment: One commenter (IV-D-20) disputed the terminology used in § 63.1253(d)(2)(i) of the proposed rule. This commenter indicated that Raoult's law and Henry's law are vapor-liquid equilibrium relationships, not methodologies to calculate partial pressures. The commenter further explained that activity coefficients also are not used to calculate partial pressures, but serve as correction factors for nonideality in the liquid phase of a vapor-liquid system.

Response: The commenter is correct, but EPA also believes the language in the proposed rule is acceptable. The equations in the rule for estimating emissions from many of the unit operations include terms for the HAP partial pressure. The simplest approach to estimating these partial pressures is to assume the vapor and liquid phases are in equilibrium. Under certain system conditions, the equilibrium relationship is represented by Raoult's law or Henry's law. Thus, the practical result for the purposes of this rule is that Raoult's law and Henry's law are used to estimate partial pressures. Similarly, a vapor-liquid equilibrium relationship that includes an activity coefficient to correct for nonideality in the liquid phase is also used to calculate partial pressures.

Comment: Two commenters (IV-D-20 and IV-D-31) expressed concern about the procedures in the proposed rule for estimating emissions from multicomponent systems. The commenters concur with EPA that Raoult's law is appropriate for miscible systems. The commenters also acknowledged that use of Henry's law is generally more accurate than Raoult's law in predicting the vapor mole fraction for mixtures below the solubility limit. However, the commenters stated that using Henry's law is excessively difficult and unworkable because Henry's law constants have not been determined (and are often difficult to generate in a laboratory) for many of the solvents and reagents used in the pharmaceuticals industry. The commenters speculated that errors in estimating the Henry's law constants would probably yield inaccuracies comparable to the errors from applying Raoult's law to these mixtures. Commenter

IV-D-31 also stated that the use of equations based on Raoult's law will generally lead to higher emissions estimates than the use of Henry's law, thereby adding a safety margin to the estimate.

For multicomponent systems in which the compounds are not miscible or are only partially miscible, the commenters recommended using an approach in which each liquid phase is treated independently, and emissions from each phase are calculated separately. Commenter IV-D-31 explained that the recommended method is preferable because activity coefficients are difficult to estimate; to develop activity coefficients, experimental data over the entire range of compositions, temperatures, and pressures that could be encountered in the process would be needed. Two other commenters (IV-D-15 and IV-D-17) stated that the requirement to use experimentally obtained activity coefficients is unreasonable.

Response: The EPA reviewed the language in the proposed rule regarding vapor-liquid equilibrium relationships and determined that it is acceptable as is. Except when using the 1978 CTG equations, the final rule specifies that owners and operators assume one of four vapor-liquid equilibrium (VLE) relationships apply, depending on the system conditions. These relationships are: (1) Raoult's law, (2) Henry's law, (3) a VLE relationship based on the use of activity coefficients (obtained experimentally or from models) to correct for nonideality in the liquid phase, and (4) the assumption that components of the system behave independently so that the sum of all HAP vapor pressures is equal to the total HAP partial pressure. If the components are miscible in one another, Raoult's law must be used. However, if a miscible solution is not well characterized by Raoult's law, activity coefficients must be used. For dilute aqueous mixtures, Henry's law must be used. The EPA rejects the commenters argument to use Raoult's law because Henry's law constants are not available; Table I of Appendix C in 40 CFR 63 contains Henry's law constants at 25°C and 100°C for 125 of the most common organic HAP compounds. For other HAP compounds, the owner or operator must estimate the Henry's law constant. For systems with multiple liquid phases, the owner or operator may either use activity coefficients or, as suggested by the commenter, assume the components behave independently and assume the HAP vapor pressures and partial pressures are equal. When using the 1978 CTG equations, the final rule indicates that Raoult's law may be used in all situations.

12.3 EMISSION ESTIMATION EQUATIONS VERSUS ENGINEERING ASSESSMENTS

Status at proposal. Section 63.1253(d)(2)(iii) of the proposed rule listed two conditions under which the owner or operator could conduct an engineering assessment to show that the equations in the rule are not appropriate: (1) if available test data and the results of calculations using the equations differ by more than 20 percent or (2) if the owner or operator can demonstrate that the emission estimation equations are not appropriate for a given batch emissions episode.

Comment: Four commenters (IV-D-15, IV-D-17, IV-D-20, and IV-D-23) stated that both of the conditions under which use of the equations is considered inappropriate for estimating emissions should be deleted from the rule. Commenter IV-D-17 believes variability in analytical techniques likely exceeds 20 percent and, thus, it is unreasonable to disallow the use of equations if available test data show a greater than 20 percent discrepancy with calculated values. Commenter IV-D-23 requested that the first condition be revised to state that the use of the equations is inappropriate only if the test data show emissions to be more than 20 percent *higher than* the estimated values. The commenter's rationale for this request is that facilities may want to use a more conservative (i.e., higher) value so that small changes in purge rates or temperatures do not significantly affect the uncontrolled emissions estimate. Commenters IV-D-15 and IV-D-20 believe the requirement is unreasonable because the pharmaceutical industry does not test over a single batch emission episode and, thus, the results of the test will not be representative of emissions estimated by the equations.

Commenters IV-D-15, IV-D-17, and IV-D-20 believe the second condition is unreasonably restrictive and unduly burdensome on facilities because many of the operations in the pharmaceutical industry (e.g., fermentation, formulation, and extraction) are not described by the equations in the proposed rule. The commenters estimated that more than one quarter of the industry's operations would require a demonstration for each step in the process. The commenters also stated that this requirement would result in a tremendous burden on State permitting authorizes that must review the demonstrations.

Response: For the final rule, the engineering assessment provisions were rewritten to clarify EPA's intent. Batch emission episodes may be due to a unit operation that is described by an equation in the rule or to a unit operation that is not described by an equation in the rule.

Estimating emissions using the applicable equation is always the standard approach for emissions episodes that are covered by an equation. However, an owner or operator also always has the opportunity to conduct an engineering assessment to demonstrate and get approval to use another emission estimation technique. The intent of the first condition is to indicate that an owner or operator could include such a discrepancy between test data and calculations in an engineering assessment and it would be considered evidence that the equation is not appropriate. In this case, the rule does not disallow the use of the emission estimation equations, but such a difference in results would be justification for using a different approach to estimate emissions (provided, of course, that the permitting authority agrees that the test data were obtained under "representative conditions"). The purpose of the second condition is to indicate that other information may also be used in the engineering assessment as evidence that an equation is not appropriate. For example, if an owner or operator has developed or obtained an algorithm to represent how the contents of the vapor space change over time as a vessel containing one HAP is charged with material containing another HAP, the owner or operator may choose to conduct an engineering assessment to justify using the algorithm rather than the vapor displacement equation in the regulation. Again, the permitting authority would have to approve the use of any proposed alternative to the equation.

The conditions have nothing to do with estimating emissions for batch emissions episodes from unit operations that are not described by equations in the rule. For such emissions episodes, an owner or operator would be required to conduct an engineering assessment to show how emissions will be estimated. The owner or operator does not have to explain why the equations are not appropriate for estimating emissions from these unit operations.

12.4 CALCULATION OF CONTROLLED EMISSIONS

Comment: Two commenters (IV-D-20 and IV-D-31) stated that § 63.1253(d)(3) should be revised to allow use of techniques in the 1978 CTG when calculating controlled emissions from a condenser. The commenters stated that the procedures in the 1994 ACT (and by implication, the proposed rule) cannot be used because they specify the use of system temperature, whereas the correct technique, which is used in the 1978 CTG, is to use the exit gas temperature from the condenser. According to commenter IV-D-31, even when the equations in the 1978 CTG and the 1994 ACT are identical (e.g., for vapor displacement and vacuum

systems), controlled emissions estimates differ because of "implementation differences." The commenter states that the procedure in the 1978 CTG is to apply the gas exit temperature to calculate chemical vapor pressure, but under the 1994 ACT the procedure is to use the design HAP emission flow rate, HAP vapor temperature, and condenser type.

Response: The final rule retains the requirement from the proposed rule that owners and operators estimate controlled emissions from control devices that control less than 10 tons/yr using either a design evaluation or, if the control device is a condenser, emission estimation equations. However, the final rule clarifies the emission estimation requirements by including specific equations for eight categories of process vent emissions. Each equation is based on the ideal gas law using the receiver temperature and pressure. Except for heating, the equations use the same volumes that are used in estimating uncontrolled emissions; the heatup equation uses the moles of noncondensable gas that are used in the equation to calculate uncontrolled emissions. Calculated volumes and moles of noncondensable gases are multiplied by the ratio of HAP partial pressure to noncondensables partial pressure at the temperature of the receiver.

13.0 MONITORING

13.1 COMPLIANCE WITH PARAMETRIC LEVEL

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) object to the use of monitoring parameters for the determination of a source's compliance status on a continuous basis. The commenters maintain that, for many emission streams controlled in this industry (e.g., batch, nondedicated, possibly manifolded together and routed to common control), an exceedance of a parameter level, as measured on 15-minute intervals and averaged over a 24-hour basis, does not necessarily constitute a violation of the 93 percent control requirement for the process, on an annual basis.

The commenters also provided examples of situations in which an exceedance of a parameter would not necessarily involve a violation of MACT emission limits and cited the following generic situations where a parameter exceedance may not cause a violation of the applicable control efficiency standard:

1. The parameter is conservative, i.e., the control will operate with 93 percent efficiency even if the parameter is not attained;

2. The loading on the control device is less than the assumed loading used to set the parameter, so the control device provides 93 percent control efficiency even though the parameter has not been attained;

3. The actual compounds in the emission streams are easier to treat than those used to set the parameter; and

4. The excursion occurs when there are little or no HAP emissions from the process routed to the device.

The EPA has, in the proposed preamble, solicited comment on this issue, and in particular, has questioned why the industry cannot set multiple parametric levels for control devices to account for different operating scenarios. The commenters counter that, especially in

the case of manifolded, end-of-line devices, it is not possible to predict with precision what conditions will exist at any point in time. Rather than establishing, up-front, a complex "grid" of parameters that will serve all potential combinations of operating scenarios, they believe that conservative parametric levels could be set as a screening mechanism for determining whether or not emission limits might have been exceeded, with an option to evaluate actual parameter excursions on a case-by-case basis after they occur to determine whether an emission limit was actually exceeded.

The commenters recommend that the rule provide that a parameter exceedance must be reported to the permitting authority, with the opportunity to rebut the presumption that the emission limit(s) have been exceeded.

Another commenter (IV-D-07) does not agree with such after-the-fact justification of excursions. Two other commenters (IV-D-16, IV-D-14) have suggested that these sources be treated in a manner consistent with the Compliance Assurance Monitoring (CAM) rule. One of these commenters elaborated that an exceedance of a monitored parameter should not necessarily be considered an automatic violation, but that it must be reported and followed up with actual emission monitoring. Commenter (IV-D-14) stated that, should some sort of "rebuttable presumption" be allowed, the rule should provide specific guidance relative to the types of data required to demonstrate compliance to avoid each submittal becoming a "case study."

Response: It is the EPA's policy that new Part 63 rules, in particular those that require the use of a control device to reduce pollutant emissions, will include compliance determinations on two levels. First is the "traditional" performance test requirement that is based on the use of a specific test method over a set period of time and operating conditions. A performance test is generally conducted when the rule is effective (e.g., at facility startup or after an effective date for an existing facility) and may be repeated periodically thereafter. The results of the performance test are compared with an emission limitation (e.g., concentration, control efficiency, mass rate). The second element of the compliance determination in Part 63 rules is the continuous compliance obligation, which is implemented through monitoring.

In general, the EPA recognizes two basic approaches to monitoring. One method is to establish monitoring as a direct measure of continuous compliance. Under this continuous compliance monitoring approach, an enforceable value of the monitored parameter is defined and

measured. The Agency has adopted this approach in Part 63 standards, and is committed to following this approach whenever appropriate in future rulemakings. Another approach is to establish monitoring to provide a reasonable assurance of compliance by documenting continued proper operation of the control devices, indicating excursions from proper operation, and correcting the problems that cause excursions. This second approach is the basis of the CAM rule, which applies to sources that are not currently subject to Part 63 standards.

When determining appropriate continuous compliance monitoring options, EPA considers the availability and feasibility of the following monitoring strategies in a "top-down" fashion: (1) CEMS for the actual HAP emitted, (2) CEMS for HAP surrogates, (3) monitoring operating parameters, and (4) work practice standards. Thus, where available and feasible, the EPA specifies CEMS for the actual regulated compound(s) for continuous compliance monitoring. This option allows continuous compliance to be determined relative to the emission limit, just as short-term compliance is determined using a performance test. Where a CEMS for the regulated pollutant is not available or feasible, the EPA specifies monitoring a surrogate compound with a CEMS or monitoring an operating parameter that is critical to maintaining compliance performance. Only when these options are not feasible does EPA specify work practice standards as a means of ensuring continuous compliance.

When a Part 63 rule specifies a surrogate pollutant CEMS or parameter monitoring for demonstrating continuous compliance, the rule includes specific limitations and averaging times for these alternative situations. The surrogate pollutant or operating parameter limit becomes an enforceable limit for the rule. There is no requirement that an alternative limit, whether a surrogate pollutant or operational parameter, be statistically correlated with emissions or the compliance level of the regulated pollutant(s). The alternative limit is a separately enforceable requirement of the rule. The alternative limit is not secondary to the emission limit; rather, it is applied in lieu of a continuous emission limit obligation that would otherwise be measured with a CEMS.

The enforceable level for the surrogate pollutant or operating parameter may be based on measurements made during a performance test or other conditions specified by the Part 63 rule. In any case, the alternative limit ***becomes*** the continuous compliance obligation and fulfills the second compliance element for the rule.

In evaluating the use of CEMS in this standard, monitoring of individual HAP species was not found to be reasonable or technically feasible for many streams. However, in the case of continuous monitoring of surrogates, continuous TOC monitoring is considered a more viable monitoring option and is provided for in some instances in the rule. (See discussion on alternative standard and on monitoring for carbon bed systems.) Monitoring of control device operating parameters is considered appropriate for many other emission sources, and therefore, most of the other monitoring options provided in the final rule are based on parametric monitoring.

The EPA has considered the commenters' argument that an exceedance of a monitoring parameter is not necessarily an exceedance of an emission limit, especially as described in the generic situations provided in the comments. The Agency acknowledges that a parameter exceedance does not necessarily mean that the source has exceeded the emission limit. However, as discussed above, under the EPA's approach to continuous compliance in Part 63 rules, the continuous parameter monitoring limit is a separate requirement that is not rebuttable through contrast with actual or estimated HAP emission values. In addition, regarding the first three situations cited by the commenters, the EPA believes that given the flexibility the owner or operator has to select operating parameters, including the option retained from the proposed rule that allows the owner or operator to set multiple parameter levels for different operating conditions, the burden is on the source to remain within the operating limit defined for the parameter or parameters.

To address the potential disparity between parameter limit exceedances and emission limit exceedances, the final rule contains two different types of continuous compliance violations. Where a source is using a CEMS to monitor compliance with the 20 ppmv alternative standard, an exceedance is defined as a violation of the emission limit. Similarly, because the exit gas temperature of a condenser is so closely correlated with emissions, a condenser temperature exceedance is considered a violation of the emission limit. Exceedances of other types of parameter limits are defined as violations of an operating limit, rather than violations of the emission limit.

In response to industry's preference to evaluate emissions after an exceedance of a conservative parameter level to determine whether an emission limit was exceeded (thereby eliminating the need for a complex grid of preset parameter levels), EPA believes that the establishment of compliance levels ***prior*** to operation of the device or process is imperative; otherwise, the constant opportunity for rebutting a violation of the standard would render the standard unenforceable. While EPA is sensitive to industry's need to minimize the compliance burden, EPA believes that the burden placed on State agencies to consider the amount of information that the rebuttable presumption option would encourage is not reasonable.

In response to the fourth generic situation described by industry, EPA has provided clarification in the final rule of situations (no flow, or low flow) when exceedances of preset parameters would not constitute a violation of the emission standard or the operating parameter.

For reasons described above, EPA rejects the assertion that the parametric levels should not be used as a direct indicator of compliance. The EPA believes that conditions in the proposed rule that have been retained in the final rule, including options for setting parameters, coupled with clarifying the averaging times for compliance determinations and establishing valid data criteria for monitored parameters should address the commenters' concerns, while retaining the enforceability of the standard. The final rule provides options for pre-setting multiple parameter levels to account for variation in batch emission stream characteristics within emission sources (as proposed), and to account for variability in combined stream characteristics in manifolds.

The final rule provides owners and operators with the option of setting averaging times based on either a "block" of time suitable for the expected variations of emission stream characteristics from a batch process (determined by the owner or operator, with some restrictions), or a 24-hour basis (as proposed). Features of this option include:

1. Any exceedance of the "block" is a violation for every day (24-hour period) of the block;
2. Averages are based on 15-minute readings; and
3. Facility can opt for a mix of monitoring periods.

The option carries the following restrictions:

1. It will not be available for the alternative standard;

2. The facility cannot change monitoring options in mid-stream; and

3. The duration of the batch cannot be intermittent and must be established prior to the compliance period.

The final rule also provides owners and operators with an opportunity to verify compliance based on a review of operating logs during periods of exceedances. Exceedances will not constitute violations of Subpart GGG in the following situations:

1. During periods when a parameter has been set based on worst-case conditions, or other conditions that were not representative of the conditions in the device during the exceedance, if the owner or operator has predetermined other levels that ensure compliance with the standards for these representative periods; and

2. If predetermined levels have been established, the owner or operator can determine compliance for discrete streams in manifolds.

Additionally, monitored data obtained during periods in which no or low flow to the control device occur should not be considered valid; during such periods, data should be excluded from the averages. The use of a flow indicator to identify and exclude such periods from compliance average is required in the final rule, if they cannot otherwise be predicted.

This option carries the following restrictions:

1. It will not be available for the alternative standard (i.e., 20 ppmv; no parameter monitoring allowed); and

2. Owners and operators will not be allowed to develop new operating parameters "after the fact" using protocols;

13.2 INCLUSION OF MONITORING EQUIPMENT IN THE START-UP, SHUT-DOWN, AND MALFUNCTION PLAN

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that the start-up, shutdown, and malfunction plan developed pursuant to the General Provisions should clearly consider monitoring equipment, as well as process and control equipment. The commenter recommended that General Provisions 63.8(c)(4) and (7) be incorporated into this rule, and that recorded data should not be used in data averages or calculations, or to meet any data availability requirement when the data are recorded during out-

of-control periods, calibration checks, and zero (low-level) and high-level calibration drift adjustments.

Response: The EPA agrees with this comment and has clarified the provisions in the final rule related to the startup, shutdown, and malfunction plan. In addition, EPA has also included minimum QA/QC specifications and calibration requirements for parameter monitoring equipment that is not considered a continuous monitoring system (CMS) and cross-referenced the applicability of the general provisions 63.8 where applicable to monitors that are considered CMS, such as those used to demonstrate continuous compliance with the 20 ppmv alternative standard. These requirements will enable the owner or operator to establish the validity of the monitoring data.

13.3 EXEMPTIONS FROM MONITORING

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that devices controlling less than 10 tons/yr HAP emissions should not be subject to a requirement to take a measurement every 15 minutes. They maintain that daily measurement of a parameter is adequate for assuring compliance with the standard. Additionally, the commenters state that the rule should not require monitoring during batch episodes less than 15 minutes in duration. This provision is unworkable because of the number of short duration (less than 15-minute) batch emission episodes that could be routed to a single control device.

Additionally, several commenters suggest eliminating continuous (15-minute) monitoring provisions in the following situations:

1. For scrubber flow or carbon adsorption systems (IV-D-28);
2. For vents >1 ton/yr, before control, because it is too costly (IV-D-32); and
3. For process vents meeting the 2,000 lb/yr alternative (IV-D-20).

Response: The EPA believes that the requirement to take 15-minute readings for devices controlling at least 1 ton/yr HAP is not unreasonable. The cutoff for continuous monitoring was set at 1 ton/yr because EPA wanted to reduce the compliance burden on facilities with smaller control devices. The EPA also notes that, in light of concerns by commenters regarding the potential for being out of compliance with the standards based on parameter monitoring data, the suggestion to move from 96 15-minute readings (for a 24-hr averaging time) to one reading per

24 hours would place a significantly higher emphasis on the single reading for a compliance determination. Additionally, since emission stream characteristics in this industry are variable, the use of one single reading may not represent true conditions over the monitoring period

The EPA agrees with commenters suggesting that 1 reading per 15-minutes is the practical limit of monitoring frequency. Therefore, the final rule does not require monitoring during batch episodes less than 15-minutes in duration. The wording of the final rule requires an owner or operator to measure and record the parameter level at least every 15 minutes, during the period in which the control device "is functioning in achieving the required HAP removal." This means that one reading must be taken for every 15 minute period of continuous venting from any combination of emission episodes manifolded to the control device. Additionally, if the parameter level changes, at least one reading must be recorded, even if the monitoring period is less than 15-minutes. Thus, even when individual emission episodes are shorter than 15 minutes, one reading is required if venting occurs for at least 15 minutes due to overlapping or "contiguous" episodes. On the other hand, no monitoring would be required if each of the emission episodes that an owner or operator is controlling to comply with the rule lasts less than 15 minutes, the parameter level indicating compliance remains the same, and they are separated by periods of no flow or venting from vents that do not need to be controlled.

As a result of this change, the definition of a valid hour of data as used in the definition of an excursion also has been modified in the final rule. At proposal, monitoring data would not constitute a valid hour of data if measured values are unavailable for any of the 15-minute periods within the hour. For the final rule, the word *required* has been added before the phrase "15-minute period" to address the fact that less than four data points per hour may be allowed for some control devices.

The EPA does not agree that the continuous monitoring provision for scrubber liquid flow should be eliminated. Maintaining the established liquid flow rate is necessary to maintain performance. The final rule requires monitoring of scrubber liquid flow rate or pressure drop.

For regenerative carbon adsorption systems, the monitoring provision in the final rule allows an alternative to continuous monitoring of outlet HAP or TOC concentration; monitoring of the regeneration cycle characteristics based on absolute worst-case load in conjunction with an annual check for bed poisoning is allowed. For nonregenerative carbon adsorbers, the

monitoring provisions require establishing and monitoring the maximum time interval between replacements based on the conditions anticipated under absolute worst case.

The EPA does not agree with the suggestion that monitoring not be required for process vents in processes meeting the 2,000 lb/yr alternative. Because monitoring requirements are based on the amounts of HAP compounds entering the control devices (which may serve combinations of process vents and processes), not on the individual processes themselves, there is no direct relationship between processes that comply with the 2,000 lb/yr alternative and the devices that are used to achieve these levels.

13.4 CLARIFICATIONS

13.4.1 Clarify "Periodic Verification"

Comment: One commenter (IV-D-14) requested that the rule define what is meant by "periodic verification" that the device is working properly, per 63.1254 (b)(1) .

Response: The periodic verification described in the proposed rule is specified for devices that control less than 1 ton/yr HAP emissions. Per the final rule, the verification shall include, but not be limited to, a periodic verification that the device is "operating properly." This demonstration is based on the design evaluation conducted on the device. The method for determining what constitutes a valid periodic demonstration is meant to be flexible enough to allow sources discretion to propose methods to the Agency prior to the compliance date. For this reason, the selected periodic verification method is presented in the source's precompliance report, which is required to be submitted 1 year prior to the compliance date of the standard for Agency approval.

13.4.2 Clarify Monitoring Cutoffs

Comment: One commenter (IV-D-08) stated that it is not clear how the 10 tons/yr or the 1 tons/yr cutoffs for monitoring are applied.

Response: The proposed and final rules require that owners and operators estimate uncontrolled emissions from their processes prior to conducting performance tests and setting parametric monitoring levels. When evaluating what performance test and monitoring requirements apply to control devices, the emission estimates conducted for each process should be used to determine the total uncontrolled HAP emissions entering the respective devices.

Because the cutoffs are based on annual mass entering the device, the projected emissions should be based on permitted allowable production levels.

13.4.3 Clarify When Monitoring is Not Required

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) stated that the rule should clarify that no monitoring is required in the following cases :

1. For condensers, under no flow conditions (Commenter IV-D-28 recommended using a flowmeter);

2. For all devices, when no HAP emissions are occurring, or when a regulated process/tank is not venting to a control device (IV-G-01, IV-D-15); and

3. For all uncontrolled streams (IV-D-35, IV-D-20).

Response: In the discussion provided in Section 12.1 of this document, EPA has clarified instances when periods of monitoring data will not be used to determine compliance with the standards. These periods include periods of no flow to the control device. Secondly, this standard applies to emissions of HAP almost exclusively, except in cases where compliance is with the 20 ppmv TOC outlet emission limit. Therefore, it is EPA's intent that control devices not controlling HAP emissions for the purposes of this standard are not required be monitored.

The EPA's intent in the proposal also was not to require monitoring for uncontrolled emission streams. This intent was clarified in the final rule.

13.4.4 Clarify Combustion Chamber Monitoring Location

Comment: Commenter (IV-D-23) suggested that sections 63.1254(a)(7) and (b)(8) referring to the location of the combustion temperature measurement probe be clarified. The term "exiting" the combustion chamber could be at either the top or the bottom of the heat transfer packing. The commenter suggested that the term "combustion temperature average temperature" may be more useful.

Response: The EPA has in the past clarified that, for incinerator monitoring, the temperature monitoring device can be placed in the ductwork immediately downstream of the incinerator's firebox, or combustion chamber. (EPA-450/3-90-016b, Background Information for Promulgated Standards: Reactor Processes in the Synthetic Organic Chemical Manufacturing Industry).

13.5 MONITORING SPECIFIC TO CONTROL DEVICES

13.5.1 Carbon Adsorption Systems and Scrubbers

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04, IV-D-14, and IV-D-30) support EPA's provisions for carbon adsorption systems, which were placed in the docket during the public comment period. Other additional changes were suggested, as follows:

1. For nonregenerative carbon units, monitor carbon bed weight or time in service once per day for <10 tons/yr units and once per shift for >10 tons/yr units as an alternative.

2. For scrubbers using caustic solutions to remove acids (such as hydrochloric acid), pH in the scrubber effluent should be monitored along with scrubber liquid flowrate.

3. For <10 tons/yr scrubbers, measure scrubber flow rate daily. For >10 tons/yr units, measure scrubber flowrate every 15 minutes.

4. Also, "water" scrubbers should be changed to "liquid" scrubbers.

Response: The EPA disagrees with the first and third suggestions because, as stated in earlier discussions in this document, EPA has made an effort, in both the proposed rule and the final rule, to provide some relief from monitoring for smaller units, regardless of their type, by establishing the 1 ton/yr criterion for 15-minute monitoring. The EPA agrees with suggestions 2 and 4 and has made the required revisions to the final rule.

13.5.2 No Approval for Alternative Parameters

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) believe that the rule should not require Agency approval to establish parametric ranges or triggers at levels other than those measured during a performance test. Instead, these commenters believe that sources should simply be required to keep a record of the rationale used to establish the levels or ranges. Additionally, these commenters stated that for continuous processes, the rule should allow the establishment of parameters other than at the average of the levels achieved during a performance test, which would be consistent with the proposed rule's provisions for batch process vents.

These commenters also stated that, based on 63.1254(c), which provides two avenues for requesting approval of alternative parameters (General Provisions 63.8(f) or the precompliance report), most of the industry will choose to establish alternatives via the precompliance report,

because 63.8(f) is so limited in scope that it provides almost no opportunity to identify and implement such alternatives. Lastly, the commenters suggested that future requests for alternative monitoring be implemented via amendments to the precompliance report.

Response: The intent of requiring approval for parameters that are different than what would be arrived at during a performance test is to allow owners and operators the flexibility to set parameter monitoring levels that would ensure compliance without imposing higher control levels than what is required because of testing under worst-case conditions. The reason that this method requires approval is that there are no replicable protocols for arriving at such levels. While EPA has given sources the flexibility to set levels, EPA believes some mechanism should be available for reviewing agencies to review and approve such compliance measures. The request for alternative parameters is required to be submitted in the precompliance report. Secondly, EPA agrees that the option of setting parameters at levels other than those established in performance testing should be provided for continuous sources as well as batch sources, again provided there is opportunity for Agency review via the precompliance plan. This option was clarified in the final rule.

13.5.3 Suggestions for Alternative Parameters

Comment: The commenters also support the general concept of allowing alternative monitoring strategies, but suggested that more monitoring options be included in the rule. Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) recommended that the alternatives include the New Jersey "pick list" of standard permit conditions, which were included in the comments.

Commenter (IV-D-20) agrees that the alternatives suggested by EPA on page 15762 of the proposed rule federal register notice be included in the appropriate paragraph of 62.1254(a) and (b). Specifically, the commenter agrees that the following parameters are appropriate: (1) coolant temperature and flow for condensers (commenters IV-D-08 and IV-D-23 concur), (2) pressure drop and fluid composition for scrubbers, and (3) periodic vent testing and/or predetermined replacement for carbon.

In addition, the commenter recommends that 63.1254 (c) be amended to read:

"(c) the owner or operator may request approval to monitor parameters other than those required by paragraphs (a)(2) through (7) and (b)(4) through (8) by including the request in the precompliance report."

Regarding the measurement of condenser coolant flowrate, commenter IV-D-08 stated that setting the coolant temperature at a temperature arrived at through a proper engineering analysis is appropriate because monitoring the coolant temperature is more cost effective than installing outlet gas sensors, because the sensors would be subject to harsh service from chemical exposure and rigorous cleaning to meet FDA guidelines.

Commenter IV-D-23 added that for batch processes, where substantial continuous flow is absent, exit gas temperature measurements can be erroneous due to the effect of flow fluctuations. In order to correct these problems, a steady inert gas purge would have to be introduced in the inlet (thereby diluting the mixture somewhat and rendering the condenser less effective) to offset the convective heat gain from the ambient air to the temperature probe.

Response: The EPA believes that, while monitoring of coolant flow to ensure compliance with the standard may be a reasonable alternative for some systems, sources must demonstrate that the measurement of coolant temperature for each condenser system will achieve the required outlet gas temperature. This demonstration is expected to be made through appropriate heat transfer calculations and verified condenser (heat exchanger) system specifications (i.e. heat transfer coefficients, heat transfer areas) in addition to providing actual temperature measurements verifying the relationship between coolant temperatures and outlet gas temperatures. The EPA agrees that such a determination should be made available to the reviewing agency in the precompliance report.

In response to comments regarding the use of other parameters, EPA believes that sources have the flexibility to select other parameters, provided that they submit such requests in the precompliance report.

13.6 CONTROL DEVICE MAINTENANCE PROCEDURES

Comment: Two commenters (IV-D-08 and IV-D-23) commented on the proposed provisions for maintenance for control devices. Commenter IV-D-23 supported the inclusion of such provisions, but recommended that the provisions include maintenance of the piping, ductwork, or closed vent system that ducts emissions from the equipment to the control device

within the permitted 240 hours. The commenter further suggested that the provisions also include "unplanned, emergency" maintenance. Since closed vent systems and control device requirements are relevant to several additional sections of the rule, commenter IV-D-23 provided recommended language for revising 63.1252(g). One commenter (IV-D-08) stated that the standards for planned routine maintenance of control devices should include a provision which allows an extension of the 240 hours per year planned routine maintenance period.

Response: The proposed 240 hours per year for planned routine maintenance was mistakenly applied to all control devices in the proposed rule; however, it should only have been applied to storage tanks. The startup, shutdown, and malfunction provisions prohibit the shutdown of control devices during operation; however, EPA recognizes that for storage tanks, it is impossible to "not operate" (i.e., not have breathing losses) during a period of time in which an add-on control device would be undergoing planned maintenance. Therefore, EPA has in the final rule allowed an amount of time (240 hours per year, based on the duration of a typical degassing and cleaning of a tank) in which the control devices for storage tanks *only* can be nonoperational due to planned routine maintenance. All other situations that require unplanned, emergency maintenance should be addressed through the startup, shutdown, and malfunction provisions.

14.0 RECORDKEEPING REQUIREMENTS

14.1 GENERAL RECORDKEEPING REQUIREMENTS

Comment: Many commenters (IV-D-08, IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-D-40, IV-G-01, and IV-G-04) found the recordkeeping and reporting requirements in §§ 63.1255 and 63.1256 to be excessive. Most commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) felt that the record keeping and reporting requirements in §§ 63.1255 and 63.1256 plus those the Part 63 General Provisions should be simplified and substantially reduced. These commenters and commenter IV-D-08 said that the requirements should be streamlined to reduce paperwork burdens on the industry and to comply with the Paperwork Reduction Act of 1995. Commenter IV-D-40 also suggested substitutions for 15-minute monitoring, vent additions, etc.

Response: As noted in several related comments, the pharmaceutical manufacturing industry involves a wide variety of processes, products, and resulting emissions. In order to demonstrate compliance with the necessary MACT requirements, detailed records are needed to have a reliable, documented record of how the source complied with the regulation. The EPA has made a concerted effort to reduce the recordkeeping requirements of the final pharmaceutical rule. The EPA recognizes that unnecessary recordkeeping and reporting requirements would burden both the affected sources and EPA enforcement agencies.

The EPA reviewed the recordkeeping required by the proposed rule and has eliminated those areas where duplicative and inapplicable recordkeeping requirements were proposed. Most of these changes involved referenced General Provision requirements that are not directly relatable to this industry. Clarifications and/or additional language has been added to tailor the recordkeeping requirements to the relevant data needs from pharmaceutical manufacturing operations.

Comment: Commenter IV-D-35 suggested that sources be required to establish an effective environmental management system and monitoring and record keeping systems. These methods would not mandate 'command and control trivia' and would eliminate the current paperwork burden. The commenter discussed the following provisions and why they should be set aside: Sections 63.8, 63.9, 63.10.

Response: The EPA believes an effective environmental management system can be used to comply with all of the requirements of the final rule providing the system is based on meeting the MACT requirements in the final rule. Furthermore, an effective system should provide much, if not all, of the required recordkeeping and reporting information. Sources are free to submit an alternative compliance plan to the appropriate agency to review/approve in lieu of any or all recordkeeping/reporting/monitoring requirements.

Comment: Many commenters (IV-D-17/13/15/19/20/21/23/24/28/34/35/38, IV-G-01, and IV-G-04) reiterated the industry's great need for flexibility in processes and equipment and the desire to avoid costly and time-consuming Title V revisions. The commenters recommended updating compliance plans to indicate new regulated entities and/or new requirements resulting from a change. The commenters listed specific items to be included in the minor permit modification application, and also defined methods to be used by facilities that have not yet been issued a Title V permit or that trigger NSM requirements. Commenter IV-D-34 said that the Title V applicable requirements should be: to have a compliance plan, to update the plan when compliance requirements change, to submit the plan to the permitting authority, and to operate according to the plan. Sources should be required to obtain Title V permit revisions when sources first become subject to the rule or when affected sources trigger new source modification requirements. Commenter IV-D-15 offered slightly more detailed requirements for a compliance plan, timing specifics, and limits to the "process change". Commenter IV-D-16 requested more information on "process change".

Response: While it is important for sources to remain cognizant of how changes made to a process or control equipment may affect their title V operating permit, the Agency cannot include any such allowances in the final rule. The Clean Air Act mandates that EPA develop NESHAP for the pharmaceutical manufacturing industry and that the NESHAP be based on MACT. Title V requirements are likely to be different (i.e., HAP versus VOC) and trying to

streamline those requirements is beyond the scope of the NESHAP activities. However, within the scope of this NESHAP, EPA addressed management of change issues in the preamble to the final rule.

14.2 MULTIPLE VIOLATIONS

Comment: Five commenters (IV-D-15, IV-D-17, IV-D-28, IV-D-35, and IV-D-40) asserted that § 63.1255 (d) and (e) unfairly multiply violations. A violation should be considered a single violation regardless of the number of unit operations or the number of equipment items linked to the control device. Commenter IV-D-17 recommended that the violation should be one of a "MACT emission standard (not a parameter exceedance)." Commenter IV-D-28 made two recommendations concerning daily average control efficiency.

Response: The Agency does not agree with the commenters argument. Multiple violations are directly tied to the process basis of the regulation. However, EPA notes that the alternative standard provides a mechanism for the finding of only one violation per control device.

14.3 DATA AVAILABILITY

Comment: Two commenters (IV-D-31 and IV-D-35) raised issues related to data availability. Commenter IV-D-31 stated that the proposed requirements for data availability are unreasonable and impracticable and, therefore, must be revised. The commenter also stated that these requirements are more stringent than those for other industries and that the data availability provisions should cover "manual" recordkeeping as wall as "instrumental". Both commenters (IV-D-31 and IV-D-35) stated that § 63.1256(b)(2) may not always be possible for the pharmaceutical industry. Commenter IV-D-31 also said § 63.8(c)(4) of Part 63 (an exemption from certain data availability requirements) should be included in (rather than excluded from) the pharmaceutical MACT rule. Commenter IV-D-35 suggested adding "monitoring equipment" to § 63.8(e)(4) of Part 63 instead.

Response: The Agency does not agree with the commenters that the data requirements associated with monitoring excursions are more stringent than for other industries, nor are they unreasonable or impracticable. Data from existing pharmaceutical manufacturing facilities indicate that similar requirements are being used successfully and are being complied with readily.

15.0 REPORTING REQUIREMENTS

15.1 NOTIFICATION OF COMPLIANCE STATUS REPORT

Comment: Commenter IV-D-17 indicated that the requirements for the Notification of Compliance Status report listed in § 63.1256 (a)(1) duplicate most of the requirements listed in the General Provisions (§ 63.9 (h)) and request some additional information. The commenter requested clarification of the overlap and suggested two possible resolutions. His first choice, and that of Commenter IV-D-23, was that EPA "establish all of the requirements of the Notification of Compliance Status in § 63.1256 and clearly state the requirements under § 63.9(h) are superseded." Commenter IV-D-23 objected to the requirement for Initial Notification and would like it deleted. The commenter said, "at a minimum, EPA should eliminate Section 63.9(b)(2)(iv)." and that the information required for the Precompliance Report under § 63.1256 (a)(2) should be trimmed significantly. Commenter IV-D-08 joined commenters IV-D-17 and IV-D-23 in stating that many of the reporting requirements "impose undue and onerous restrictions upon the [needed] flexibility" of the industry. He also asked for changes to precompliance reporting (§ 63.1256 (a)(2)(iii)). Commenter IV-D-27 asked that reporting requirements be added to substantiate compliance with the pollution prevention alternative. The same commenter suggested that, in addition to the requirements listed in § 63.1256 (a)(1), two specific guidelines be added, the baseline year be changed to 1990, and EPA develop guidance and case studies on the pollution prevention alternative.

Response: The Agency reviewed all of the recordkeeping and reporting requirements identified in the proposed rule, including the requirements associated with the Notification of Compliance Status report and those similar requirements in the General Provisions. The Agency agrees that the requirements cited by commenters II-D-17 and IV-D-23 were duplicative and has eliminated those from the final rule. With regard to the comment involving the pollution prevention alternative, the Agency has changed the basis of the baseline factor to a 3-year

average (see discussion under P2 alternative) and has included more language clarifying how owners and operators can demonstrate compliance with the P2 standard (P2 demonstration summary).

15.2 PROCESS CHANGES

Comment: Commenters IV-D-17, IV-D-15, and IV-D-34 requested that the reference to the definition of process change in § 63.1256(b)(3) be deleted because the associated examples are confusing. The commenters suggested that process changes should be managed following the "expedited procedures for management of change, as noted above." Commenter IV-D-08 also requested reducing the requirements in relation to process changes.

Response: The EPA has clarified the language for making process changes in the final rule. Additionally, management of change is addressed in the preamble to the final rule.

Comment: Commenters IV-D-15 and IV-D-28 proposed specific amount changes to the emission rate increases from process changes that trigger reporting. Commenter IV-D-28 suggested that the increase of 1 lb/yr in § 63.1256 (b)(3) be changed to 1,000 lb/yr. The same commenter also suggested examples of trigger requirements. Commenter IV-D-15 listed four desired changes including "a 'significant' increase in actual emissions, i.e., 10 tons/yr of a single HAP." Commenter IV-D-07 asked that the rule define a "process change as one that causes the emission rate ... to increase by a specific amount per year."

Response: The EPA has deleted the process change trigger of 1 lb/yr and has clarified the language for making process changes in the final rule.

15.3 FREQUENCY OF EXCESS EMISSIONS REPORTING

Comment: Three commenters (IV-D-17, IV-D-20, and IV-D-34) suggested that "semiannually" be substituted for "quarterly" in § 63.1256 (b), thereby Subpart GGG would become consistent with Part 63 of the General Provisions. Commenter IV-D-17 also suggested that a decreasing frequency of reporting be allowed as in the General Provisions.

Response: The final rule clarifies that reports shall be submitted on a schedule consistent with the General Provisions.

15.4 PRECOMPLIANCE REPORTING OR COMPLIANCE DATES

Comment: Several commenters (IV-D-08, IV-D-19, IV-D-23, and IV-G-01) raised concerns with the precompliance reporting requirements. Commenter IV-G-01 stated that

submittal dates for reports and notifications due prior to compliance are much too early and that these early dates are unnecessary and can be counterproductive. The responsibility for gaining agency approval before the compliance date and for submitting early in complicated cases should belong to the source. Commenters IV-G-01 and IV-D-23 said that § 63.1256 (a)(2) should require the Precompliance Report only 3 months prior to the compliance date, not with the application for construction (which might occur 3 to 5 years before startup). Commenter IV-D-23 said that § 63.1256 (a)(2)(iii) should be covered in the pretest notification rather than the Precompliance Report. Commenters IV-D-08 and IV-D-23 said that the precompliance reporting requirements in § 63.1256 (a)(2) are burdensome and restrictive and they should be streamlined. Commenter IV-D-23 suggested that the precompliance report be submitted at the option of the source and that it include only information that involves alternatives not explicitly detailed in the rule itself. Commenter IV-D-19 requested that the EPA explain the purposes of the precompliance report required in § 63.1254 (b)(1) and identify all the items it should include. Two commenters (IV-D-07 and IV-D-16) provided input regarding precompliance reports. Commenter IV-D-07 requested that "owners and operators give prior notification of the use of alternative parameters in the precompliance report." This commenter also suggested that periodic testing be done to correlate actual emission rates to alternative parameters. Commenter IV-D-16 said that the due date for the precompliance report is valuable because it "provides a practical means of ensuring that a source is aware of the upcoming deadline."

Response: The Agency reviewed the submittal dates and data requirements for the reports due prior to the compliance date and found them to be consistent with those required for other similar chemical manufacturing industries. However, EPA did reduce the submittal dates for both the precompliance report and the emissions averaging implementation plan to 6 months prior to the compliance date. Also, the Agency extended the period of time for which to approve or disapprove the plans from 60 days to 90 days. As noted by commenters IV-D-07 and IV-D-16, early notification of a source's intent to use alternative parameters is a valuable asset to an enforcement agency and the affected source. However, the Agency is confident that the 90 day period of approval or disapproval, coupled with shorter submittal time frames prior to the compliance date will allow owners and operators and the enforcement agency ample time to

review and approve of compliance plans. The final rule is also more specific in the items required in the precompliance report.

15.5 GENERAL COMMENTS ON REPORTING REQUIREMENTS

Comment: Commenter IV-D-28 requested simplification of the reporting requirements in § 63.1253 (g) for planned maintenance. The commenter believes that sources should be required to report only the time periods set aside for planned routine maintenance and the tasks anticipated. Commenter IV-D-23 requested that § 63.1255 (b)(4) be deleted because it is unnecessary for compliance with these reporting requirements.

Response: The reporting requirements involving routine maintenance include the date and time when routine maintenance occurred and the control device did not meet the applicable specification to allow the enforcement personnel to review the relevant emissions data and compare the maintenance times with relevant parameter monitoring. No technical justification was provided by the commenter as to why the reporting requirement should be eliminated. The EPA believes that these provisions are necessary for proper enforcement of the standard and has retained them in the final rule.

Comment: Two commenters (IV-D-16 and IV-D-27) recommended that the regulation clearly explain that the Quarterly Monitoring Reports to update equipment information (§ 63.1256 (b)(3)) "should only be used for minor or administrative updates. Otherwise, a permitting authority may not be aware of a significant change."

Response: The EPA believes the final language is clear on this point and that sources will respond appropriately.

Comment: Commenter IV-D-28 said that "tank turnovers" in § 63.1255 (b)(5) is unclear and is important for major source facilities because the solvent storage tanks are never emptied. The commenter suggested the following definition: tank volume by January 1; add gallons delivered since January 1; divide the total by the tank capacity; the result is the number of tank turnovers to the date of the exercise.

Response: The EPA agrees with the commenter's interpretation of the term "turnover." However, this term has not been defined in the final rule. Because this term is used extensively in EPA guidance documents, the EPA believes that it is familiar to the regulated community.

16.0 ALTERNATIVE STANDARD

Comment: Numerous commenters (IV-D-17, IV-D-12, IV-G-01, IV-D-24, IV-D-40, IV-D-15, IV-D-13, IV-D-23, IV-D-35, IV-D-20) expressed interest in EPA developing an alternative standard for facilities that aggregate uncontrolled emissions and treat them with common control devices. The need for such an alternative standard is based on the complicated compliance determination, reporting, and recordkeeping requirements imposed by the proposed rule, which is process-based. The commenters state that the rule as written provides a disincentive for aggregating vents to a common dedicated control system. Therefore, an alternative standard has been proposed by the commenters. This aggregate control alternative would be available in circumstances when emissions from more than one "regulated entity" are manifolded together and would treat all emissions vented to the common device under the aggregate alternative standard. Nonmanifolded vents would be treated as otherwise specified in the proposed rule. The alternative proposed by the commenters allows for different control devices, but also provides that incineration technology be used as reference control technology, meaning that, if the incinerator met certain criteria, it would automatically qualify as an acceptable device for the aggregate control alternative.

Response: The EPA agrees with the commenters that an alternative standard for common control of multiple processes (i.e., process vents) would simplify the rule for some of the facilities utilizing control devices such as thermal oxidizers. Therefore, EPA included an alternative standard in the final rule for those sources opting to manifold multiple process vents to a common control device. Such sources can opt to meet the alternative standard in § 63.1252(c)(3) which requires the control device to achieve an TOC or hydrogen halide concentration of 20 ppmv or less. The calibration of the outlet monitor is to be based on the predominant HAP in the inlet/outlet stream or methane as the calibration gas for TOC. Any facility considering such a control strategy should also note that any process vents not

manifolded to the common control device must still achieve 93 percent control for existing sources and 98 percent control for new sources.

17.0 WASTEWATER

17.1 DEFINITIONS

Comment: One commenter (IV-D-17) recommended defining the following 11 phrases in the MACT rule: average concentration, automated monitoring and recording systems, closed biological treatment process, continuous record, continuous recorder, control device, enhanced biological treatment system, open biological treatment process, reference control technology for wastewater, sewer line, and wastewater stream. These phrases are used in sections of the HON that are referenced in the MACT rule.

Response: All of the phrases except reference control technology are defined in § 63.1251of the final rule; sewer line also was defined in the proposed rule. The definitions for all of the phrases except wastewater stream are the same as their definitions in § 63.111. Wastewater stream is defined as water that contains an average concentration of partially soluble and/or soluble HAP compounds of at least 5 ppmw and a load of at least 0.05 kg/yr, that is discarded from a PMPU, and that is not exempted from the provisions of subpart GGG. Wastewater is a general term that refers to any individual wastewater stream or aggregated wastewater stream. The pharmaceuticals standard does not include a reference control technology option; thus sections of the HON that are used in this rule were modified by eliminating the term reference control technology. The final rule also uses the term annual average concentration, which is defined accordingly.

Comment: One commenter (IV-D-32) recommended that the definition of wastewater be revised to avoid a misinterpretation that the requirements apply to streams before the associated recovery operation. Similar revisions were made in the HON by redefining "chemical manufacturing process unit."

Response: The EPA agrees with the commenter that streams before associated recovery devices are not to be considered wastewater. With changes in the definition of two terms in the rule, the EPA believes this point is clear. The phrase "waste management units"was removed from the definition of PMPU, and, in the definition of "wastewater," the phrase "discarded from equipment that is part of the affected source"was replaced with "discarded from a PMPU." With these changes, the rule states that water is not wastewater until it is discarded from a PMPU. The rule also states that nondedicated recovery operations are processes themselves, while recovery devices associated only with one process are part of that process, which in turn is part of a PMPU. Thus, the discharge from a recovery device, which is discarded from a PMPU, is considered to be wastewater; water upstream of a recovery device is within a PMPU, and thus it is not wastewater.

Comment: One commenter (IV-D-10) contended that hoses should not be regulated as "containers." In the definition for "container," hoses are listed as an example of a container. The commenter disagreed with this classification because the regulatory requirements for containers, such as tightly-fitting solid covers, are not appropriate for hoses.

Response: The EPA agrees with the commenter. "Hoses" were deleted from the list of examples of containers.

Comment: One commenter (IV-D-08) requested clarification of the definition of "point of determination." The commenter questioned whether each wastewater stream exiting a piece of equipment during a process must be evaluated as a POD or whether all wastewater streams from a single process, or from all processes in a building, may be theoretically combined to form one POD. The commenter argued that if each wastewater stream exiting a piece of equipment is considered a POD, the number of POD's at a facility could be very large. Substantial resources would, therefore, be required to evaluate HAP concentrations in the streams. The commenter estimated that at one of their facilities, there are 2,800 points where wastewater exits a piece of equipment and is discharged to the sewer system.

Response: A POD is defined as the point at which wastewater is discharged from a PMPU. If soluble and/or partially soluble HAP compounds are not recovered from water before discharge, each discharge point from process equipment and storage tanks is a POD. If one or more water streams are routed to a recovery device, only the discharge from the recovery device

is a POD. Any other combination of streams, such as streams from all processes in a building, may not be combined to create a single POD. Although some facilities, especially those with many processes and few recovery devices, may have a large number of POD's, the EPA believes it is important to identify high concentration and high load streams that are amenable to control prior to opportunities for losses due to emissions to the atmosphere, prior to dilution with other wastewater streams, and prior to partial treatment of the wastewater stream. If dilution or partial treatment prior to a control determination were allowed, some wastewater streams that would have required control based on the concentration criteria would not meet the requirement for control and would therefore not be treated. However, to mitigate the burden of evaluating every wastewater stream, the rule also allows an owner or operator to designate wastewater streams as affected wastewater. These designated streams could be combined before control, and only the characteristics of the aggregated stream would need to be determined (but the concentration compliance option could not be used with designated streams).

17.2 APPLICABILITY CUTOFF

Comment: One commenter (IV-D-09) expressed two concerns with the applicability threshold requirement of 1 Mg/yr in § 63.1252(d)(1)(iii). First, the commenter believes that the regulation of wastewater should be specific to the source category generating the wastewater, not based on the total wastewater from the facility. The commenter pointed out that, in a similar requirement in the HON, the 1 Mg/yr threshold was applied to the sum of all chemical manufacturing process units subject to the HON, not the entire facility. Second, the commenter described a situation in which one pharmaceutical manufacturer leases buildings to other companies that will likely be subject to this rule. The commenter is concerned that the company leasing space could discharge to the wastewater treatment system of the other company, thereby forcing regulatory requirements on the other company and gaining a competitive advantage.

Response: The language in the rule was modified to clarify that the discharge of 1 Mg/yr of soluble and/or partially soluble HAP in the total yearly volume of all wastewaters generated applies only to wastewater from the affected source. This was EPA's original intent.

The final rule clarifies provisions regarding offsite treatment and onsite treatment not owned or operated by the source. These provisions specify that an owner or operator may not transfer wastewater or residuals unless the transferee has submitted to the EPA a written

certification that the transferee will manage and treat any wastewater and residuals in accordance with the wastewater provisions in the rule. The EPA assumes manufacturers that agree to treat wastewater from other manufacturers that lease buildings on the leasors property will establish lease rates that reflect the cost to treat that wastewater. The EPA also assumes a leasee will ensure that the leasor will treat the leasees wastewater before signing the lease. Thus, EPA does not believe the rule provides a competitive advantage to either party.

17.3 EXEMPTIONS

Comment: Several commenters (IV-D-02, IV-D-17, IV-D-19, and IV-D-32) requested that the list of exempt wastewater in proposed Section 63.1252(d)(2) be expanded to include other wastewater streams that are insignificant sources of HAP. The combined list of additional exemptions recommended by the commenters is as follows: laboratory wastewater; sample purges; leaks from well-maintained pump packings and seals; relief device discharge; minor leaks in addition to "spills"; losses from normal material handling operations; discharges from safety showers; rinsate from personal safety equipment; wastewater discharged to an underground injection well; repair and maintenance wastewater; rinsate from empty containers; startup and shutdown wastewater: and wastewater generated as a result of emergencies and process malfunctions.

Response: Because EPA can not address every example of wastewater generated at a facility through a specific exemption or non-exemption, the agency cautions the commenters to rely on the *de miminis* level for deciding what streams to consider. However, some situations presented by the commenters have been addressed below. Wastewater from laboratories has not specifically been exempted. Leaks from pump seals are addressed in Appendix A; they are not wastewater. Leaks not covered by the equipment leak provisions, and losses from normal material handling operations, would be considered spills. Discharges from safety showers were exempted in the proposed rule and will continue to be exempted. Rinsate from personal safety equipment may be similar to wastewater from safety showers. Wastewater discharged to an underground injection well will not be exempted, but discharge to a permitted underground injection well will be allowed as a treatment option (see the response to comment 7 in Section 18.11). Maintenance (or repair) wastewater is not exempted because of its high potential for emissions. Rinsate from empty containers would be considered maintenance wastewater and

thus will not be exempted. Wastewater from startup, shutdown, and malfunctions (or emergencies) is not exempted. However, the wastewater provisions will not apply to startup, shutdown, or malfunction wastewater from a particular emission point if (1) the startup, shutdown or malfunction precludes the ability of that emission point to comply with the wastewater provisions and (2) the owner or operator follows the provisions in the startup, shutdown, and malfunction plan.

17.4 GENERAL REQUIREMENTS FOR WASTE MANAGEMENT UNITS

Comment: One commenter (IV-D-17) requested that provisions to allow the use of pressure relief valves on waste management units be included in the MACT rule. The commenter explained that a pressure relief valve is needed because of the potential for over pressurization of waste management units under certain situations such as fire, gas generation due to microbial activity, failure in a nitrogen blanketing system, the presence of extremely volatile material, and failure of a transfer pump shut off. The commenter noted that provisions allowing pressure relief valves are included in the HON under Section 63.132(b)(3)(I)(A) and (B).

Response: The EPA agrees that, in some situations, a vessel must relieve in the event of an unplanned, emergency event to prevent physical damage. Therefore, the final rule incorporates language allowing for such safety devices (see definitions). However, the rule specifically states that routine venting is not allowed from such devices.

17.5 REQUIREMENTS FOR WASTEWATER TANKS

Comment: Three commenters (IV-D-08, IV-D-17, and IV-D-24) requested clarification of the statement in Section 63.1252(d)(3) that addresses wastewater tanks. The statement reads "... tanks for which it can be demonstrated that less than 5 percent of the total soluble and/or partially soluble HAP is emitted from a wastewater tank described in Section 63.133(a)(1), in addition to a tank with surface agitation, be equipped with a fixed roof."

One commenter (IV-D-08) asked if this statement overrides the requirement of Section 63.133(a)(1) which requires a fixed roof and a closed-vent system for wastewater tanks used for mixing. This commenter also asked (1) if the term "surface agitation," which is not defined in the proposal, is equivalent to mixing and (2) whether the 5 percent of the total HAP measurement is based on influent concentration or mass.

Because of the redundancy in Section 63.1252(d)(3) statement with the requirement in the HON that all tanks must be covered, the other two commenters (IV-D-17 and IV-D-24) questioned whether it was EPA's intent to exempt wastewater tanks that meet the less than 5 percent HAP criteria from the fixed roof requirement. These two commenters requested that EPA allow the use of uncovered tanks for the storage of wastewater if less than 5 percent of the total HAP in the wastewater is emitted to the air.

Response: This section was revised to clarify EPA's intent, which is to provide an alternative means of demonstrating compliance for tanks otherwise subject to control requirements under § 63.133(a)(1). Section 63.133(a) specifies that, at a minimum, all wastewater tanks must have a fixed roof, and some wastewater tanks must also have controls such as floating roofs, closed-vent systems and a control device, or the equivalent. Section 63.133(a)(1) specifies that tanks otherwise meeting the size and vapor pressure requirements to use only a fixed roof must also add controls if the contents of the tank are heated, treated by means of an exothermic reaction, or sparged. The intent of the statement in § 63.1252(d)(3) is to indicate that operating and maintaining a fixed roof satisfies the control requirements in § 63.133(a)(2) for subject tanks if the owner or operator demonstrates that the total soluble and/or partially soluble HAP emissions from the tank are no more than 5 percent higher than emissions of the same compounds would be if the contents of the tank were not heated, treated with an exothermic reaction, or sparged.

17.6 REQUIREMENTS FOR INDIVIDUAL DRAIN SYSTEMS

Comment: One commenter (IV-D-08) asked if the requirements of Section 63.136 of the HON are applicable to individual drain systems during those times when no affected wastewaters are discharged to a particular drain system. The commenter pointed out that it is possible that an affected wastewater may be discharged to a drain system only once per year. The commenter expressed specific concern with the inspection requirements. The commenter stated that the individual drain system requirements are burdensome and not cost effective.

Response: The EPA believes it is important to suppress emissions from individual drain systems that receive or manage an affected wastewater (or residual). Therefore, the final rule retains the requirement that these individual drain systems be either covered and vented through a closed-vent system to a control device or equipped with a water seal or tight-fitting cap or plug.

Additionally, these controls must be visually inspected semiannually. The EPA disagrees that this inspection is burdensome; it is simply good operating practice. If an owner or operator believes the quantity of affected wastewater to be conveyed does not justify the suppression requirements, alternative means of transferring the small amount of affected wastewater (e.g., containers) would be acceptable under the rule.

Comment: One commenter (IV-D-08) stated that 15 calendar days is generally not enough time to complete a typical sewer repair.

Response: It is not clear what the commenter considers to be a typical sewer repair. However, the EPA believes 15 days to repair gaps, cracks, or holes in covers, plugs, caps, vapor collection systems, control equipment, improper work practices, and unburied sections of sewer line is reasonable in most situations. Furthermore, the rule allows for delay of repair if: (1) repair is infeasible without a shutdown, (2) purging material from the equipment for immediate repair would result in greater emissions than the delay, (3) the equipment is no longer used to treat affected wastewater, or (4) if parts are unavailable in the 15-day timeframe due to circumstances beyond the control of the owner or operator. Thus, the time allowed to complete repairs will remain at 15 calendar days.

Comment: Four commenters (IV-D-08, IV-D-17, IV-D-19, and IV-D-24) stated that the provision in the enhanced biological treatment option requiring indirect dischargers to demonstrate that soluble HAP emissions from wastewater collection systems leading to a POTW are less than 5 percent of the soluble HAP in the wastewater from the POD's is unnecessary and burdensome. The commenters referred to PhRMA studies that were cited in the Basis and Purpose Document as evidence that emissions from all but "totally open" collection systems would be less than 5 percent. Two commenters (IV-D-17 and IV-D-24) pointed out that these studies showed methanol volatilization from sewers is 6 percent for worst-case, totally open systems and typically less than 0.5 percent for closed reaches and drop systems. Based on the results of these studies, three commenters (IV-D-17, IV-D-19, and IV-D-24) recommended that an engineering study be required only for those facilities that discharge soluble HAP to a POTW with a totally open collection system with "design features that would facilitate volatilization losses." The other commenter (IV-D-08) noted that the proposed rule did not describe how facilities were to demonstrate the emission levels.

Response: The intent of the requirement is to ensure that emissions from collection systems are suppressed when the enhanced biotreatment option is selected. The EPA reexamined municipal sewer systems and determined that the primary potential for emissions occurs at the headworks (the term "headworks" in the final rule has been replaced with "waste management units up to the activated sludge unit"). Thus, the final rule will indicate that no demonstration is necessary if the headworks is covered. Otherwise, the owner or operator will need to demonstrate that emissions of soluble HAP from the waste management units up to the activated sludge unit do not exceed 5 percent of the total HAP in the wastewater entering the units. For either scenario, waste management units at the facility must comply with the emission suppression requirements.

Comment: Three commenters (IV-D-17, IV-D-24, and IV-D-32) requested that EPA exclude individual drain systems from the requirements of § 63.136, and allow such drain systems to be vented to the atmosphere, if they manage wastewater that contains only soluble HAP compounds and de minimis amounts of partially soluble HAP compounds. For these provisions to apply, one commenter (IV-D-24) added the condition that the partially soluble HAP concentration be less than 50 mg/L, and two commenters (IV-D-17 and IV-D-24) recommended that the owner or operator demonstrate total HAP emissions from the individual drain system and any associated wastewater tanks be less than 5 percent of the total HAP in the wastewater The commenters requested the changes because they believe the potential for soluble HAP emissions from individual drain systems is low; one commenter (IV-D-17) cited PhRMA's municipal sewer study described in comment 3 of this section as support for this position. One commenter (IV-D-32) also stated that the cost of converting existing individual drain systems to meet the proposed requirements would be prohibitive. This commenter also predicted that sources would switch from biological treatment to steam stripping and/or incineration, which would result in a net increase of combustion product emissions.

Response: As discussed in the response to comment 3 in this section, losses from the collection system must be minimized to ensure compliance with the standard. Thus, the requirements in the final rule are the same as those in the proposed rule.

17.7 DE MINIMIS THRESHOLD

Comment: One commenter (IV-D-10) requested that the definition of wastewater be revised, as in the HON, to include a de minimis HAP concentration and flowrate, below which an aqueous stream is not considered "wastewater." The commenter contended that if the definition is not revised, the rule will impose unnecessary burdens, such as requiring the characterization of wastewater streams that have very small annual HAP loadings and potentially additional recordkeeping and reporting activities.

Response: The EPA reevaluated the definition of wastewater and determined that including a de minimis would be reasonable. Under the final rule, wastewater is defined as water that contains an average concentration of partially soluble and/or soluble HAP compounds of at least 5 ppmw, has an annual load of at least 0.05 kg/yr, and is discarded from a PMPU. A flowrate cutoff is not considered to be appropriate because of the short term nature and fluctuation of many discharges.

17.8 ANALYTICAL METHODS

Comment: One commenter (IV-D-17) stated that the methodology for conducting the wastewater analysis (Section 63.1253(b)(9)) for determining speciated and total HAP concentrations contains errors, is hard to follow, and should be rewritten.

The commenter pointed out that the introduction to Section 63.1253(b)(9) does not reference Section 63.1253(b)(9)(iii), which specifies that the Clean Water Act analytical methods Nos. 624, 625, 1624, 1625, and 8270 may be used to measure HAP concentration in wastewater. In addition, the commenter noted that Section 63.1253 (b)(9)(i) is not a method of analysis, but rather specifies how to perform calculations for determining speciated and total HAP concentrations.

The commenter also indicated that the equation in Section 63.1253(b)(9)(i)(A) for calculating aqueous phase concentrations of speciated HAP from purge gas concentrations is used improperly. The commenter explained that calculating the aqueous phase concentration from the purge gas concentration is unnecessary when CWA analytical methods are used because these methods already provide aqueous phase organic HAP concentrations. Furthermore, the commenter noted that, under the HON, the aqueous phase HAP concentrations from CWA methods may be used directly, and use of the equation is specifically prohibited, except when

data are collected using Method 305. Therefore, the commenter recommended that the rule only require use of the equation with data from Method 305.

To correct the errors discussed above, the commenter suggested replacing the introductory sentence of Section 63.1253(b)(9) with the following:

> "Wastewater analysis shall be conducted in accordance with paragraph (b)(9)(ii) or (b)(9)(iii) of this section. Wastewater concentrations of HAP measured using the methods specified in paragraph (b)(9)(ii) shall be calculated from the analytical results using the equation presented in paragraph (b)(9)(i)(A). Total HAP concentrations shall be calculated using the equation in paragraph (b)(9)(i)(B)."

Response: The EPA agrees with the commenter that § 63.1253(b)(9) of the proposed rule contains errors that need to be corrected. The final rule clarifies that the CWA methods may be used to measure HAP concentrations in wastewater. In addition, the equation was removed from the rule, as was done in the HON.

17.9 MACT FLOOR AND MACT

Comment: One commenter (IV-D-32) disagreed with EPA's determination of the MACT floor for wastewater at existing sources. The commenter pointed out that EPA identified 101 major sources and that there are many other sources that would be affected by the regulation if the applicability section is not modified. Therefore, the MACT floor determination of 54 percent control would change if EPA included all facilities affected by the regulation under the proposed applicability section.

Response: Applicability is clarified in section 3.1 of this document. The EPA believes these clarifications eliminate the likelihood that the rule would apply to types of facilities other than the types represented in the 101 in the initial analysis. Therefore, the MACT floor would not change.

Comment: One commenter (IV-D-17) requested that EPA lower the level of control for vented waste management units from 95 percent to 93 percent because of the following two considerations: (1) the level of control has been transferred from the HON without justification, and (2) the 95 percent level exceeds the 93 percent level of control for process vents, which may preclude facilities from economically using manifolded vent control systems for process and wastewater vents.

Response: MACT for process vents is based on an overall control of 93 percent on a process bases, which includes a mix of vents controlled to levels above 93 percent and others controlled to lower levels or uncontrolled. Thus, manifolded wastewater and process vents are likely to be controlled with a device that is at least 95 percent efficient. In determining MACT for wastewater sources, EPA considered the reductions in HAP emissions associated with treatment systems, as well as the control achieved by suppression of vented HAP vapors. The final rule requires owners and operators to demonstrate 93 percent for process vents and 95 percent for vented wastewater management units. Also, if HAPs are water-scrubbed from a process vent, the facility must demonstrate compliance for both the vent standards and the wastewater standards.

17.10 BIOLOGICAL TREATMENT AND COMPLIANCE ISSUES

Comment: One commenter (IV-D-17) urged EPA to modify the default methanol biodegradation rate in Table 37 of the Appendix to the HON, or at a minimum correct the default value in the pharmaceutical MACT rule to one that reflects the demonstrated biodegradation rate of methanol in pharmaceutical wastewater. The commenter pointed out that based on their review of the data and meetings with EPA representatives and EPA consultants, a first-order biodegradation constant of 0.2 L/g ML VSS-hr cannot be scientifically-supported with the available data. The commenter also pointed out that, when compared to the rates of less biodegradable List 1 chemicals, the value in the HON is logically incorrect. According to the commenter, the available biodegradation rate data for methanol supports a value of 8.6 L/g VSS-hr at 20 deg. C. A summary of the compiled biodegradation rate data along with supporting data that were not already in the MACT rule docket was submitted by the commenter.

Response: To prepare a response to this comment, EPA reexamined the methanol biodegradation rate data provided by (1) PhRMA (including the new data submitted with the comment) and (2) the National Council of the Paper Industry for Air and Stream Improvement, Inc. (NCASI). In the six studies summarized by PhRMA, the first order biodegradation rate constant of methanol (K1) varied over 3 orders of magnitude; this variation suggests that the biorate is site specific. The higher K1 values generally correlated with higher methanol concentrations in the wastewater. The reported lower 90 percent confidence interval of the geometric mean is 3.5 L per gram biomass per hour (and the geometric mean is 8.6 L per gram

biomass per hour). The K1 values obtained from analysis of the data in the NCASI studies ranged from about 3.8 L per gram biomass per hour for a surface aeration unit and a conventional activated sludge unit to 12 L per gram biomass per hour for a covered pure oxygen unit.

Based on these data, EPA determined that a methanol K1 value of 3.5 L per gram biomass per hour is reasonable for pharmaceuticals facilities that are direct dischargers, and 0.2 L per gram of biomass per hour is reasonable for indirect dischargers. However, EPA does not believe the data are sufficient to change the default K1 for methanol in WATER8 (or in Table 37 of the HON). The WATER8 model is used to estimate emissions from wastewater with a wide range of methanol concentrations, which often are lower than those seen in the Pharmaceuticals Industry (or Pulp and Paper Industry). The default values in the WATER8 data base are intended to be reasonable values that can be used by a wide variety of industries, and facilities with site-specific values can substitute those values in place of the default values.

Comment: One commenter (IV-D-17) stated that the regulation should explicitly state that biological treatment processes in compliance with §§ 63.1252(d)(4)(ii)(B), (d)(4)(ii)(C), (d)(4)(iii), and (d)(5) need not be covered and vented as required in §§ 63.133 through 63.137. The commenter stated that this addition is needed because the provisions for tanks do not specifically exclude open biological treatment units from the tank requirements.

Response: The EPA agrees with the commenter that not all open biological treatment units need to be covered. The final rule indicates that biological treatment units need not be covered provided that procedures for demonstrating compliance with the selected control option are met. The changes are based on language in §§ 63.138(a)(3) and 63.145(g).

Comment: Several commenters (IV-D-08, IV-D-12, IV-D-17, IV-D-24, and IV-G-01) stated that EPA should revise the compliance requirements for the enhanced biotreatment option. Three commenters (IV-D-17, IV-D-24, and IV-G-01) requested that the compliance demonstrations for the enhanced biotreatment option be based on those parameters related to soluble HAP removal, and not on general compliance with all NPDES permit limits and requirements which include many parameters that do not relate to soluble HAP removal (e.g., coliform and metals according to Commenter IV-D-17, and coliform and TSS according to Commenter IV-D-12). One commenter (IV-D-08) requested that EPA develop an option which allows measurement of a surrogate parameter such as Chemical Oxygen Demand to demonstrate

removal of organics. Three commenters (IV-D-17, IV-D-24, and IV-G-01) recommended using biochemical oxygen demand (BOD) and total suspended solids (TSS) as surrogate parameters for measuring soluble HAP removal. Commenters IV-D-17 and IV-D-24 recommended that POTW's meet 5-day BOD and TSS maximum monthly average concentration limits of 30 mg/L, to be consistent with EPA's secondary treatment requirements. For direct dischargers, these two commenters recommended that the MACT standard be equivalent to the treatment limits provided in the effluent limitation guidelines at 40 CFR 439. These two commenters also stated that EPA's definition of significant noncompliance in Appendix A of 40 CFR 123.45 should be used as the basis for defining acceptable enhanced biotreatment operation for both POTW's and direct dischargers. One commenter (IV-D-17) further stated that the indirect discharger, not the POTW, is the entity that should be in compliance with the pretreatment provisions at 40 CFR 403 and 439.

Response: The EPA reevaluated the enhanced biotreatment option and determined that the requirements should be structured more like the requirements in the HON. All wastewater permit requirements were deleted in the final rule. Also, the same definition of enhanced biological treatment system that is in the HON was added. The enhanced biological treatment option would be available for POD streams that contain soluble compounds and less than 50 ppmw of partially soluble compounds. A performance test would not be required for an open biological treatment unit if (1) the unit is an enhanced biological treatment unit, (2) the POD wastewater streams treated in the unit contain only soluble compounds and less than 50 ppmw of partially soluble compounds, and (3) suppression requirements upstream of the treatment unit are met (to the facility boundary). Requirements for POTW's would be the same as onsite (except that suppression provisions would not be required on the municipal sewer system if the owner or operator demonstrates less than 5 percent of total partially soluble and soluble HAP in the WW is emitted from the municipal sewer system); as under the offsite treatment provisions in the HON (63.132(g)), the facility would have to ensure that the POTW submits certification that the POTW complies with these requirements.

Comment: One commenter (IV-D-08) questioned whether, unlike the requirements of § 63.1252(d)(4)(ii)(A) and (B), and in contradiction to the opening sentence of § 63.1252(d)(4),

the option provided in § 63.1252(d)(4)(ii)(C) applies to all wastewater streams from pharmaceutical processes and not just each affected wastewater stream.

Response: The control option described in § 63.1252(d)(4)(ii)(C) of the proposed rule is based on 95 percent control of total partially soluble and soluble HAP from all wastewater at the affected source in a biological treatment unit; the other control options apply only to affected wastewater. The final rule clarifies this point.

Comment: One commenter (IV-D-08) asked for clarification of EPA's intention in specifying that the procedures in 40 CFR Part 63 Appendix C be used to determine a 95 percent reduction in HAP in wastewater. The commenter stated that if the intention is to use the procedures only to calculate biodegradation, then Appendix C should be revised to delete the language in Sections I and III that discuss using the procedures to determine if a biological treatment unit must be covered and vented to an air pollution control device.

Response: The EPA agrees with the commenter that clarification of the provisions in § 63.1252(d)(4)(ii)(C) is needed. Appendix C is to be used as written. For any biological treatment unit, demonstrating compliance using this procedure would involve determination of the fraction of organic compounds degraded in the unit. If this procedure is used for an open biological treatment unit, the unit would not need to be covered and vented if the biodegradation rate is at least 95 percent of the total soluble and/or partially soluble HAP in the wastewater.

Comment: One commenter (IV-D-08) asked if reduce "by biological treatment" in § 63.1252(d)(4)(ii)(C) means biodegradation of 95 percent of each specific HAP or an overall 95 percent reduction in mass through all phases of biological treatment, including biological destruction, stripping, and sludge adsorption.

Response: The rule was clarified to indicate that a series of treatment devices is allowed to comply with the standard. The language will be structured similar to that in § 63.138(a)(7) and §§ 63.145(a)(7) and (a)(9) of the HON.

Comment: One commenter (IV-D-12) questioned if the permitting authority referred to in the compliance provisions for the enhanced alternative referred to the air permitting authority or the wastewater discharge permitting authority. The commenter continued on to say that if it is the wastewater permitting authority, then the provision is not necessary because compliance with wastewater permits is required under the Clean Water Act.

Response: The EPA agrees with the commenter that requiring compliance with the wastewater permit under this rule is duplicative and unnecessary. This provision was deleted from the rule as part of the changes described in the earlier response.

Comment: One commenter (IV-D-17) asserted that there were four conflicts between the requirements for biological treatment units in § 63.1252(d)(4)(ii)(C), the compliance provisions in § 63.1253(e)(2) and (e)(5), and the monitoring requirements in § 63.1254(a)(6). According to the commenter, biological treatment units covered by § 1252(d)(4)(ii)(C) should not be subject to the requirements in § 63.138(j), as cross-referenced from § 63.1253(e)(2); the commenter's rationale is that §§ 63.145(f) and (g), which are cross-referenced from § 63.138(j), do not apply to biological treatment units because these sections are not cross-referenced from § 63.1252(d)(4)(ii)(C). Similarly, the commenter believes wastewater tanks in biological treatment systems in compliance with § 63.1252(d)(4)(ii)(C) should not be subject to the monitoring requirements of § 63.143 (and Table 12 of subpart G), as cross-referenced from § 63.1253(e)(5), because § 63.143(b) cross-references § 63.138, which in turn also cross-references §§ 63.145(f) and (g). The commenter also indicated that § 63.145(i) should be deleted from § 63.1253(e)(2) because it refers to performance tests for control devices, not treatment processes. Finally, the commenter indicated that § 63.1254(a)(6) should be modified to specify separate monitoring requirements, based on compliance with 40 CFR Part 63 Appendix C, for biological treatment processes in compliance with § 63.1252(d)(4)(ii)(C).

Response: The commenter correctly noted conflicts between provisions in the proposed rule and in the January 17, 1997, revisions to the HON. However, the proposed rule actually cross-referenced sections in the April 1994 HON final rule. When examined from that perspective, EPA believes the conflicts are resolved. For example, a cross reference to the April 1994 version of 63.145(i) was appropriate because that section described compliance procedures for biological treatment processes in addition to the requirements in Appendix C. Cross-references from 63.1253(e)(2) and (e)(5) to the April 1994 versions of 63.138(j) and 63.143, respectively, for biological treatment units also were appropriate (i.e., 63.143(c) referred to monitoring requirements for biological treatment units in Table 12, and 63.138(j) referred to Appendix C for biological treatment units). Similarly, a cross-reference from 63.1254(a)(6) to the April 1994 version of 63.138 was appropriate because 63.138(e) described the 95 percent

control option for biological treatment units. To alleviate the confusion, the rule was rewritten to be consistent with the January 17, 1997, revisions to the HON, and the specific compliance procedures were incorporated in the rule directly, not cross-referenced.

17.11 NONBIOLOGICAL TREATMENT AND COMPLIANCE OPTIONS

Comment: Two commenters (IV-D-17 and IV-D-24) noted that the treatment requirements in the proposed rule do not specify the operating conditions under which performance demonstrations for regulated wastewaters are to made. Both commenters pointed out that in Section 63.145(a) of the HON, percent removal requirements are determined under representative operating conditions or operating ranges, which they interpreted to mean the standard is an average that may be exceeded under certain conditions. Both commenters also noted that Section 63.145(a) of the HON also specifies design evaluations, the RCRA compliance option, testing equipment installation, treatment using a series of treatment processes and HAP that do not have to be considered during performance tests, all of which are also essential elements for determining compliance with the treatment requirements. The commenters suggested that the omitted elements be incorporated either into Section 63.1252(d)(4) or 63.1253(b) or (e), or Section 63.1252(d)(4)(ii) should reference Section 63.145(a) of the HON.

Response: The EPA agrees with the commenters that the provisions in § 63.145(a) of the HON are essential elements for determining compliance. They were inadvertently left out of the proposed rule, but they were included in the final rule. However, the commenters misinterpreted the provisions about representative treatment process operating conditions. These provisions mean the owner or operator is to conduct a test under representative operating conditions to demonstrate that the standard is met. If actual operating conditions vary, such that there are multiple representative operating conditions, the owner or operator must supplement the test results with modeling and/or engineering assessments to demonstrate that the standard is met over the entire range of operating conditions. The provisions do not allow the owner or operator to determine an average control level based on operation above the standard under some conditions and below the standard under other conditions.

Comment: One commenter (IV-D-17) stated that Section 63.1252(d)(4)(i) should be deleted because a stream that is recycled to a process does not meet the definition of wastewater in the proposed rule. The commenter explained that under the HON the POD is defined as the

point where process wastewater exits the chemical manufacturing process unit. Therefore, material recycled to a chemical manufacturing process is not wastewater and is not subject to the provisions of the proposed rule.

Response: The EPA agrees that § 63.1252(d)(4)(i) is no longer applicable based on changes in the definitions of wastewater and POD. As noted elsewhere in this document, the definition of wastewater was changed to incorporate the concept that a water stream is not wastewater until it is discarded from the PMPU, the POD was defined as the discharge point from the PMPU, and recovery devices were defined to either be part of the PMPU or the PMPU's by themselves. Therefore, material recycled to a process will not be subject to treatment provisions (although it may be subject to emission suppression requirements).

Comment: One commenter (IV-D-17) supported including the option of allowing recycling wastewater residuals to the production facility and suggested replacing the last two sentences of 63.1252(d)(4)(A) and (B) and 63.1252(d)(4)(iii) with the following:

"Waste management unit and treatment process residuals shall be managed according to 63.138(h) and 63.138(k)."

Response: The EPA agrees with the commenter. The rule indicates that residuals shall be managed according to the provisions in § 63.138(k). These provisions are stated in the rule, not cross-referenced.

Comment: Two commenters (IV-D-17 and IV-D-32) stated that the wastewater treatment requirements for soluble HAP should include a bottoms concentration cutoff such as that provided for partially soluble HAP. One of the commenters (IV-D-17) discussed the provisions for partially soluble HAP versus soluble HAP. The proposed MACT requires that the total mass of each partially soluble HAP in regulated wastewater be reduced, by removal or destruction, by 99 percent or to a level less than 50 ppm by weight. However, for regulated wastewater that contains soluble HAP, the level of treatment performance is 90 percent reduction, removal or destruction of total mass of each individual soluble HAP. The commenter believes that the proposed treatment performance for soluble HAP is inconsistent with the SID. In this document, the tower stripper modeling outputs indicate that the stripper was evaluated to achieve a bottom concentration of 1,000 mg/L soluble HAP. Also, the analysis considered total soluble HAP removal, and not individual speciated HAP removal. The commenter recommended specific

wording for Section 63.1252(d)(4)(ii)(B) that includes a bottoms concentration cutoff and a standard in terms of total soluble HAP rather than individual soluble HAP.

Response: The EPA agrees with the commenter that a concentration option is needed for streams soluble HAP. The final rule includes a concentration cutoff of 520 ppmw for total soluble HAP as an alternative to the requirement that the mass of each individual soluble HAP be reduced by 90 percent.

Comment: Three commenters (IV-D-17, IV-D-24, and IV-D-34) requested that EPA provide the same range of treatment options in the MACT wastewater provisions that are available in the SOCMI HON. According to the commenters, including these treatment options would allow facilities to choose the most cost-effective control option and facilitate compliance demonstrations. One commenter (IV-D-34) requested that EPA use actual text in the standard rather than incorporating the treatment options by referencing the HON.

The treatment options that the commenters asked EPA to provide are:

1. Treatment in a RCRA unit as specified in Section 63.138(h) of the HON;

2. Offsite treatment or onsite treatment in units not owned or operated by the source as specified in Section 63.132(g) of the HON; and

3. Sequential treatment processes as specified in Section 63.138(a)(7) of the HON.

With respect to treatment option No. 1, the commenters pointed out that in the HON, requirements for design evaluations or performance tests are waived since RCRA treatment units (including incinerators, boilers, heaters, and underground injection wells) are already regulated. One commenter (IV-D-17) requested that the new provision add an exemption for any waste management unit (such as, a container, tank, or surface impoundment) that is regulated by Subpart CC of 40 CFR 264.

Response: The EPA agrees with the commenters that RCRA treatment units, offsite or onsite treatment in units not owned by the source, and treatment in series are acceptable methods of demonstrating compliance. These options were added to the rule. In addition, the design evaluation and performance test provisions do not apply to the RCRA treatment units because the compliance requirements under RCRA meet or exceed the requirements in this rule.

Comment: One commenter (IV-D-17) stated that the regulation should include the fraction removed (Fr) values to be used when demonstrating compliance with the treatment

options, instead of referencing the HON. The commenter suggested that the following wording be added to Section 63.1252(d)(4)(ii)(A) and (B) and 63.1252(d)(4)(iii):

"The Fr values in Section 63.145(c)(5) and (d)(8) shall be 99 percent for partially soluble compounds in Table 2 and 90 percent soluble HAP in Table 3 of this subpart."

Response: The EPA believes the change suggested by the commenter is not needed because the suggested Fr values are identical to the stated control requirements (except for some new sources that would need to control soluble HAP by 99 percent). In the HON, §§ 63.138(e)(1) and (e)(2) describe compliance options that require mass reductions by a given percentage or by the Fr values, respectively. Sections 63.145(c) and (d) both describe procedures for complying with both control options. However, if the specified percent reduction requirement and the Fr values are the same, the procedures in §§ 63.145(c)(5) and (d)(8) for complying with control based on Fr values are not needed.

Comment: One commenter (IV-D-13) requested that EPA allow the disposal of wastewater by deep well injection as an acceptable treatment option. The commenter noted that this would acknowledge the overlap with other standards applicable to the pharmaceutical industry that address deep well injection. The commenter recommended that the following provision be added at Section 63.1252(d)(4)(iv):

"Discharge wastewater or residue to an underground injection well for which the owner or operator has been issued a final permit under 40 CFR part 270 or 40 CFR part 144 and complies with the requirements of 40 CFR part 122."

Response: The language suggested by the commenter is from § 63.138(h) of the January 17, 1997 revisions to the HON, and it was included in the rule.

17.12 CROSS-REFERENCES TO THE HON

Comment: Many commenters (IV-D-08, IV-D-12, IV-D-17, IV-D-20, IV-D-24, IV-D-32, and IV-G-01) stated that the extensive use of cross-referencing to the HON makes the wastewater standard difficult to understand. They also indicated that working back and forth between the two regulations is time-consuming and confusing. The commenters requested that this extensive cross-referencing be eliminated and that the applicable sections from the HON be incorporated directly into the rule. Several commenters stated that, as written, the proposed rule is not a workable regulation for either the pharmaceutical industry or external regulatory bodies.

Additionally, four commenters (IV-D-12, IV-D-20, IV-D-24, and IV-D-32) stated that, where applicable, the wastewater provisions should be updated to reflect the January 17, 1997 revisions to the HON. Several commenters (IV-D-08, IV-D-12, IV-D-17, and IV-D-24) cited specific sections in the rule with incorrect references to the HON, and suggested that EPA review all references to the HON to identify any other incorrect references.

One commenter (IV-D-20) attached a redraft of the proposed rule that incorporates all of the HON references. The commenter stated that while redrafting the proposed rule, it was especially difficult to interpret the monitoring and recordkeeping requirements for wastewater compliance. Therefore, the redrafted proposal includes the recordkeeping requirements from the HON that the commenter believed were appropriate. The commenter stated that they attempted to reflect EPA's intent in the proposed rule as accurately as possible in the redraft.

Response: The EPA agrees with the commenters that the many cross references make the proposed rule hard to understand. Therefore, applicable language from the wastewater provisions in the HON, including the January 17, 1997, revisions, were incorporated directly in the rule.

17.13 MAINTENANCE WASTEWATER PROVISIONS

Comment: Two commenters (IV-D-10 and IV-D-32) requested that the requirements for maintenance wastewater be less stringent than those for process wastewater. One commenter (IV-D-10) stated that installing the same types of permanent conveyance and control systems for maintenance wastewaters, which occur infrequently and at any point in the process, as for process streams, which flow continually and originate from same point, would be impractical and not cost-effective. The commenters pointed out that a distinction between process and maintenance wastewater was made in the HON and suggested that EPA follow the HON requirements in 40 CFR 63.105 for pharmaceutical maintenance wastewater.

Response: The EPA believes that maintenance wastewater from this industry may have very similar characteristics to process wastewater, and therefore, sees no reasons to regulate it differently. In this respect, the wastewater provisions from this NESHAP differ from what is in the HON.

17.14 BASELINE EMISSIONS

Comment: One commenter (IV-D-17) contended that baseline wastewater emissions and the emission reductions resulting from implementation of the proposed rule are overestimated. The commenter noted improper accounting of existing wastewater treatment and controls, as well as errors related to Plant No. 126 as the reasons for the overestimation.

The commenter reported that the 1,497,273 lb HAP baseline estimate for Plant No. 126 is incorrect. The commenter also stated that this plant is not a major source and should not have been included in the baseline calculations. The commenter noted that Table 1 of the SID correctly reports Plant No. 126 as a minor source. In addition, the amount of triethylamine that Plant No. 126 reported in the CWA Section 308 questionnaire as discharged to surface water and sewer was incorrect. The amount reported was actually "in product;" the amount discharged should have been reported as zero. In addition, the commenter stated that the baseline emission estimate failed to account for alternative treatment technologies, such as thermal oxidation.

Response: The EPA reviewed the data on plant 126 and concluded that its baseline emissions should not have been used in the impacts analysis. Accordingly, the estimates of cost and cost effectiveness do not include any reductions from the referenced facility.

17.15 IMPACTS ANALYSES

Comment: One commenter (IV-D-32) compared EPA estimated costs for a steam stripper with their actual costs of a steam stripper installed to comply with the benzene NESHAP and found several discrepancies. These discrepancies are: (1) EPA estimated piping costs at 30 percent of equipment costs; the commenter's actual costs were 80 percent of equipment costs, (2) EPA estimated instrumentation costs at 10 percent of equipment and piping costs; the commenter's actual costs were 30 percent of equipment and piping costs, and (3) EPA estimated indirect installed costs at 35 percent of purchased equipment costs; the commenter's actual costs were 113 percent of purchased equipment costs. The commenter also stated that the EPA estimates were low because some major cost items such as pre-treatment, byproduct and waste storage, and a flare were excluded. After scaling to account for design capacity differences, the commenter calculated the EPA estimate to be about 10 times too low.

Response: The EPA believes the factors for piping, instrumentation, and indirect installation costs that were used in the EPA analysis are reasonable. They are standard factors

that EPA uses in cost analyses for control devices on all regulatory development projects. Some of these factors, notably the one for piping, have different values for different control devices; the factors for a steam stripper were represented with the factors for an absorber tower. Naturally, the actual values for these factors will vary from facility to facility. The EPA cannot evaluate why these three factors were higher for the steam stripper at the commenter's facility because the commenter provided neither a complete description of the system that was installed nor all of the costs for that system.

The EPA also believes that most facilities would not need pretreatment, additional storage, or a flare.

Comment: Two commenters (IV-D-17 and IV-D-32) disagreed with the assumption in EPA's cost and impacts analyses that steam stripping operations will produce recoverable material, resulting in zero waste disposal costs for the strippers. One commenter (IV-D-32) discussed the prohibitive cost effectiveness of separating a stream containing mixed or cross-contaminated solvents for reuse. The second commenter (IV-D-17) discussed the prohibitive cost of using recovered solvent as boiler fuel. This commenter provided two case histories. The first plant had submitted and later withdrew a boilers and industrial furnace (BIF) application to use recovered waste solvent as a boiler fuel. The second plant operated two boilers that burned recovered solvent but later discontinued this practice. The commenter cited operating difficulties and increased compliance costs associated with the BIF regulations as the reasons why these plants do not use recovered solvent for boiler fuel. The commenter also addressed a May 1993 strategy announced by the EPA Administrator that stated combustion in incinerators and BIF's is not the preferred disposal alternative. The commenter noted that, in light of this announcement, EPA is not approving new permits, the requirements for operation and feed streams are being tightened, many BIF's no longer use solvent as a fuel, and EPA is contradicting its own strategy by encouraging new BIF's in the MACT proposal. The commenter contended that because burning solvent waste in boilers will be economically practical for only a few plants, the cost analysis should include offsite disposal costs, which is the most probable solvent disposal method.

Response: Waste disposal costs were factored into the environmental impacts analysis for sources subject to the new source standards for wastewater. However, waste disposal costs

were not considered in the analysis for existing sources because EPA believes that the recovered solvent could either be used or sold as a secondary recyclable product.

17.16 WORDING CLARIFICATIONS

Comment: One commenter (IV-D-17) pointed out that the proposed rule does not state the averaging period for measuring or calculating the concentration of partially soluble HAP and total HAP in wastewater to determine whether the stream is regulated or exempt. The commenter discussed the information from the HON and from the pharmaceutical MACT supporting documentation that indicates an appropriate averaging period of 1 year. The commenter requested that the words "annual average" be added in front of the word "concentration" both times it is used in Section 1253(e)(1)(i). The commenter also requested that the definition of "annual average concentration," which is included in the HON rule, be added in the definitions section of the MACT rule.

Response: The EPA agrees that the concentration should be an annual average and has changed the final rule to reflect this language.

Comment: Two commenters (IV-D-08 and IV-D-12) requested clarification on the wording in Section 63.1252(d)(4)(ii). The commenters asked whether the conditions to be met are either (1) "A and B" or "C" or (2) "A" and "B or C."

Response: The rule will be clarified to indicate that the owner or operator shall comply with both (A) and (B), or comply with (C).

Comment: One commenter (IV-D-17) recommended revisions that would condense and clarify Section 63.1252(d)(1)(i)-(vi). The commenter suggested the following wording, which combines provisions (i) with (iv) and (ii) with (v) using language from the preamble:

(i) "Streams having partially soluble HAP compound concentrations of 1,300 mg/L or greater and a total yearly process HAP load of 1 Mg/yr or greater or any single POD load of 1 Mg/yr or greater."

(ii) "Streams having a combined total HAP concentration of 5,200 mg/L or greater and a total yearly process HAP load of 1 Mg/yr or greater or any single POD load of 1 Mg/yr or greater."

With the above suggested revisions, the wording in Sections 63.1252(d)(1)(iii) and (vi) should remain unchanged and (d)(1)(vi) should be renumbered as (d)(1)(iv).

Response: The EPA agrees with the commenter that these sections can be condensed. However, the wording in the rule was revised to clarify these requirements. Therefore, the above changes are no longer necessary.

17.17 EFFLUENT GUIDELINES

Comment: One commenter (IV-D-29) stated that both the 1995 Effluent Limits Guidelines, Pretreatment Standards and the NSPS: Pharmaceutical Manufacturing Category are problematic for buildings with multi-product lines because HAP change on a daily basis. The commenter also stated that in-plant steam stripping is difficult for these situations.

Response: Comment referred to the OW.

18.0 GENERAL COST COMMENTS

Comment: Commenters (IV-D-02 and IV-D-15) stated that the costs used to justify the regulatory alternatives are grossly understated. Additionally, EPA has substantially over-predicted environmental benefits and has created many expensive assurance requirements with no benefit. In considering the proposed rule, commenter (IV-D-15) projects initial costs of compliance to be approximately $10 million per facility for at least two of its facilities which will be affected by the rule, not including losses due to lost production. The other commenter (IV-D-02) estimates the costs for one facility alone at $20 million to comply with these standards.

Response: The EPA costs were developed based on the model plants that were derived from the information provided by the industry during the past 2 years. Obviously there is a major difference of opinion as to the overall costs of compliance for the EPA estimates for model plants and the two commenters' cost projections for their facilities. The EPA does not agree that the environmental benefits have been overstated, nor are the compliance assurances without benefit.

Comment: Commenter (IV-D-24) stated that the economic analysis is inadequate because it assumes that all pharmaceutical industry subcategories possess similar microeconomic characteristics. EPA assumes that the industry structure and profitability are characterized by relatively noncompetitive forces. This analysis fails to account for segments of the industry that operate in an extremely competitive environment on a global basis and which approach the perfectly competitive position of price takers. Furthermore, the economic analysis fails to accurately account for intra-company characteristics and their effect on continuing domestic production. Firms operating in a near perfectly competitive global environment can neither absorb the costs nor pass along the costs to the consumer. Shifting location of production abroad may be a necessary response to maintain competitive unit costs.

Response: The economic analysis is based on a characterization of the pharmaceutical industry as a collection of product markets with different levels of product differentiation. Both highly differentiated product markets (e.g., prescription and over-the-counter drugs) and more "commodity-oriented" markets (e.g., generics, bulk active ingredients) are captured within this general framework. In the former case, producers are seen as having more control over their price and more able to alter prices to reflect the new cost structure. In the latter case, the markets are essentially competitive and individual producers have less ability to adjust prices and pass on costs.

Within the empirical application of the model, EPA allows the data to determine the extent of each firm's product differentiation (i.e., its power over price), the estimate of the (average) elasticity of demand for their products, and the consequent ability of the firm to pass costs on to their customers. Firms specializing in highly differentiated products will tend to have high variable profit margins (as observed in the data) -- which as the commenter points out and referred to in the analysis, might best be interpreted as returns to product development rather than pure profits. The higher profit margin can be used to impute the lower demand elasticity facing highly differentiated markets. The imputed demand elasticity is what drives the EPA's estimate of the firm's ability to adjust prices, shifting burden to consumers . Alternatively, firms specializing in commodity (low differentiated) pharmaceuticals tend to have lower variable profit margins, which is used to impute a higher elasticity of demand. In the perfectly competitive case, variable profits are zero (price equals marginal cost equals ave. total cost), and the imputed elasticity of demand is infinite. Thus, the extent to which a firm specializes in commodity products should effect the variable profit margins in the data and EPA's estimate of their ability to pass costs on through higher prices.

To summarize, contrary to the suggestion made in the comment, the EPA analysis methodology reinforces the notion that regulatory effects would be more severe for producers specializing in intensely price-competitive commodity markets than for producers specializing in less price-competitive ethical drug markets. Data for those producers would presumably reflect lower variable cost margins, which would be used to indicate higher elasticity of demand facing individual producers and less control for those producers over the prices they receive. In the extreme case, the full cost absorption scenario used in the analysis, which the commenter takes

issue with, is the ultimate characterization of a perfectly competitive outcome, where no prices adjust in response to regulatory costs and impacts are greatest on producers.

Domestic and foreign production issues are addressed by EPA in a section of the economic analysis (4.4 Foreign Trade Impacts). As indicated in that section, EPA does recognize that firms could switch production abroad in response to domestic regulation (assuming no similar foreign regulation) but could not specifically estimate the extent of this problem due to lack of data. However, such movement abroad, if it occurred, would actually reduce the firm-level impacts below what is estimated by EPA as firms would choose not to incur some of the costs estimated for domestic facilities. On the other hand, domestic employment impacts would be understated to the extent that the foreign-domestic production tradeoff occurs. It seems unlikely, however, that the regulations considered here, which are small relative to industry costs and revenue are likely to induce the substantial movement abroad as referenced in the comment. Therefore, EPA does not believe a substantial omission has occurred by not explicitly estimating the movement pf domestic production abroad.

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16. ABSTRACT

On April 2, 1997, the U.S. EPA proposed the NESHAP for pharmaceutical production under authority of Section 112 of the Clean Air Act as amended in 1990. Public comments were received from 46 sources consisting mainly of States, pharmaceutical manufacturers, industry trade associations, environmental groups, and other interested parties.

All of the comments that were submitted and the responses to these comments are summarized in this document. This summary is the basis for the revisions made to the standards between proposal and promulgation.

17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
Pharmaceutical manufacturers, batch processes, MACT standards, process vents, storage tanks, equipment leaks, and wastewater treatment systems	Air Pollution control	

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