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Office of Air Quality Planning and Standards Research Triangle Park NC 27711
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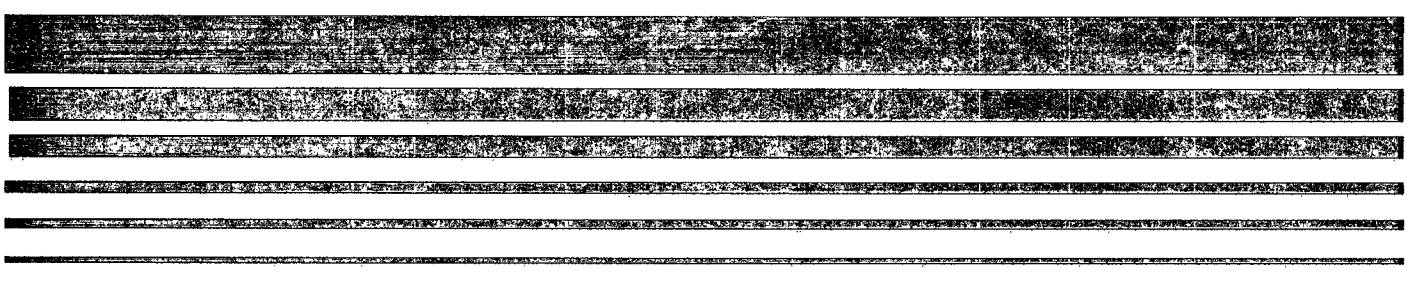
EPA

National Emission Standards for Hazardous Air Pollutants Compliance Extensions for Early Reductions - Background Information for Promulgated Standards



NESHAP

National Emission Standards for Hazardous Air Pollutants Compliance Extensions for Early Reductions - Background Information for Promulgated Standards

Prepared By
Emission Standards Division

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Air and Radiation
Office of Air Quality Planning and Standards
Research Triangle Park, North Carolina 27711

December 1992

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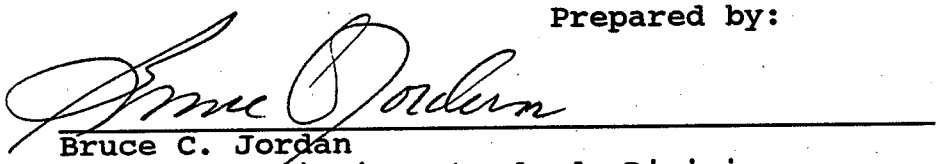
U. S. ENVIRONMENTAL PROTECTION AGENCY

Background Information
for National Emission Standards for Hazardous Air Pollutants:
Compliance Extensions for Early Reductions

Prepared by:



12/29/92
(Date)

Bruce C. Jordan
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U. S. Environmental Protection Agency
Research Triangle Park, North Carolina 27711

1. The promulgated standards establish rules for implementing the Early Reductions Program. Section 112(i)(5) of the Clean Air Act (as amended in 1990) ("the Act") allows existing sources to obtain a 6-year extension of compliance from applicable Section 112(d) standards if the source achieves emission reductions of 90 percent or more of hazardous air pollutants (95 percent or more for particulates) by certain dates specified by the Act.

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; and to the National Science Foundation; State and Territorial Air Pollution Program Administrators; the EPA's Regional Administrators; Local Air Pollution Control Officials; the Office of Management and Budget; and other interested parties.

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1.0 SUMMARY

The U. S. Environmental Protection Agency (EPA) proposed rules governing compliance extensions for early reductions of hazardous air pollutants (HAP's) on June 13, 1991 (56 FR 27338) under authority of Section 112(i)(5) of the Clean Air Act (CAA), as amended in 1990.[1] Public comments were requested in the Federal Register notice. Sixty-seven comment letters were received from industry, State and local regulatory agencies, environmental groups, and other interested parties. The comments and subsequent responses serve as the primary basis for revisions made to the rule between proposal and promulgation. The final rule was promulgated December 29, 1992 (57 FR 61970).

1.1 SUMMARY OF CHANGES SINCE PROPOSAL

The EPA has made several changes and clarifications to the Early Reductions Program rule since proposal as a result of comments received. These changes and clarifications were made in the following subject areas:

- High-risk pollutants;
- Definition of source;
- Averaging of gaseous and particulate emissions;
- Use of average emission factors for equipment leak emissions;
- Method 301; and
- Language in the regulation.

A summary of these changes is given below.

1.1.1 High-risk Pollutants

The high-risk pollutant list now contains 47 pollutants, as opposed to 35 in the proposed rule. The EPA revised the methodology used to determine high-risk pollutants and the

weighting factors assigned to some pollutants. As a result of these changes, 17 pollutants were added to the list and 5 pollutants were deleted. The weighting factors for five pollutants were also adjusted. Table 1-1 lists the pollutants added to the high-risk list and Table 1-2 lists the pollutants deleted from the list. Table 1-3 shows the adjustments made to the weighting factors for the five pollutants. Table 1-4 is the final list of high-risk pollutants and their adjusted weighting factors.

Two other provisions concerning high-risk pollutants were added to the final rule. First, a provision was added to ensure that there were no increases in radionuclide emissions as a result of the emission reduction demonstration. Second, a provision was added that will "grandfather" sources that already had approved enforceable commitments or alternative emission limits specified by permit. These sources will not have to revise post-reduction demonstrations if a pollutant is either newly-listed as a HAP under Section 112(b) or added to the high-risk list.

1.1.2 Definition of Source

Proposed paragraph (a)(4) of section 63.73 has been deleted from the source definition. Paragraph (a)(4) is a subset of (a)(5), and thus redundant. Selecting unrelated emission points to constitute a source will still be allowed, provided that the source created emits a significant quantity of HAP's as defined in the regulation.

1.1.3 Averaging of Gaseous and Particulate Emissions

The rule has been revised with respect to the combined percent reduction that can be applied to sources with both gaseous and particulate HAP's. The provision in the final rule only applies to any emission point, as opposed to the entire source, that emits both gases and particulates. An emission point that emits solely a gaseous HAP can not be combined with another emission point that emits particulate

TABLE 1-1. LIST OF POLLUTANTS ADDED TO HIGH-RISK LIST

CAS* No.	Chemical	Weighting Factor
53963	2-Acetylaminofluorene	100
532274	2-Chloroacetophenone	100
334883	Diazomethane	10
96128	1,2-Dibromo-3-chloropropane	10
79447	Dimethyl carbamoyl chloride	100
122667	1,2-Diphenylhydrazine	10
151564	Ethylenimine (Aziridine)	100
77474	Hexachlorocyclopentadiene	10
0	Manganese compounds	10
60344	Methyl hydrazine	10
0	Nickel compounds	10
684935	N-Nitroso-N-methylurea	1000
62759	N-Nitrosodimethylamine	100
56382	Parathion	10
7803512	Phosphine	10
7723140	Phosphorus	10
8001352	Toxaphene (Chlorinated Camphene)	100

*Chemical Abstract Service

TABLE 1-2. LIST OF POLLUTANTS DELETED FROM HIGH-RISK LIST

CAS No.	Chemical	Weighting Factor
98077	Benzotrichloride	10
126998	Chloroprene	10
79345	1,1,2,2-tetrachloroethane	10
584849	2,4-toluene diisocyanate	10
75354	Vinylidene chloride (1,1-Dichloroethylene)	10

TABLE 1-3. ADJUSTMENTS IN WEIGHTING FACTORS FOR SELECTED POLLUTANTS

CAS No.	Chemical	Weighting Factor Adjustment
107028	Acrolein	10 to 100
57749	Chlordane	10 to 100
76448	Heptachlor	10 to 100
118741	Hexachlorobenzene	10 to 100
0	Mercury Compounds	10 to 100

TABLE 1-4. LIST OF HIGH-RISK POLLUTANTS

CAS No.	Chemical	Weighting Factor
53963	2-Acetylaminofluorene	100
107028	Acrolein	100
79061	Acrylamide	10
79107	Acrylic acid	10
107131	Acrylonitrile	10
0	Arsenic compounds	100
1332214	Asbestos	100
71432	Benzene	10
92875	Benzidine	1000
0	Beryllium compounds	10
542881	Bis(chloromethyl)ether	1,000
106990	1,3-Butadiene	10
0	Cadmium compounds	10
57749	Chlordane	100
532274	2-Chloroacetophenone	100
0	Chromium compounds	100
107302	Chloromethyl methyl ether	10
0	Coke oven emissions	10
334883	Diazomethane	10
132649	Dibenzofurans	10
96128	1,2-Dibromo-3-chloropropane	10
111444	Dichloroethyl ether	10
79447	Dimethyl carbamoyl chloride	100
122667	1,2-Diphenylhydrazine	10
106934	Ethylene dibromide (Dibromoethane)	10
151564	Ethylenimine (Aziridine)	100
75218	Ethylene oxide	10
76448	Heptachlor	100

TABLE 1-4. LIST OF HIGH-RISK POLLUTANTS (Concluded)

CAS No.	Chemical	Weighting Factor
118741	Hexachlorobenzene	100
77474	Hexachlorocyclopentadiene	10
302012	Hydrazine	100
0	Manganese compounds	10
0	Mercury compounds	100
101688	Methylene diphenyl diisocyanate (MDI)	10
60344	Methyl hydrazine	10
624839	Methyl isocyanate	10
0	Nickel compounds	10
62759	N-Nitrosodimethylamine	100
684935	N-Nitroso-N-methylurea	1,000
56382	Parathion	10
75445	Phosgene	10
7803512	Phosphine	10
7723140	Phosphorus	10
75558	1,2-Propylenimine (2-Methyl aziridine)	100
1746016	2,3,7,8-Tetrachlorodibenzo-p-dioxin	100,000
8001352	Toxaphene (chlorinated camphene)	100
75014	Vinyl chloride	10

HAP within a source for the purposes of averaging the emission reduction.

1.1.4 Use of EPA Average Emission Factors for Equipment Leak Emissions

The EPA has changed the rule to allow the use of the EPA's average emission factors for equipment leaks to determine base year emissions only if no reductions in equipment leak emissions are claimed as part of the reduction demonstration. The equipment leak source in Appendix B has also been clarified to be specific to the individual component types.

1.1.5 Method 301

A number of changes and corrections to Method 301 have been made as a result of public comments. The applicability of the method has been broadened to cover other media.

1.1.6 Miscellaneous Changes to the Rule

A number of minor changes have been made to the proposed rule. Two changes affect the determination of base year and post-reduction emissions. First, the definition of "actual emissions" has been clarified to exclude startup and shutdown emissions due to malfunctions. Second, it is no longer a requirement to provide evidence of production curtailments or shutdowns for post-reduction demonstrations. Such reductions will become conditions of the Title V permit.

Other minor changes include: (1) the suggested statement of commitment in the enforceable commitment has been revised to be more consistent with the actual requirements; (2) the length of time allowed to provide source test results to support the post-reduction demonstration has been increased to 120 days from 90 after the permit submittal deadline; (3) reference to Part 71 federal permitting rules has been deleted because they have not been issued; and (4) the term "post-control" has been changed to "post-reduction" throughout the rule to recognize that reductions can be achieved through means other than control technology.

1.2 SUMMARY OF IMPACTS OF PROMULGATED ACTION

The Early Reductions Program is a voluntary program. The Program provides optional means of complying with future standards developed under Section 112 of the CAA.

Because the Program is voluntary, no environmental, economic, or energy impacts are directly associated with the rule. However, should an owner or operator choose to take advantage of the Early Reductions provisions, the public health and the environment would gain from reductions in HAP's before such reductions would otherwise be required by the standard-setting process.

In addition, any economic and energy impacts will occur sooner at sources making early reductions of HAP's. However, because of the greater flexibility to apply cost-effective control measures than would be available under a Section 112(d) standard, the owner or operator will realize a net savings with respect to meeting a Section 112(d) standard.

At this time, it is not possible to quantify early reductions benefits or impacts. These will depend on how many source owners or operators are able to take advantage of the Early Reductions Program, the types of sources, which reduction measures will be implemented, and the requirements of otherwise applicable Section 112(d) standards.

1.3 REFERENCES

1. Federal Register. National Emission Standards for Hazardous Air Pollutants for Source Categories: Proposed Regulations Governing Compliance Extensions for Early Reductions of Hazardous Air Pollutants. 56 FR 27338-27374. June 13, 1991.

2.0 SUMMARY OF PUBLIC COMMENTS

A total of 67 comment letters were received. In addition, comments were received at a public hearing held following proposal of the rule. All of the comment letters and public statements have been recorded and placed in the docket (Docket No. A-90-47). A list of commenters, their affiliation, and the docket item number assigned to their correspondence is shown in Table 2-1. The comments have been organized into the following categories:

2.1 Definition of Source;
2.2 Base Year Emissions;
2.3 Enforceable Commitments;
2.4 Allowable Emission Reductions;
2.5 Demonstration of Early Reduction;
2.6 High-Risk Pollutants;
2.7 State Authority;
2.8 Interface with Title V Permits;
2.9 Interface with Section 112(g) Modifications;
2.10 Interface with Title I Provisions;
2.11 Test Methods and Procedures; and
2.12 Miscellaneous Comments.

2.1 DEFINITION OF SOURCE

2.1.1 Comment: A number of commenters contended that the definition of source is too broad, especially in paragraphs 4 and 5 (IV-D-06, IV-D-20, IV-D-22). Other commenters felt the definition should be consistent with the definition proposed in Title V of the CAA to avoid confusion (IV-D-13, IV-D-14, IV-D-16, IV-D-31). One commenter suggested restricting the definition to Section 63.73(a)(1) and (3)(IV-D-60). Finally a

TABLE 2-1. LIST OF COMMENTERS ON THE PROPOSED EARLY REDUCTIONS RULE

Docket Item Number[a]	Commenter and Affiliation
IV-D-2	Mr. Gordon D. Strickland Vice-President Chemical Manufacturers Association 2501 M Street, NW Washington, DC 20037
IV-D-2	Mr. Edwin T. Still Kerr-McGee Corporation Kerr-McGee Center Oklahoma City, Oklahoma 73125
IV-D-3	Ms. Mary Anne Hunter Environmental Coordinator Arvin Industries, Inc. 1531 13th Street Columbus, Indiana 47201
IV-D-4	Mr. George Smith Chair, Air Quality Lone Star Chapter, Sierra Club 6014 Woodbrook Houston, Texas 77008
IV-D-5	U.V. Henderson General Manager Environment and Product Safety Texaco, Inc. PO Box 509 Beacon, New York 12508
IV-D-6	Ms. Kathleen F. Dalton NY State Department of Environmental Conservation 50 Wolf Road Albany, New York 12233
IV-D-7	Mr. Roger Etter Koch Industries, Inc. PO Box 2256 Wichita, Kansas 67201

TABLE 2-1. LIST OF COMMENTERS ON THE PROPOSED EARLY REDUCTIONS RULE (continued)

Docket Item Number[a]	Commenter and Affiliation
IV-D-8	Ms. Dorothy P. Bowers Executive Director Corporate Environmental Resources Merck & Co., Inc. PO Box 2000 Rahway, New Jersey 07065-0900
IV-D-9	Mr. Michael C. Thompson Manager, Government Relations Whirlpool Corporation Benton Harbor, Michigan 49022
IV-D-10	Mr. George P. Ferreri Director, Air Management Division State of Maryland Dept. of the Environment 2500 Broening Highway Baltimore, Maryland 21224
IV-D-11	Mr. Charles D. Bennett Environmental Coordinator Ashland Petroleum Company PO Box 391 Ashland, Kentucky 41114
IV-D-12	Mr. John Mancini American Electronics Association 1225 Eye Street, SW Washington, DC 20005
IV-D-13	Mr. Carl S. Pavetto Bureau Chief, Bureau of Air Mgmt State of Connecticut Dept. of Environmental Protection 165 Capitol Ave. Hartford, Connecticut 06106
IV-D-14	Mr. Richard A. Valentinetti, Director Air Pollution Control Division State of Vermont Agency of Natural Resources Montpelier, Vermont

TABLE 2-1. LIST OF COMMENTERS ON THE PROPOSED EARLY REDUCTIONS RULE (continued)

Docket Item Number[a]	Commenter and Affiliation
IV-D-15	Mr. Robert P. Miller Chief, Air Quality Division State of Michigan Dept. of Natural Resources PO Box 30028 Lansing, Michigan 48909
IV-D-16	Mr. David R. Jordan, ALAPCO President Mr. Richard E. Grusnick, STAPPA President STAPPA/ALAPCO 444 North Capitol Street, NW Washington, DC 20001
IV-D-17	Mr. John L Wittenborn Mr. William M. Guerry, Jr. Collier, Shannon & Scott 3050 K Street, NW Washington, DC 20007
IV-D-18	Mr. John A. Dege Issue Manager, Clean Air Act DuPont Chemicals Wilmington, Delaware 19898
IV-D-19	Mr. Thomas X. White Assistant Vice-President Pharmaceutical Manufacturers Assoc. 1100 Fifteenth Street NW Washington, DC 20005
IV-D-20	Mr. Dennis R. Lunderville Director, Air Resources Division State of New Hampshire Dept. of Environmental Sciences 64 North Main Street Concord, New Hampshire 03302-2033
IV-D-21	Ashok K. Jain National Council of the Paper Industry for Air and Stream Improvement,Inc. (NCASI) PO Box 14483 Gainesville, Florida 32604

TABLE 2-1. LIST OF COMMENTERS ON THE PROPOSED EARLY REDUCTIONS RULE (continued)

Docket Item Number[a]	Commenter and Affiliation
IV-D-22	Mr. Michael J. Bradley Executive Director Northeast States for Coordinated Air Use Management (NESCAUM) 85 Merrimac Street Boston, Massachusetts 02114
IV-D-23	R.L. Arscott Chevron Corporation PO Box 7924 San Francisco, California 94120-7924
IV-D-24	Mr. Brian L. Taranto Exxon Chemicals Americas PO Box 3272 Houston, Texas 77253-3272
IV-D-25	Mr. Roger D. Randolph State of Missouri Department of Natural Resources PO Box 176 Jefferson City, Missouri 65102
IV-D-26	Mr. Steve Spaw, Executive Director Texas Air Control Board 12124 Park 35 Circle Austin, Texas 78753
IV-D-27	Mr. Ralph F. Hall, Counsel Energy and Environmental Affairs Eli Lilly and Company Lilly Corporate Center Indianapolis, Indiana 46285
IV-D-28	Mr. David W. Dunn Sterling Chemicals PO Box 1311 Texas City, Texas 77592-1311

TABLE 2-1. LIST OF COMMENTERS ON THE PROPOSED EARLY REDUCTIONS RULE (continued)

Docket Item Number[a]	Commenter and Affiliation
IV-D-29	Mr. Lawrence C. Tropea Director Corporate Environmental Control Reynolds Metals Company PO Box 27003 Richmond, Virginia 23261-7003
IV-D-30	Mr. Thomas J. Carr Vice-President, Technical Affairs Motor Vehicle Manufacturers Association 7430 Second Avenue, Suite 300 Detroit, Michigan 48202
IV-D-31	Mr. James D. Boyd Executive Officer State of California Air Resources Board 1102 Q Street Sacramento, California 95812
IV-D-32	E. J. Mazeski Vice-President and Secretary PPG Industries One PPG Place Pittsburgh, Pennsylvania 15272
IV-D-33	Mr. Charles D. Malloch Director, Regulatory Management Monsanto Company 800 N. Lindbergh Boulevard St. Louis, Missouri 63167
IV-D-34	Terry F. Yosie Vice-President American Petroleum Institute 1220 L Street, NW Washington, DC 20005
IV-D-35	Mr. Robert C. Kaufmann Director, API/NFPA Air Quality Program American Paper Institute & National Forest Products Association 1250 Connecticut Avenue, NW, Suite 210 Washington, DC 20036

TABLE 2-1. LIST OF COMMENTERS ON THE PROPOSED EARLY REDUCTIONS RULE (continued)

Docket Item Number[a]	Commenter and Affiliation
IV-D-36	Ms. Mary J. Legatski Director, Government Relations Synthetic Organic Chemical Manufacturers Association, Inc. 1330 Connecticut Ave, NW, Suite 300 Washington, DC 20036-1702
IV-D-37	Ms. Sara Schotland Cleary, Gottlieb, Steen & Hamilton 1752 N Street, NW Washington, DC 20036
IV-D-38	Emil Romagnoli Director, Government Affairs ASARCO Incorporated 1155 Connecticut Ave., NW Washington, DC 20036
IV-D-39	Mr. David Doniger Senior Attorney Natural Resources Defense Council 1350 New York Avenue, NW Washington, DC 20005
IV-D-40	Tipton R. Tyler Basic Acrylic Monomer Manufacturers 1330 Connecticut Avenue, NW Washington, DC 20036-1702
IV-D-41	Mr. Gordon D. Strickland Vice-President Chemical Manufacturers Association 2501 M Street, NW Washington, DC 20037
IV-D-42	Mr. Gordon D. Strickland Vice-President Chemical Manufacturers Association 2501 M Street, NW Washington, DC 20037

TABLE 2-1. LIST OF COMMENTERS ON THE PROPOSED EARLY REDUCTIONS RULE (continued)

Docket Item Number[a]	Commenter and Affiliation
IV-D-43	Mr. Gordon D. Strickland Vice-President Chemical Manufacturers Association 2501 M Street, NW Washington, DC 20037
IV-D-44	Mr. Walter Roy Quanstrom Vice-President Amoco Corporation 200 East Randolph Drive Chicago, Illinois 60680-0703
IV-D-45	Mr. Gordon D. Strickland Vice-President Chemical Manufacturers Association 2501 M Street, NW Washington, DC 20037
IV-D-46	Ms. Barbara Harris Morin Principal Engineer, Division of Air and Hazardous Materials State of Rhode Island and Providence Plantations 291 Promenade Street Providence, Rhode Island 02908-5767
IV-D-47	Mr. Jon Heinrich, Chief Planning Section, Bureau of Air Management State of Wisconsin, Department of Natural Resources 101 South Webster Street Madison, Wisconsin 53707-7921
IV-D-48	Mr. Dale A. Duhon Corporate Environmental Engineer Great Lakes Corporation PO Box 1958 El Dorado, Arkansas 71731

TABLE 2-1. LIST OF COMMENTERS ON THE PROPOSED EARLY REDUCTIONS RULE (continued)

Docket Item Number[a]	Commenter and Affiliation
IV-D-49	Mr. Thomas A. Robinson Vulcan Chemicals PO Box 530390 Birmingham, Alabama 35253-0390
IV-D-50	Mr. Alan T. Roy, Manager Pollution Control Allied Signal Inc. PO Box 831 Hopewell, Virginia 23860
IV-D-51	Mr. Bryce Harthoorn Deere & Company John Deere Road Moline, Illinois 61265-8098
IV-D-52	Mr. J. David Thornton, Section Manager Program Development & Air Analysis Section Minnesota Pollution Control Agency 520 Lafayette Road Saint Paul, Minnesota 55155-3898
IV-D-53	Mr. Vincent Lajiness, Director Environmental Legislative & Regulatory Affairs The Coastal Corporation One Woodward Avenue Detroit, Michigan 48226
IV-D-54	Ms. Louise T. Noell Manager, Product Stewardship BASF Corporation 100 Cherry Hill Road Parsippany, New Jersey 07054
IV-D-55	Mr. Gordon D. Strickland Vice-President Chemical Manufacturers Association 2501 M Street, NW Washington, DC 20037

TABLE 2-1. LIST OF COMMENTERS ON THE PROPOSED EARLY REDUCTIONS RULE (continued)

Docket Item Number[a]	Commenter and Affiliation
IV-D-56	Mr. Milton Feldstein Air Pollution Control Officer Bay Area Air Quality Management District 939 Ellis Street San Francisco, California 94109
IV-D-57	Mr. Nick Nikkila Director of Engineering South Coast Air Quality Mgmt. District 9150 Flair Drive El Monte, California 91731
IV-D-58	Mr. Dennis L. Arfman Mr. Jeffrey W. Schwarz Bradley, Campbell, Carney & Madsen 1717 Washington Avenue Golden, Colorado 80401-1994
IV-D-59	Mr. Leonard D. Verrelli, Chief Air Quality Management State of Alaska Dept. of Environmental Conservation PO Box O Juneau, Alaska 99811-1800
IV-D-60	Mr. Richard E. Grusnick, Chief Air Division Alabama Dept. of Environmental Management 1751 Dickinson Drive Montgomery, Alabama 36130
IV-D-61	Mr. Gordon D. Strickland Mr. Ron Van Mynen Chemical Manufacturers Association 2501 M Street, NW Washington, DC 20037
IV-D-62	Ms. Deborah A. Sheiman Resource Specialist Natural Resources Defense Council 1350 New York Avenue, NW Washington, DC 20005

TABLE 2-1. LIST OF COMMENTERS ON THE PROPOSED EARLY REDUCTIONS RULE (continued)

Docket Item Number[a]	Commenter and Affiliation
IV-D-63	Mr. John M. Clouse, Program Manager Stationary Sources Program, Air Pollution Control Division Colorado Department of Health 4210 East 11th Avenue Denver, Colorado 80220-3716
IV-D-64	Ms. Nancy Wittenberg, Director Department of Environmental Protection State of New Jersey CN 027 Trenton, New Jersey 08625-0027
IV-D-65	Mr. H. Richard Seibert, Jr. National Association of Manufacturers 1331 Pennsylvania Avenue, NW Washington, DC 20004-1703
IV-D-66	Mr. David F. Zoll Vice-President Chemical Manufacturers Association 2501 M Street, NW Washington, DC 20037
IV-D-67	Mr. Peter P. Baljet, Chairman National Air Conservation Commission American Lung Association 1726 M Street, NW Washington, DC 20036-4502
IV-F-1	Public Hearing in the matter of: Proposed Rule for the Early Reductions Provision of Title III of the Clean Air Act. Transcript of Hearing. Research Triangle Park, North Carolina. July 11, 1991, with attachments (Items 1 and 2)
IV-F-1a	Statement of J. Hovious, on behalf of the Chemical Manufacturers Association, before the U. S. Environmental Protection Agency, Research Triangle Park, North Carolina. July 11, 1991.

TABLE 2-1. LIST OF COMMENTERS ON THE PROPOSED EARLY REDUCTIONS RULE (concluded)

Docket Item Number[a]	Commenter and Affiliation
IV-F-1b	Testimony of M.W. Pucci, AT&T, before the U. S. Environmental Protection Agency, Research Triangle Park, North Carolina. July 11, 1991.

[a] The docket number for this project is A-90-47. Dockets are on file at the EPA's Air Docket in Washington, D.C.

number of commenters support the broad definition of source (IV-D-02, IV-D-05, IV-D-08, IV-D-12, IV-D-17, IV-D-19, IV-D-24, IV-D-27, IV-D-28, IV-D-29, IV-D-30, IV-D-32, IV-D-33, IV-D-34, IV-D-35, IV-D-36, IV-D-38, IV-D-49, IV-D-57, IV-D-58).

Response: The definition of source for purposes of Section 112(i)(5) is consistent with the definition of source under Section 112 of the CAA. Nothing precludes different definitions or interpretations of the term "source" in other parts of the CAA. The Title V permitting authority will be required to establish permit limits for a facility during the permit process required by the Title V permit program. It may well be that one permit for a contiguous facility may contain permit limits for multiple Section 112(d) sources. Whether participating in the Early Reductions Program or not, many industrial facilities will be subject to more than one Section 112(d) standard and thus may have more than one Section 112(d) source as part of its permit.

The commenters' conclusion that the EPA should change the definition of "source" to match that of a Section 112(d) source proceeds from an incorrect assumption. The commenters assume that at the time a facility owner or operator undertakes to make early reductions, or enters into an enforceable commitment to do so, a determination of the "source" can be made for purposes of "the otherwise applicable Section 112(d) standard."

However, in many instances, this will not be possible because of the structure of Section 112(i)(5). The Early Reductions provision requires a facility owner or operator to make the reductions prior to proposal of a Section 112(d) standard, or enter into an enforceable commitment to do so before proposal provided the reductions are demonstrated before January 1, 1994. If the otherwise applicable Section 112(d) standard has not yet been proposed and "source" has not been defined for that standard, it would be impossible for an owner or operator to know whether the necessary reductions had been made or could be made to achieve the 90 (95) percent reduction for gaseous and

particulate HAP's, respectively.

As recognized by Senator Durenberger and others, the EPA will have broad discretion in defining "source" for any particular Section 112(d) standard. In some cases, a source will be a process unit, in others it will be an entire plant, (see 126 Cong. Rec. S16927 [3rd col. daily ed. Oct. 27, 1990][1]). Congress could not have meant to so restrict the Early Reductions Program to only those companies who owned or operated emission points that the EPA has clearly defined as a source before proposal of a particular Section 112(d) standard. Moreover, because it would be impossible at this time to identify all possible sources that may be subject to Section 112(d) standards, it is impossible for the EPA to list each and every type of source for the Early Reductions Program.

The EPA's definition of "source" recognizes the flexibility set forth in the statute. The EPA, or the State authority if operating under a delegated program, must review the applicant's Early Reductions submittal to ensure that it is consistent with one of the proposed regulatory definitions under the Early Reductions Program. Given the limitation described above, the EPA developed a definition of source for this provision that is designed to encompass the broad definition of source contained in Section 112(a), which incorporates the broad definition of Section 111(a).

2.1.2 Comment: The multipart definition of source is too broad and will allow for arbitrary groupings of sources. The commenter suggests that the definitions be narrowed to eliminate arbitrary groupings and require functional groupings. In addition, it is suggested that the EPA establish source definitions for Section 112(d) standards as early as possible, and that these definitions be used for the Early Reductions Program (IV-D-46). Another commenter suggested that the definition of source in Section 63.73(a)(1) be expanded to cover all the sources that the EPA is now actively developing standards for and that are expected to be included in the first phase of standard proposals

expected by the end of 1991, including the HON package (IV-D-50, IV-D-64).

Response: The EPA has not yet determined which groups of emission points will constitute a source for any particular Section 112(d) standard. The definition of source is set forth in a manner consistent with the broad statutory definition. Section 112 will establish standards for hundreds of different types of industrial processes and other sources that emit HAP's. It is impossible to determine at this time how source might be defined for any particular source category to be regulated by a Section 112(d) standard. The list of potential source categories to be subject to regulation does not necessarily aid in the definition of source. In some instances, an industrial source category (e.g., a particular type of manufacturing process) may have one source for purposes of a Section 112(d) emission limit. In other instances, multiple sources may be included within any source category, e.g., tanks in a process could be one source and wastewater emissions from the same process may constitute another source within the same source category. The EPA has not yet developed any specific definitions of source for all of the categories listed in 57 FR 31576 (source category listing).[2]

2.1.3 Comment: One commenter contended that the EPA's Section 63.73(a)(1) definition in of source proceeds from an error in equating "source" and "source category," and interprets sources listed in Appendix B as "source categories" (IV-D-39).

Response: The commenter fundamentally misunderstands the EPA's definition of source and how it relates to the "source category." As the commenter suggests, the EPA is to identify source categories that emit HAP's. The EPA is not saying, however, that it must know each category before it can make the linkage to Section 112(i)(5). A "source category" for the purpose of defining industry types to be regulated and the "source" to which a standard specifically applies may be quite different (e.g., in the new source performance standard for electric utilities the applicable "source" is the steam boiler).

The single "source" listed in Appendix B also exemplifies this distinction; this source, equipment leaks, is contained within a source category--the synthetic organic chemical manufacturing industry (SOCMI). Furthermore, equipment leaks are a special situation that the EPA believes should be addressed separately, as equipment leak emissions arise from the pumps, valves, connectors, and other equipment that is integrally associated with a more traditional "source," i.e., building, structure, facility, or installation.

The outcome of a regulatory negotiation involving equipment leaks published by the EPA designated equipment leaks as a separate source (56 FR 9318; March 6, 1991).[3] The EPA proposed the equipment leak rule as part of the hazardous organic national emission standard for hazardous air pollutants (NESHAP)(HON), which will be promulgated under Section 112(d). The publication of the outcome of the regulatory negotiation identifies equipment leaks as a sufficiently distinct source to separate them for the purposes of early reductions. The EPA will determine the definition of source for the HON in that rule.

The EPA is allowing the option of including equipment leaks as part of a designated Early Reductions source, leaving equipment leaks out of the source or identifying equipment leaks solely as the source.

Indeed, once the EPA defines a source category, the issue of the source definition may still remain. In some instances, individual facilities within a source category may constitute an entire source. In other instances, each source subject to a Section 112(d) standard may only constitute a portion of the facility within a source category. Thus, it is the regulated source that is important for the purposes of determining otherwise applicable Section 112(d) standards, not the source category. Because the EPA has not defined source for particular Section 112(d) standards (except in one instance), the EPA's definition reflects the range of possibilities contemplated by the definition of source in the statute.

2.1.4 Comment: One commenter objected to proposed paragraph 63.73(a)(2) and another argued that a plantwide definition of source was expressly prohibited, citing a floor statement by Senator Durenberger (IV-D-39, IV-D-67).

Response: Section 111(a)(1) (incorporated into the definition of "existing source" in Section 112) defines a "stationary source" as "any building, structure, facility, or installation which emits or may emit any hazardous air pollutant." This term is obviously broad enough to encompass an entire plant or facility. In some instances, a Section 112(d) standard may encompass an entire facility, which certainly includes the concept of a plantwide source.

Moreover, the definition of major source, which covers an entire contiguous facility under common ownership or control, may consist of a single stationary source. "Major source" is defined as ". . . any stationary source or group of stationary sources . . ." (see Section 112 (a)(1) of the CAA). Thus, contrary to the commenter's assertions, the definition of source under Section 112 expressly encompasses a plantwide definition of source, among other configurations. The proposed and final regulations reflect that statutory language.

Finally, a closer reading of the complete referenced Durenberger statement expressly confirms that the source to which a Section 112(d) standard might apply could be a specific portion of a facility or encompass an entire contiguous facility (see 126 Cong. Rec. S 16927 [3rd. col.][1]). If the EPA has the discretion to establish a Section 112(d) standard for a source that encompasses an entire contiguous facility, then it follows that an entire contiguous facility may be a source under Section 112(i)(5).

2.1.5 Comment: One commenter objected to the proposed Section 63.73(a)(3) because it allows an applicant to define a grouping of points that constitutes a building, structure, facility, or installation as a source. The commenter cites proposal preamble language that explains that emission points

having a functional or geographical relationship could be defined as a source under this part of the definition and concludes that there is no statutory basis for this type of grouping (IV-D-39).

Response: Subparagraph 63.73(a)(3) directly follows the definition of source in the statute. As noted, a "stationary source" is any "building, structure, facility or installation which emits, or may emit, any hazardous air pollutant" (see Section 111(a)(3) of the CAA). The phrase "functional or geographical relationship" merely gives meaning to the statutory terms. For example, a "building" suggests a geographical grouping of emission points (it may also have a functional relationship). Likewise, an "installation" suggests some type of unit that undertakes a particular function, such as a wastewater treatment system. As the EPA develops Section 112(d) standards, it will define "source" for particular standards considering these types of logical groupings of emission points. However, because the EPA has not yet defined what will constitute a "source" for a particular Section 112(d) standard prior to its proposal (with the single exception noted earlier), the language of this rule reflects the range of options available within the statutory definition.

2.1.6 Comment: Several commenters contended that subparagraphs (a)(4) and (a)(5) of the proposed definition are contrary to the statute because they allow "bubbling" across two or more sources. One commenter noted that previous guidance from the EPA precluded the use of "bubbling" to avoid Section 112(d) standards (IV-D-06, IV-D-39, IV-D-67).

Response: As discussed in the proposed rule, the EPA believes that the provisions of Section 63.73(a)(4) and (5) are consistent with the statute and the underlying purposes of the Early Reductions provisions. However, the EPA is deleting subparagraph (a)(4) because (a)(4) is redundant with the

provisions of (a)(5), as any combination of emission points that would meet the language of proposed paragraph (a)(4) would also fit with the language of (a)(5).

The EPA has concluded that unrelated emission points may be considered as a single source for purposes of the Early Reductions Program, provided that the emission points are all under common ownership or control and are located "within a contiguous area" such as a common plant site and constitute a significant level of emissions. The individual emission points to be aggregated do not have to be located next to one another or be functionally related in order to be grouped as a source, provided that they are all located within the same contiguous facility.

The conclusion that aggregating unrelated emission points is permissible for purposes of the Early Reductions Program is confirmed not only by the statutory language and case law discussed above, but also by the statutory policies and legislative history of the Early Reductions Program. In Section 112(i)(5)(E), Congress authorized a form of emissions trading by allowing offsetting reductions of one HAP against reductions of other HAP's for purposes of the Early Reductions Program. Aggregation of emission points is merely another form of emissions trading.[a]

Nevertheless, the rule is not inconsistent with the general emissions trading policy referenced by the commenter (51 FR 43814; December 4, 1986),[4] i.e., that "bubbling" may not be used to avoid a Section 112(d) standard. The Early Reductions

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[a]This conclusion is limited to the context of the Early Reductions Program for several reasons. In particular, Congress specifically contemplated netting one hazardous pollutant against another for purposes of the Program. Congress indicated in the legislative history that it wishes the EPA to encourage participation in this Program to obtain early reductions (see discussions below); and the statutory requirement of 90 percent reductions raises quite different factual and policy issues than might be applicable elsewhere.

provision does not provide a mechanism for a source to avoid applicability of a Section 112(d) standard. Rather, it provides for compliance extension in the form of an alternative emission limit for the source for a period of 6 years in exchange for the source having achieved a certain emissions reduction level by a specified date (either by January 1, 1994, or before proposal of an otherwise applicable Section 112(d) standard). The source must meet the Section 112(d) standards when the compliance extension has expired.

Moreover, the legislative history indicates that Congress wanted the EPA to encourage participation in the Program (see H.R. Rep. No. 101-490, 101st. Cong., 2d Sess. 332 [May 17, 1990][5]: "In the administration of this provision the EPA thus should strive to encourage companies to take advantage of this incentive to reduce emissions early."). In addition, the significance threshold (i.e., 10 tons per year [tpy], or 5 tpy at a contiguous plant site less than or equal to 25 tpy) is designed to ensure that substantial real reductions are achieved and that the Program is not trivialized. The flexibility afforded through aggregating emission points offers greater incentive to participate in the Early Reductions Program. Greater overall participation in the Program, combined with the minimum threshold for early reductions achieved, will help ensure that the reductions achieved under the Program are both real and substantial and the concomitant environmental benefits maximized.

The commenter argues further that the random pooling approach that allows for credits undertaken in the past demonstrates that subparagraph (a)(5) is inconsistent with the purposes of the statute. The commenter argues that the justification for random pooling--to encourage greater participation in the Program and thereby reduce air toxics emissions--is not present if a source can include past reductions in the pool. The commenter concludes that any pollution reduction measure undertaken prior to the enactment of the law cannot have been dependent on the incentive of pooling. The

commenter acknowledges that past reductions can be credited, but that they should not be pooled with unrelated, uncontrolled emission points to demonstrate an early reduction.

The statute affords a 6-year extension for those sources that achieve a 90 (95) percent reduction in emissions by a specified time. Those emission reductions may have occurred at any time back to 1987, and in limited instances 1985 or 1986. The commenter assumes that the only time applicants will use the grouping of emissions points under proposed paragraphs (a)(4) and (a)(5) is to get credit for past actions, while making no additional reductions, and obtaining a 6-year extension for remaining uncontrolled emission points within the Early Reductions source. This will not be the case. The EPA has discussed tentative Early Reductions plans with many companies and has received several enforceable commitments that indicate that the flexible definition of source is encouraging prospective emission reduction projects.

In many instances, the EPA expects that an applicant will group some recently well-controlled emission points with others, some or all of which may have controls installed on them. The ability to apply credits in excess of 90 (95) percent reduction from one point to a point unable to achieve 90 (95) percent by itself provides an incentive to control the second point enough to cover the shortfall.

For example, suppose the applicant previously controlled a 100-ton emission (point A) to a 98-percent control level, i.e., it now emits 2 tons of HAP's. The applicant also has a second 100-ton uncontrolled emission (point B). Existing control measures for point B indicate that maximum achievable control technology (MACT) will likely require at least 90-percent reduction. However, a much less expensive technology can reduce emissions from point B by 85 percent, i.e., to 15 tons.

Furthermore, the owner has determined that a net savings would be realized if 85 percent control could be implemented now and MACT implemented 10 years later, compared with meeting MACT

in 4 years. The extra time gained from a compliance extension would also allow development of process modifications that would completely eliminate HAP emissions from the source. Without proposed paragraph (a)(5), the applicant will have no incentive to install any controls on point B prior to a Section 112(d) standard because that point by itself will not be reduced by 90 (95) percent, short of installing MACT control anyway. However, if an additional 5 tons can be credited from emission point A, the source will have an incentive to participate in the Program by including points A and B, and thereby substantially reduce overall air toxics emissions from that source.

Without the option of proposed paragraph (a)(5), the source would not seek a compliance extension for point B and would have no incentive to enter the Program, and the emissions from the two points will be 102 tons. By entering both points in the Program using proposed paragraph (a)(5), the source's emissions will be 17 tons, which is greater than a 90 (95) percent reduction from the original 200 tons being emitted by the two points. Moreover, there is no basis in the law for penalizing those that made reductions between 1987 and the passage of the CAA Amendments of 1990 in defining a source.

2.1.7 Comment: A number of commenters believe that Section 63.74(b) of the regulation, which defines significant emissions, unnecessarily restricts participation in the Program by small (but major) stationary sources. The cost and burden of the reduction demonstration will prevent trivial submissions (IV-D-05, IV-D-12, IV-D-23, IV-D-28). Other commenters further suggest that the limits be set at 3 tpy for 25-ton-or-greater facilities and 1 tpy for less-than-25-ton facilities (IV-D-34, IV-D-44). One commenter suggested adding "20 percent of the HAP emitted in the base year from the entire contiguous facility" to the significance definition (IV-D-38). Another commenter agrees that the Early Reductions Program should focus on major emitters (i.e., 10 tpy or 5 tpy at 25-ton facilities) (IV-D-08). Another commenter feels that the definition of significant should include

only 10 tpy sources. Allowing sources that emit 5 tpy at 25 tpy sources allows resources to be wasted on small sources (IV-D-26). Finally, one commenter supports the concept of significant emission reduction as it applies to the definition of source, but pointed out that the multiple definition of source may make review time longer than anticipated by the EPA because of it's complexity (IV-D-47).

Response: The EPA's definition of source is designed to provide broad flexibility in defining source for purposes of the Early Reductions provisions. The goal is to encourage widespread participation in this Program to achieve early reductions of air toxics emissions. The significance threshold included in Section 63.73(b) is designed to ensure that significant reductions occur. It is important to point out, however, that the 5 to 10 ton threshold of significant emissions applies to only subparagraph (a)(4) (formerly (a)(5) in the proposed rule; proposed paragraph (a)(4) has been deleted in the final rule). Thus, any process unit or other entity that meets any definition in (a)(1) through (a)(3) is eligible for an Early Reductions extension, even if it emits less than the 5 or 10 ton threshold. Thus, the EPA anticipates that, in most instances, even smaller facilities will be able to participate in the Program.

Although EPA could have considered other thresholds, such as 3 tons/25 tpy or 20 percent of any plant's emissions, as suggested by some commenters, the levels chosen are a reasonable attempt to balance the various factors involved, including allowing participation and ensuring significant reductions.

2.1.8 Comment: Within the source definition developed by Section 63.73(a)(3), it is not clear if an applicant has the choice of designating two or more common facilities (those servicing more than one production unit) as two or more sources or whether it is necessary to define all common facilities as a single source. The commenter requests clarification of this issue (IV-D-50).

Response: Under Section 63.73(a)(3), it is possible to define a unit, such as a wastewater treatment system that serves multiple parts of an entire plant, as a single source.

2.1.9 Comment: The definition of "process or production unit" should be expanded to state that a process or production unit can contain many sources or can be a part of a larger single source (IV-D-02).

Response: The current regulation does not use the terms "process or production unit." The current source definition allows source to be defined as a group of emission points that can be identified as a facility, building, structure, or installation for the purposes of establishing standards under Section 112(d) of the CAA. Under this definition, a process unit would certainly qualify. The definition of source also allows for any combination of emission points, provided that the emission reductions are significant, i.e., greater than 10 tpy at a facility that emits greater than 25 tpy or 5 tpy at a facility that emits 25 tpy or less.

2.1.10 Comment: The source definition should specify that an "entire facility under common ownership or control" may include facilities with different Standard Industrial Classification (SIC) codes at the same location (IV-D-02).

Response: The CAA, and now the Early Reductions regulation, describe a contiguous "area" under common ownership or control. The definition of source allows a facility to include different SIC codes, as long as the portions of the facility are under common ownership or control. In addition, proposed paragraph (a)(5) (now paragraph (a)(4)) of Section 63.73 of the rule allows combinations of emission points, provided that the emission reduction from such combinations is significant. Therefore, emission points with different SIC codes may be combined as a source, as long as the source, as defined by the owner or operator, meets one of the source definitions contained in the regulation.

2.1.11 Comment: Research operations should not be included in the source definition for early reductions because the pollutants and emissions from these operations are highly unpredictable (IV-D-08).

Response: The Early Reductions Program allows the owner or operator the option of including or excluding emissions from research facilities in the definition of source. The predictability of emissions from research operations may vary from source to source. There may be a research operations source that has predictable emissions. If a source includes research operations and the base year or post-reduction emissions prove not to be sufficiently reliable or well-documented, Section 63.78(b)(3) of the regulation allows the permitting authority to deny the application. If the emissions are reliable and meet the requirements of Section 63.74, research facilities defined as part of a source may be granted an extension.

2.1.12 Comment: Once a group of emission points has been accepted as a source by the EPA, the source definition should remain constant throughout the Program. When a Section 112(d) standard is proposed, the definition of source in the standard should not affect the already defined source (IV-D-27).

Response: Once an individual source is defined and accepted by the EPA as part of the Early Reductions Program, the Early Reductions source will not change as a result of a Section 112(d) standard. Any particular Section 112(d) standard may apply to the entire Early Reductions source or to a subset of emission points within that source. All emission points included in the defined Early Reductions source are entitled to a six-year extension from all otherwise applicable Section 112(d) standards. At the end of the 6-year period, emission points within the Early Reductions source affected by the earliest applicable Section 112(d) standard must meet those standards. Emission points not affected by the earliest Section 112(d) standard, must continue to meet the alternative emission limitation until six years after the compliance date of any Section 112(d) standard

applicable to the emission point. Any emission points not included in the Early Reductions source definition, but included in the source definition for a Section 112(d) standard must achieve reductions according to the compliance schedule in the applicable standard.

2.1.13 Comment: An owner or operator should have the flexibility to redefine the source during the 6-year extension period if a decision is made to restart a shutdown portion of the source or if significant process changes are made. The new source could exclude the restarted or changed portion but must continue to achieve 90 (95) percent reduction from base year emissions (IV-D-29).

Response: Once an individual source is defined and accepted by the EPA as part of the Early Reductions Program and the source has been granted a 6-year extension by permit, the source cannot be redefined. If a portion of the original source restarts or expands, those emissions must be accounted for in the post-reduction emissions. If part of a source shuts down or curtails production, and production of the same product is increased at another unit or is replaced by a new unit at the plant site that was not included as part of the original source, the HAP emissions from the increased production outside of the Early Reductions source must be accounted for as well. This is to ensure that emissions from the source are not simply moved elsewhere in the plant. Owners and operators must give careful consideration to the designation of "source" when applying for the Early Reductions Program in light of potential future expansions.

If an owner or operator anticipates increased production in certain areas of a facility, several options are available. The flexibility of the source definition allows the applicant to define a source that does not include the portion of the facility that may expand. The applicant may also reduce emissions from the base year by greater than 90 (95) percent, thereby allowing for subsequent increases in emissions that would still meet the

required reduction. If the owner or operator can anticipate what changes will be made to the source, the owner or operator may coordinate with the State to determine the most appropriate type of alternative emission limitation (i.e., a numerical emissions limitation for each emission point or other requirement) that may allow more flexibility for expanding one portion of the source. The EPA recognizes that process changes are necessary, but to participate in this Program, overall source emissions must remain at a level that is 90 (95) percent of the base year emissions. The permitting authority may revise or adjust alternative emission limits through permit modifications, as appropriate, provided that the overall 90 (95) percent reduction for the source is maintained during the extension.

2.1.14 Comment: The source definition is confusing. The paragraph states that "emission reductions from a source are considered significant if..." but proceeds to define the base year emissions of the facility and not the reductions. Change the language to establish a size threshold (IV-D-59).

Response: The purpose of the Early Reductions Program is the reduction of emissions. The purpose of the significance test is to focus resources on significant emission reductions. Such reductions are quantitatively linked to the base year emissions because the emission reduction is 90 (95) percent of the base year. Therefore, in order to determine if "significant" reductions can result from a source, base year emissions must be established.

2.1.15 Comment: The regulation needs to clarify what happens when the Section 112(d) source definition is different from the Early Reductions Program source definition (IV-D-59).

Response: Emission points that are part of the source defined for the Early Reductions Program are granted a 6-year extension from compliance with an applicable Section 112(d) standard. Any emission point that is not part of an Early Reductions source must comply with appropriate Section 112(d) standards. At the end of the 6-year extension, emission points

that are part of an Early Reductions source must then meet Section 112(d) or Section 112(f) standards if the standards apply to those emission points.

Emission points within the Early Reductions source that are not covered by a Section 112(d) standard will be required to continue meeting the 90 (95) percent reduction specified by the original alternative emission limitation. This emission limitation must be met until 6 years after the compliance date of the last applicable Section 112(d) standard that affects the source.

This scenario will create a staggered reduction of emissions from the Early Reductions source as various Section 112(d) standards are promulgated and the 6-year extensions to each standard expire. Eventually, all emission points at a facility will be in compliance with any applicable Section 112(d) or Section 112(f) standard. It should be noted that after the 6-year extension, at which time some emission points of the original Early Reductions source will apply the Section 112(d) standard, the source may not average increased reductions from these emission points to achieve 90 (95) percent reduction from the Early Reductions source. The emission points not covered by the Section 112(d) standard must comply with the alternative emission limitations set by the permit as if the other emission points now covered by Section 112(d) were continuing to emit at the level prior to installation of the control required to meet the Section 112(d) standard.

2.1.16 Comment: In the source definition, (a)(2) and a(5) do not include references to Section 112(d). Is it assumed that only sources listed in accordance with the provisions of the CAA are to be included in the early reductions calculations (IV-D-52)?

Response: Any source submitted that meets the definition of "source" as described in Section 63.73 of the Early Reductions regulations will be accepted as a source under the Early Reductions Program. The paragraphs in the regulation do not

refer to the CAA because it is not necessary for an Early Reductions applicant to be on the list of source categories to be covered by Section 112(d) standards.

2.1.17 Comment: The final rule should include guidelines that would allow emission increases to occur during the extension period without jeopardizing the extension. The commenter feels this flexibility is needed to encourage participation in the Program without impeding possible growth and expansion of facilities (IV-D-50). Another commenter requested that the rule specify how equipment moves or process changes within a source with an approved permit under the Early Reductions Program will be handled (IV-D-27, IV-D-28). Another commenter suggested that the EPA allow emission increases with production increases in one portion of the source if HAP emissions from other portions of the source are further reduced to offset the increases (IV-D-45).

Response: If an owner or operator anticipates increased production in certain areas of a facility, several options are available. The flexibility of the source definition allows the applicant to define a source that does not include the portion of the facility that may expand. The applicant may also reduce emissions from the base year by greater than 90 (95) percent, thereby allowing for subsequent increases in emissions that would still meet the required reduction. If the owner or operator can anticipate what changes will be made to the source, the owner or operator may coordinate with the State to determine the most appropriate type of alterative emission limitation (i.e., a numerical emissions limitation for each emission point or other requirement) that may allow more flexibility for expanding one portion of the source. The EPA recognizes that process changes are necessary, but to participate in this Program, overall source emissions must remain at a level that is 90 (95) percent of the base year emissions. The permitting authority may revise or adjust alternative emission limits through permit modification, as appropriate, provided that the overall 90 (95) percent reduction for the source is maintained during the extension.

2.1.18 Comment: The proposed rule should clarify what happens to an existing Early Reductions permit in the event that the source adds a new line identical to those included in the source that has been given a 6-year extension. Must the new line comply with Section 112(d) or can it be added to the source (IV-D-33)?

Response: In most cases, new emission points will not be able to participate in the Early Reductions Program. The CAA specifies that a compliance extension may be granted only to an existing source. New emission points would thus be outside the scope of the Early Reductions source and, therefore, would be subject to Section 112(d) standards, if previously proposed.

The only exception occurs when the entire plant site or an entire enclosed building is defined as the source by the applicant and a "new" process unit is constructed within the plant site or building, respectively, and emits less than 10 tpy of HAP's. The new unit must then be included as part of the Early Reductions source and the source must maintain the original 90 (95) percent emission reduction from base year emissions. Emissions from the existing points in the original source must, therefore, be reduced to compensate for the additional emissions from the new points. If, however, emissions from the new line exceed 10 tpy of a single HAP or 25 tpy of total HAP's, the new unit is considered, for the purposes of Early Reductions only, a source by itself and thus would not be part of the original Early Reductions source, regardless of the source definition.

The EPA will distinguish between existing sources and new sources in other rules. However, the Early Reductions Program will occur before proposal of Section 112(d) standards and before other rules that will distinguish between existing and new sources are finalized. Furthermore, the Early Reductions Program applies only to existing sources. Therefore, the EPA had to make an administrative determination for the purposes of Early Reductions that new units emitting greater than 10 tpy of total HAP's are new sources. The EPA may distinguish between new sources and existing sources differently in other rulemakings.

2.2 BASE YEAR EMISSIONS

2.2.1 Comment: The commenter suggests that 1990 be used as the base year in order to be consistent with Title I. There is concern that the use of earlier base years may result in many companies qualifying because of reductions in emissions that have resulted from economic downturns or other external factors (IV-D-46).

Response: The CAA specifically states that the base year not be earlier than 1987. However, the owner or operator may choose 1985 or 1986 as the base year if the source can demonstrate that EPA received the supporting HAP emissions data pursuant to an information request under Section 114 the EPA prior to November 15, 1990. The EPA is allowing the owner or operator to choose any base year after 1986 to provide maximum flexibility. However, emission data developed during years other than the base year, including years prior to 1985, can be used for determining base year emissions if the data are representative of operating conditions in the base year. Owners or operators will have to demonstrate the applicability of these data to base year conditions.

2.2.2 Comment: Two commenters were concerned with potential delays in the review process and suggest that base year emissions be automatically accepted if the EPA does not complete the review in a specified time frame (IV-D-02, IV-D-45).

Response: The EPA's goal is to review all enforceable commitments and submittals within the times identified in the rule. However, the EPA intends to adequately review all submittals, and will take whatever time is necessary to ensure that the applications are complete and verifiable. The EPA will not automatically accept base year emissions that have not been reviewed because of time constraints. The purpose of reviewing base year emissions early is to provide some assurance to the submitter that the base year emissions for early reductions will be approved at permit review.

2.2.3 Comment: Some facilities reported data to the EPA in 1984 and would like these data to be acceptable as base year emissions (IV-D-05).

Response: The CAA specifically states that the base year not be earlier than 1987. However, as noted above, an owner or operator may choose 1985 or 1986 as the base year only if the source owner or operator can demonstrate that EPA received the supporting data pursuant to an information request under Section 114 prior to November 15, 1990. However, emission data developed during years other than the base year, including years prior to 1985, can be used for determining base year emissions if the data are representative of operating conditions in the base year. Owners or operators will have to demonstrate the applicability of these data to base year conditions.

2.2.4 Comment: Once base year emission data have been reviewed and accepted by the EPA, no further auditing of such data should be allowed (IV-D-09, IV-D-19, IV-D-34, IV-D-35). Another commenter requested that if early base year review is retained, any presumption of "clearance" for such base year be dropped (IV-D-39).

Response: Acceptance of base year emission data does not provide an absolute shield against revision should the data later be found incorrect. Reviewers and commenters are urged to present any criticisms during the early review period regarding base year data. Applicants can make appropriate modifications at that point and proceed with reasonable confidence that their emissions are acceptable. Base year emissions that have been reviewed and approved are still subject to additional review if errors or fraud are discovered at a later date. Discovery of incorrect or fraudulent information in the emission data or supporting materials after initial approval could potentially invalidate the base year and/or require the applicant to make revisions.

2.2.5 Comment: Base year emissions that are substantially greater than other years should be acceptable as long as the

emissions were within permit levels because production rates vary (IV-D-29, IV-D-35).

Response: The CAA specifically states that base year emissions cannot be "artificially or substantially greater than emissions in other years prior to implementation of emissions reduction measures." Permit levels are simply a maximum acceptable emission limit and may not reflect "actual and verifiable" emission levels as required by the CAA. Therefore, comparison of base year emissions to permit levels does not determine the relationship of base year emissions to emissions in other years. Even emissions well within permit levels, but substantially greater than other years, would not be allowable. For example, a permit may be written to allow 100 tpy, but if the source was emitting 30 tpy in years other than the base year, base year emissions of 60 tons would not be allowable. It is clearly the intent of the CAA to avoid the use of unusually high emission levels to count towards the base year, which would lead to overstating reductions achieved and minimize the benefits to the environment achieved by the Early Reductions Program.

2.2.6 Comment: The commenters believe that use of the EPA's average emission factors for estimating base year equipment leak emissions should be allowed (IV-D-02, IV-D-05, IV-D-08, IV-D-11, IV-D-19, IV-D-28, IV-D-34, IV-F-1a).

Response: Average equipment leak emission factors developed by the EPA generally may not be used in establishing base year emissions. Use of the EPA's average emission factors for base year emissions would artificially inflate the base year estimate. Subsequent use of a more source-specific method for the post-reduction demonstration would result in lower estimated emissions, but, in fact this would only be a "paper" reduction. As mentioned in the preamble to the proposed regulation, source owners or operators can establish emission levels for equipment leaks using any procedure except for average emission factors established in the document entitled "Protocols for Generating

Unit Specific Emission Estimates for Equipment Leaks of VOC and VHAP," EPA-450/3-88-010, October 1988.[6]

The EPA has considered allowing use of average emission factors to establish equipment leak emissions only in the case where no equipment leak emission reduction will be claimed; i.e., when equipment leak emissions are the same in the base year and post-reduction. The EPA is allowing this exception because it will result in greater actual emission reductions from the source. The source will have to control nonequipment leak emission points to a greater extent to compensate for the over-estimate of the post-reduction equipment leak emissions. In addition, it is noted that equipment leaks must be less than 10 percent of base year source emissions, or the source could not achieve a 90 (95) percent overall reduction.

Appendix B has also been clarified to better describe the equipment leak "source." The negotiated regulation for equipment leaks (56 FR 9315; March 6, 1991)[7] requires that certain equipment in HAP service within a process unit to which the equipment leak standards apply must be viewed as a whole. This means that valves, pumps, or connectors within a process unit must be considered together because the regulation is written in terms of percent leaking components across a process unit. In other words, valves, pumps, or connectors cannot be split up such that, for example, some of the valves in a process unit have an Early Reductions alternative emission limitation and the others meet the Section 112(d) standard. For example, it must be that either all valves within a process unit are in the Early Reductions Program or none are. A "process unit" is a collection of equipment associated with a unit process operation, including storage and transfer of feed materials to the operation and final or intermediate product from the operation, and operations treating wastewater from the unit process operation.

The logic for requiring inclusion of all the valves, pumps, or connectors from a process unit would not extend to the other equipment covered by the equipment leak rule, such as

pressure relief devices or product accumulator vessels, which will be subject to individual standards applicable to each device or vessel. Equipment subject to such "piece-specific" standards could individually be assigned alternative emission limits as part of an Early Reductions source or meet the Section 112(d) standard, and are not constrained by the process unit coverage.

2.2.7 Comment: The commenter would like to narrow the scope of HAP emissions to cover only major emission points that are more quantifiable (versus numerous small emission points that may not have data) (IV-D-09).

Response: Hazardous air pollutants are produced by both major and minor emissions points. Although it would be easier to cover only the major points, minor points may be numerous and contribute significantly to total HAP emissions or be responsible for many high-risk pollutants that have a great impact on human health. Therefore, both major and minor emission points must be accounted for in determining base year and post-reduction HAP emissions.

2.2.8 Comment: The commenters would like Toxics Release Inventory (TRI) data to be acceptable for submission as base year emissions data if the source for which the compliance extension is being requested is consistent with the source definition for which the TRI data apply (IV-D-12, IV-D-19, IV-D-27, IV-D-30, IV-F-1b).

Response: The TRI data alone are not sufficient to support base year emissions. The Early Reductions Program requires more rigorous support for emissions data than is required by TRI. If the supporting information for the TRI data meets all the requirements of the Early Reductions Program, then that information will be acceptable. Supporting documentation for the Early Reductions Program must stand on its own merits.

2.2.9 Comment: Concerning base year emissions, the regulation should clarify the term "substantially greater" than other years (IV-D-27, IV-D-52).

Response: The determination of "substantially greater" is necessarily subjective. "Substantially greater" will be determined in large part by historical emissions variations of the source and the reasons for the variations. If an application is denied because base year emissions are found to be "substantially greater" than other surrounding years, the reviewer will provide rationale for this determination. Each base year review will be judged on a case-by-case basis. The enabling document ("Enabling Document for Regulations Governing Compliance for Early Reductions of Hazardous Air Pollutants," EPA-450/3-91-013, November, 1992)[8] provides guidance to reviewers and submitters to better understand what is "substantially greater." To avoid later problems with this issue, it is recommended that the applicant request a preapplication conference to discuss the specific details surrounding base year emissions. The preapplication meeting should be held with the appropriate EPA Regional Office and the State.

2.2.10 Comment: Early Reductions applicants should not be required to submit evidence that base year emissions are not artificially high or that emission reductions due to lower production rates or shutdown are permanent. The seriousness of violating Section 114 and being subject to enforcement provisions of Section 113 make it unnecessary that an owner or operator be required to submit evidence in the permit application. Evidence should be provided only at the specific request of the reviewing agency (IV-D-08).

Response: Early Reductions applicants will be required to submit evidence demonstrating that base year emissions are not artificially high. Submission of this information provides reasonable assurance to the applicant that base year emissions will be acceptable for an Early Reductions demonstration, except in the case of error or submittal of fraudulent information. Prior approval of base year emissions facilitates the Title V application review process where the actual reduction demonstration is made.

The regulation has been changed with regard to providing evidence of lower production rates and shutdowns. Sources will not be required to show evidence that lower production rates or shutdowns are permanent for the extension duration. This will be accomplished by making the shutdown or lower production rate conditions of the Title V permit.

2.2.11 Comment: The proposed rule should provide guidance for the assessment of trace pollutants and impurities. There should be a minimum amount required to make an assessment (IV-D-32, IV-D-50, IV-D-60).

Response: Trace pollutants and impurities will be handled on a case-by-case basis. General policy would be difficult to develop for all pollutants. For example, small quantities of dioxin may be considered significant while the same quantity of another non-high-risk pollutant would be considered an inconsequential trace amount.

Based on process and product knowledge, owners or operators should be aware of the possible presence of HAP's in their source emissions. If trace quantities of HAP's are expected or known to be emitted, owners or operators should account for their presence. The actual determination of the quantity of emissions may be similar to the determination for small, insignificant emission points. Generally, testing will not be required. The source owner or operator may make conservative assumptions in the calculations used to determine the quantity that may be emitted. If trace HAP's are neither expected nor known to be present, then there is no need to make an assessment. The EPA expects participants in the Program to quantify all HAP's reasonably expected to be present.

2.2.12 Comment: The EPA should provide guidance regarding: (1) how sources should measure fugitive emissions covered by the Section 112(d) standard and those not covered by the Section 112(d) standard, (2) what supporting documentation will be required to be submitted for sources relative to their measurements of fugitive emissions and, (3) whether the

measurements for fugitive emissions sources that are covered by the Section 112(d) standard will be more or less quantitative than the fugitive emissions sources that are not covered by a the Section 112(d) standard (IV-D-32).

Response: As mentioned in the preamble to the proposed regulation, source owners or operators can establish emission levels for equipment leaks using any procedure except for average emission factors established in the document entitled "Protocols for Generating Unit Specific Emission Estimates for Equipment Leaks of VOC and VHAP," EPA-450/3-88-010, October 1988.[6] Average EPA equipment leak emission factors may generally not be used in establishing base year emissions. Use of EPA average emission factors for base year emissions would artificially inflate the base year estimate. Subsequent use of a more source-specific method for the post-reduction demonstration would result in lower estimated emissions, but, in fact, this would only be a "paper" reduction. As discussed in a previous comment, EPA will allow use of average emission factors to establish equipment leak emissions only in the case where no equipment leak reduction will be claimed; i.e. equipment leak emissions are the same in the base year and the post-reduction year.

The same extent of documentation is required for equipment leak emissions as is required for all other emission points outlined in Section 63.74(d) of the regulation. Acceptable techniques to establish equipment leak emissions are described in the "Protocols" document mentioned earlier. If an owner or operator would like to use a different emission estimation technique based on like sources or some other information, these techniques will be discussed on a case-by-case basis at a preapplication meeting. Owners or operators who wish to submit equipment leak estimates based on another technique are encouraged to schedule a preapplication meeting. Finally, the Early Reductions Program has no bearing on equipment leak sources that are affected by standards other than those in

Section 112(d). These equipment leak sources must meet the measurement requirements of whatever standards apply to them.

2.3 ENFORCEABLE COMMITMENTS

2.3.1 Comment: The only penalty for a source that fails to achieve an enforceable commitment should be reversion to the applicable Section 112(d) standard. The source should be treated as though it never submitted an Early Reductions application or enforceable commitment (IV-D-02, IV-D-24).

Response: The regulations give applicants submitting an enforceable commitment ample time to reconsider their commitments and allow them to rescind commitments by December 1, 1993, without penalty. However, once that deadline has passed, applicants must show that they have achieved the required reductions by January 1, 1994, or be subject to penalties. If a source does not achieve reductions by January 1, 1994, the source will not receive a 6-year extension for compliance with Section 112(d) standards. Failing to meet the enforceable commitments without penalty would defeat the intended purpose of Congress.

2.3.2 Comment: The proposed rule needs to clarify the apparent inconsistency for submittal of revised data. In one paragraph the rule reads "EPA is not proposing a time limit for submittal of revised data." In another it states "If the revised base year emissions data are not received by the reviewing agency within 90 days of notifying the applicant of disapproval of base year emission data, the source will be considered to have withdrawn the enforceable commitment and a notice to that effect will be sent to the applicant" (IV-D-30).

Response: Base year emissions that are submitted as part of an enforceable commitment must be revised and resubmitted, or notification of intent to revise and resubmit must be accomplished within 90 days after notification of disapproval or the application will be considered by the EPA to be withdrawn. This allows the reviewing agency to recognize in a timely fashion which commitments will be revised and which will be rescinded.

Because of the large number of applications expected to be received by the EPA, a deadline for resubmittal or notification of intent to continue in the Program is necessary to expedite the review process and to identify those sources that do not wish to pursue reduction demonstration. A withdrawal alerts the reviewing agency not to pursue penalties after January 1, 1994 if the source fails to meet the required reductions. Base year emissions that are submitted for early review and not as part of an enforceable commitment do not have a deadline for resubmittal. The regulation has been clarified to distinguish the differences between resubmittal schedules.

2.3.3 Comment: A grace period should be allowed for sources that cannot make commitment deadlines because of external forces beyond their control (e.g., delay by the permitting authority to approve a modification in the control plan) (IV-D-19).

Response: The CAA requires that the reductions specified in the commitment must be achieved by January 1, 1994 in order for a source to receive a Section 112(d) compliance extension. The Early Reductions regulations allow test data to demonstrate that the reductions have been achieved to be received as late as March 31, 1994. The reductions, however, must have been achieved by the date specified by the CAA. If a source cannot achieve the reductions required by the enforceable commitment, the applicant may rescind the commitment as late as December 1, 1993 without penalty. Therefore, the applicant should have adequate time to assess whether or not the source can achieve the reductions and to take whatever action he deems appropriate.

2.3.4 Comment: The EPA should delay the January 1, 1994 deadline, if possible, to allow completion of major reduction projects (IV-D-28).

Response: The CAA specifically states that enforceable commitments must be achieved before January 1, 1994. This date cannot be changed without Congressional amendment of the CAA.

2.3.5 Comment: The commenter suggests that once an enforceable commitment is accepted, the only demonstration a source should

need to make to be issued a Part 70 permit is that everything outlined in the enforceable commitment has been completed. The permitting agency should not be given the opportunity to second-guess the plan presented in the enforceable commitment (IV-D-44).

Response: The control plan outlined in the enforceable commitment is a general, nonbinding strategy that the facility will implement to reduce emissions and is not enforceable. The facility develops the plan with the goal of reducing emissions by 90 (95) percent. As the facility implements the plan, however, it may discover that the emission reduction can be better met with another control strategy. The control plan presented in the enforceable commitment must, therefore, remain somewhat flexible. The general plan is required to assure the reviewing authority that the reductions can be achieved and that the source owner or operator has given serious consideration to achieving early reductions. The control plan will not likely be questioned or denied unless the plan indicates that the required reductions will not be met or the plan does not appear reasonable. The ultimate test will not be whether or not the described control plan will be followed, but a demonstration that the reductions have actually occurred.

2.3.6 Comment: The deadline for submittal of enforceable commitments should be delayed as much as possible. The early dates will cause a flood of nonachievable commitments because facilities did not have time to evaluate the situation before the deadline (IV-D-28).

Response: The CAA specifies that enforceable commitments must submitted prior to proposal of an applicable Section 112(d) standard. This date cannot be changed without Congressional amendment of the CAA. Nonachievable commitments can be rescinded up to December, 1, 1993.

2.3.7 Comment: In addition to base year emissions, public comments should be solicited on the proposed control plan (IV-D-04).

Response: The public will be able to review control plans that are included as part of the base year review and enforceable commitment applications. However, approval or disapproval of the application will not be dependent on the proposed control strategy. Facilities will have some flexibility in meeting their enforceable commitment as long as the reductions are 90 (95) percent of the base year emissions.

2.3.8 Comment: How do sources submit an enforceable commitment before proposal of a Section 112(d) regulation if the regulation is proposed before the Early Reductions regulations are promulgated (e.g., the SOCMI/HON sources) (IV-D-27)?

Response: Sources covered by Section 112(d) regulations scheduled for proposal prior to promulgation of the Early Reductions regulations should submit an enforceable commitment according to guidelines provided in the proposed regulation. If changes in the promulgated Early Reductions regulations affect a submittal based on the proposed regulations, the applicant will be given the opportunity to make appropriate changes to the enforceable commitment. The changes may include altering the definition of the Early Reductions source.

2.3.9 Comment: There is a discrepancy in the preamble language and the language in the proposed regulation regarding enforceable commitments. The regulation states that a company will be held to the emission limitations contained in the enforceable commitment, while the preamble does not. The EPA should clarify that the emission reductions in the enforceable commitment are enforceable (IV-D-64).

Response: The proposed preamble and regulation are consistent regarding the enforcement of enforceable commitments. The preamble to the proposed regulation states on page 27356 that "...once a source has made a commitment to achieve early reductions, an enforcement action may be brought against that source if it fails to achieve the reductions...." Later on the same page the preamble states that "Any source that does not rescind the commitment prior to December 1, 1993, and fails to

achieve a 90 (95) percent reduction before January 1, 1994 will be subject to penalties for the emission reductions not achieved until compliance is achieved with either the enforceable commitment or the Section 112(d) standard for all affected sources." This is consistent with the language in Section 63.80(c) of the regulation, which states that "If a source subject to an enforceable commitment fails to achieve reductions before January 1, 1994, sufficient to qualify the source for an extension under this subpart, the source shall be considered to be in violation of the commitment and shall be subject to enforcement action under Section 113 of the CAA."

2.4 ALLOWABLE EMISSION REDUCTIONS

2.4.1 Comment: Hazardous air pollutant reductions achieved as a result of New Source Performance Standards (NSPS), Prevention of Significant Deterioration (PSD), VOC reductions, State requirements, or shutdowns should not be included in an Early Reductions demonstration. Only reductions achieved for toxic control should be used for this Program (IV-D-06).

Response: The statute provides that the Administrator shall issue a permit to a source that achieves a 90 (95) percent reduction in emissions of HAP's that allows the source to meet an alternative emission limit reflecting the 90 (95) percent reduction in lieu of the otherwise applicable standard issued under Section 112(d) if the reduction is made before the proposal of a Section 112(d) standard or if the source enters into an enforceable commitment before proposal of the standard and to make such reductions before January 1, 1994. The statute further provides that the reduction will be determined with respect to verifiable and actual emissions in a base year not earlier than calendar year 1987. There is no limitation in the statute as to the reasons those reductions were made.

2.4.2 Comment: Several commenters expressed concerns that the requirements for extensions are too flexible, thereby allowing many industries to qualify without making any additional reductions beyond those realized for unrelated reasons.

Commenters believe that only truly voluntary reductions should be credited toward extensions. Specifically, the commenters contend that credit should not be given for shutdowns due to economic conditions, compliance requirements, and other CAA requirements (IV-D-13, IV-D-14, IV-D-22, IV-D-26, IV-D-46). Other commenters suggest changing the base year emission deadline to 1990 to eliminate the problem (IV-D-06, IV-D-16, IV-D-20, IV-D-60, IV-D-62, IV-D-64, IV-D-67).

Response: It is clearly the intent of the CAA to credit sources for emission reductions accomplished by any means, as long as the emission reductions are actual and verifiable and made prior to proposal of an applicable standard or, in the case of an enforceable commitment, by January 1, 1994. According to the legislative history of the CAA, the Early Reductions Program initially was limited to voluntary reductions. Some commenters on the draft legislation suggested that limiting qualified reductions was unfair. For example, facilities located in States with extensive air toxics programs would not be able to benefit from early reductions. After considering this and other comments, there was a deliberate change to the CAA amendments to allow any reductions in emissions after the base year. The EPA interprets this change as the intent of Congress to expand the Program to allow all early reductions, regardless of how they are achieved.

2.4.3 Comment: The commenter agrees that average fugitive equipment leak factors should not be used but would like the EPA to establish the maximum percent reduction that can be claimed by standard options. For example, a plant with an NSPS program that proposed a 500 parts per million (ppm) leak definition could use x percent control. This would greatly reduce the burden on the reviewer (IV-D-26).

Response: The NSPS factors are based on modeling of emissions from hypothetical plants given a number of assumptions such as frequency of monitoring, leak rate, repairability, etc. The factors were developed to provide nationwide estimates of

emissions and should not be applied to specific sources for the purposes of this Program. The CAA requires "actual and verifiable" emissions and verification of this requirement can be obtained only through screening at individual sources.

2.4.4 Comment: The Early Reductions Program should accept all reductions of actual emissions regardless of whether the base year emissions are in compliance with regulated or permitted levels. It was the intent of Congress to reduce current emissions (IV-D-27).

Response: Sources should not be rewarded for being out of compliance with any existing regulations. Sources can take credit for reductions achieved as a result of compliance with regulations after the base year, but will not be allowed to count base year emissions that are in excess of those allowed.

2.4.5 Comment: The definition of "malfunction" should clarify whether excess emissions incurred during startup and shutdown are considered malfunctions or routine. The commenters have been treating startups and shutdowns as routine (IV-D-33, IV-D-52).

Response: Scheduled startups and shutdowns are considered routine. Emissions created by these routine operations can be counted toward base year emissions. However, startups and shutdowns associated with malfunctions are not routine and cannot be included with base year emissions. "Actual emissions," as defined in the proposed rule, do not include excess emissions from a malfunction. Likewise, other emissions from startups and shutdowns directly attributable to the malfunction should not be included. In order to clarify this exclusion, the definition of actual emissions in the Early Reductions regulation has been modified to read "... does not include excess emissions from a malfunction or any startups and shutdowns associated with a malfunction."

2.4.6 Comment: The commenter is concerned with the definition of malfunction. As it is written in the proposed regulation, "failures that are caused entirely or in part by poor maintenance, careless operation, or any other preventable upset

conditions or preventable equipment breakdown shall not be considered malfunctions." This will allow facilities to earn emission reductions by performing maintenance on a unit that has been neglected (IV-D-39).

Response: Facilities will not be allowed to credit emission reductions if the base year emissions were in violation of emission standards. However, poor maintenance, careless operation, or any other preventable upset conditions or preventable equipment breakdown that result in emissions that are not in violation of any emission standard are not considered malfunctions and can be credited toward base year emissions. Thus, the Early Reductions Program provides an incentive for facilities to improve their maintenance and operation practices (which would not otherwise be required), resulting in a net benefit to the environment.

2.5 DEMONSTRATION OF EARLY REDUCTIONS

2.5.1 Comment: Several commenters urge the EPA to require particulates to be controlled to 95 percent, with no offsets of gaseous pollutants allowed (IV-D-06, IV-D-14, IV-D-16, IV-D-20, IV-D-25, IV-D-31, IV-D-46, IV-D-57, IV-D-64). Other commenters support the weighted average approach for gaseous and particulate mixtures. (IV-D-30, IV-D-32, IV-D-34).

Response: At proposal, the EPA recognized that there may be sources that have already achieved 95 to 99 percent reduction in particulates through control measures employed prior to the earliest allowable base year, but that have significant potential reductions from relatively uncontrolled gaseous HAP emissions. If, for an Early Reductions demonstration, such sources were required to reduce gaseous HAP's by 90 percent as well as reduce the remaining particulate emissions by another 95 percent, the source may find further particulate emission reductions are not possible or that further reductions likely would exceed requirements of an applicable Section 112(d) standard for particulate emissions. In either case, the source would seek a

compliance extension and thus would not make early reductions of the gaseous HAP's.

A telephone query from a potential applicant exemplified this problem. The facility coats metal parts and has vents that release both gases and particulates. In this case, particulates are very tightly controlled (prior to the earliest possible base year) but gases are not. The caller was interested in making early reductions by reducing the gases by 90 percent, but if the source also had to achieve an additional 95-percent reduction in the already tightly controlled particulates, the source would not be able to enter the Program.

The EPA recognized that it would be beneficial from an environmental standpoint to allow a reduction in the gases without requiring an additional 95-percent reduction in particulates; i.e., without some allowance for this situation, the source would not enter the Program and no reductions in gaseous HAP's would be achieved until required by a Section 112(d) standard. The EPA therefore proposed to allow a source to average the required reductions for gases and particulates; particulates could be reduced by less than 95 percent as long as compensating reductions were achieved in gaseous HAP's. The overall target reduction would be between 90 and 95 percent and would be determined by the relative amounts of gases and particulates emitted from the source in the base year. This averaging method still would require the same amount of overall HAP emission reduction as would the separate 90 and 95 percent requirements.

The proposed averaging method could have been used at any source, whether the gases and particulates were emitted from different emission points or the same emission point. However, based on commenters' concerns, the EPA has reconsidered the applicability of the averaging method.

The statutory language in Section 112(i)(5) explicitly requires 95 percent reduction of particulate HAP's and 90 percent reduction of gaseous HAP's. The EPA, however, feels that

Congress did not consider, or was not aware of, emission points that emit both gases and particulates and that different controls are required for each, and therefore did not provide for this situation. Furthermore, the EPA believes that it would be beneficial to allow a weighted average for gases and particulates when they are emitted from the same points, especially where only small quantities of one are emitted with respect to the other, in light of the alternative of no early emission reduction.

Therefore, the final rule allows the use of the averaging at sources in which the gases and particulates are emitted from the same points. For example, if three emission points at the source emit both gases and particulates, these emission points could be aggregated to establish a combined percent reduction between 90 and 95 percent, e.g., the three points could achieve 94 percent reduction overall. The combined percent reduction would depend on the relative amounts of gases and particulates emitted by the points. By restricting the use of averaging gaseous and particulate emission reductions, the EPA notes that some sources emitting both types of pollutants, but from different points may now be unable to achieve the required early reductions if averaging were not allowed. In these cases, because emissions are emitted from different points, the source should be defined to exclude those points that create the difficulty in emission reduction. However, the source must still conform to one of the allowable definitions in the regulation.

2.5.2 Comment: Currently, sources that can only achieve a reduction of 89 percent may not participate in the Early Reductions Program. The commenter suggests that these sources be allowed to participate but that the length of the extension be determined by the achieved reductions. For example, the source should be given a 1-month extension for each 1.25 percent reduction in HAP's (IV-D-02).

Response: Participation in the Early Reductions Program is only possible if reductions of 90 (95) percent are achieved. Granting an extension for sources demonstrating 89 percent

reduction, including extensions, would not be allowed. The language in the CAA specifically calls for 90 (95) percent reductions of HAP's or an enforceable commitment prior to proposal of an applicable Section 112(d) standard in order to the included in the Program.

2.5.3 Comment: The 95-percent reduction requirements should be limited to PM-10 rather than all particulate matter because the smaller particles pose a greater health threat (IV-D-59).

Response: The CAA specifies a 95-percent reduction of particulates, without regard to size. Therefore, the Early Reductions Program requires reduction of total HAP particulates only.

2.5.4 Comment: The Early Reductions Program should allow partial reduction of HAP on a case-by-case basis. For example, a source might substitute one raw material for another, resulting in a 90 (95) percent reduction of some but not all of the HAP's generated by the process. It was suggested that Paragraph 63.72(g) be added that reads: "A source may be granted an alternative emission limitation based on the reduction of 90 (95) percent of one or more of the hazardous air pollutants, if it is determined on a case-by-case basis that the partial reduction will result in an improvement in air quality" (IV-D-29).

Response: The CAA specifies that 90 (95) percent reduction of all HAP's from the defined source must be achieved. Selective HAP reduction is not allowed, although some HAP's may be greater than 90 percent and some HAP's less thatn 90 percent as long as the overall reduction is 90 percent. The Early Reductions Program allows flexibility in defining the source, but that flexibility cannot be extended to specific pollutants within the source, to the exclusion of others.

2.5.5 Comment: Review of base year emissions should be extended to 90 days for at least the first year of the Program to allow evolving programs to adequately review the emissions (IV-D-26).

Response: The EPA recognizes that 60 days is a compact schedule. However, the EPA will continue to retain this time

limit in order to expedite the review as much as possible. In some instances, the 60-day review period may be impossible to achieve, but the EPA prefers to limit longer review times to these exceptional cases rather than extend all review periods to 90 days. As a practical matter, a 30-day completeness review combined with a 60-day acceptance review will provide an overall 90-day review time.

2.5.6 Comment: One commenter stated that the EPA should not expect emissions testing as the basis for demonstrating post-reduction emissions. The testing presumption should at least be limited to the pollutants that have an accepted test method (IV-D-35).

Response: Sources will be required to adequately document post-reduction emissions before being granted an alternative emission limit. The EPA requires the best available data to demonstrate emissions. Direct measurement of emissions is the presumed best demonstration for many cases. However, test data will not be required to demonstrate all emissions. Calculations based on engineering principles, emission factors, or material balances may be acceptable if the applicant demonstrates to the satisfaction of the permitting authority that: (1) no test method exists; (2) it is not technologically or economically feasible to perform source tests; (3) it can be demonstrated that the accuracy of a calculated estimate is comparable to source testing; or (4) emissions from one or more set of points are insignificant compared to total source emissions. The EPA agrees that in some situations (e.g., storage tank emissions or batch operations using solvent HAP's) calculations or mass balances generally will be acceptable and may be the preferred method of establishing emissions.

2.5.7 Comment: The EPA should clarify what is meant by "sufficiently variable" in Section 63.78(b)(4) of the proposed regulation. Batch manufacturing produces inherent process variations. The commenters agree that clearly unreliable emissions control measures should be grounds for denial of an

extension, but variations typical of batch processes should not be grounds for denial (IV-D-19, IV-D-27).

Response: The term "sufficiently variable" has been removed from the language of the regulation. The EPA recognizes that batch processes are inherently variable, and that variability alone should not be a reason for denial. The reason for denial will now read: "The emission of hazardous air pollutants or the performance of emission control measures is unreliable so as to preclude determination that the required reductions have been achieved or will continue to be achieved during the extension period."

2.5.8 Comment: It was suggested that a sixth reason be added to the reasons why calculations may be acceptable: it is "physically impossible to perform the testing due to configuration of the process equipment" (IV-D-30).

Response: "Physically impossible to perform the testing due to configuration of the process equipment" is the same as "it is not technologically or economically feasible to perform source tests." Therefore, this would be a valid reason not to perform source testing.

2.5.9 Comment: Commenters would like emissions to be quantified as emissions per pound of product versus a specific quantity per year. This would assist in overcoming problems with fluctuating production rates, especially with the base year (IV-D-33, IV-F-1).

Response: The statute requires 90 (95) percent reduction from base year emissions. Thus, the Early Reductions Program is concerned with absolute reductions from base year emissions, not a percent reduction from what current emissions would have been. The alternative emission limit will reflect a specific emission level that is 90 (95) percent less than base year. Sources with fluctuating production must consider future increases in emissions and make adjustments accordingly.

2.5.10 Comment: The commenter opposes any efforts by the EPA to require continuous emissions monitoring (CEM) to document

early reductions. The commenter states that the CAA clearly allows for options other than continuous monitoring (IV-D-65).

Response: Continuous emission monitoring is not a general requirement of the EPA to document that the source has achieved sufficient reductions. General monitoring requirements for permit provisions, including but not limited to, alternative emission limitations established for the Early Reductions Program, will be established according to the requirements of Title V of the CAA. Section 504 of Title V states that "continuous emissions monitoring need not be required if alternative methods are available that provide sufficiently reliable and timely information for determining compliance." Therefore, if other acceptable means for determining compliance are available, CEM will not be required. Nothing in the CAA, however, prevents the requirement of CEM for the Early Reductions Program, and CEM may be required if no other acceptable methods are available.

2.6 HIGH-RISK POLLUTANTS

2.6.1 Methodology for Selecting High-risk Pollutants

2.6.1.1 Comment: One commenter questioned the use of the three-tier methodology for selecting the high-risk pollutants. The commenter believes that the EPA should encourage early reductions of pollutants associated with actual hazards to human health (IV-D-36).

Response: The EPA devised a three-tier approach for selecting high-risk pollutants in order to systematically screen the 189 HAP's listed in Section 112(b) of the CAA. Health effects data were examined first to rank pollutants based solely on health effects. Consideration of health effects alone however, was judged insufficient to address Section 112(i)(5)(E) which describes high-risk pollutants as those for which high risks of adverse public health effects may be associated with exposure to small quantities. Accordingly, tier 2 of the analysis was exposure modeling using the EPA's Human Exposure Model (HEM). As described in the preamble to the proposed rule,

the ambient concentration predicted by the model was compared to selected risk levels to screen for pollutants likely to have an adverse effect on public health at the exposure level that was modeled.

Tier 3 of the analysis was an examination of actual emissions data using the 1989 TRI. Tier 3 was intended as a "reality check" to determine whether or not the pollutants were actually emitted at levels that could reasonably be expected to adversely affect public health. Pollutants with a low exposure potential were consequently eliminated from the high-risk list. After consideration of public comments, the EPA has decided to eliminate tier 3 from the analysis. (This decision and its impact is discussed separately below.) The EPA believes that tiers 1 and 2 adequately identify those pollutants that could reasonably be expected to adversely affect public health, and thus limited the offsetting of these pollutants in the Early Reductions Program.

2.6.1.2 Comment: Two commenters stated that insufficient data were presented on health effects and that the documentation of criteria for excluding or including a pollutant were not specified (IV-D-22, IV-D-46).

Response: The health data and selection criteria used to select the proposed high-risk pollutants can be found in the May 30, 1991 memorandum (Docket No. A-90-47, Item No. II-B-10).[9].

2.6.1.3 Comment: One commenter stated that all HAP's with the EPA's approved potency factors should be included on the high-risk list (IV-D-14).

Response: A potency factor is a measure of the probability of an individual's developing cancer as a result of exposure to a specified unit ambient concentration of a pollutant. Potency factors for the carcinogens listed in Section 112(b) of the CAA vary by several orders of magnitude. Those that have low potency factors have a low probability of causing cancer and thus are not considered to pose a high risk under the criteria used for the purposes of the Early Reductions provisions. The mere existence

of a potency factor is an insufficient reason for a chemical to be added to the high-risk list.

2.6.1.4 Comment: The commenter suggested that all carcinogens classified as Group A or B be listed, whether or not there is an approved potency factor. This commenter also recommended including pollutants identified by the National Toxicology Program (NTP) or the International Agency for Research on Cancer (IARC) because these organizations have made determinations of cancer for chemicals that may not have been reviewed by the EPA (IV-D-39).

Response: The EPA did list all carcinogens with a Group A weight-of-evidence classification because known human carcinogens were considered to be of sufficient concern to be termed "high risk." For Group B and C carcinogens (i.e., probable and possible carcinogens, respectively), the weight-of-evidence classification alone was not considered compelling enough to warrant listing a pollutant as high-risk. For these pollutants, potency and potential for exposure were given careful consideration. In addition, pollutants without a unit risk estimate, but listed as potential carcinogens of high concern under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA), were also evaluated for potency or exposure potential which resulted in additional pollutants being listed. These pollutants have received extensive review by the EPA as well as EPA external peer review.

The EPA is aware that other cancer classifications and unit risk estimates are available (such as the NTP and IARC classifications mentioned by the commenter), but for consistency, the EPA review was a primary criterion for selecting the high-risk pollutants. However, if additional information becomes available that indicates that the EPA has overlooked an important carcinogen that meets the high-risk list criteria, the EPA may amend the list.

2.6.1.5 Comment: One commenter was concerned about the health effects data bases used to make the initial selection of the high-risk pollutants. The commenter is of the opinion that many data contained in the Instructional Resources Information System (IRIS) and the data used for CERCLA Section 102 determinations are outdated, fail to incorporate the latest pharmacokinetic findings, and are more conservative than they should be because of linearized multistage (LMS) modeling. The commenter maintains that the LMS modeling (used to develop unit risk estimates) overestimates the potency of carcinogens. For noncarcinogens, the commenter says the quality of the study used to calculate the inhalation reference concentration or oral reference dose (RfC/RfD) must be considered and the evaluation must be updated with new data (IV-D-35).

Response: The information on chemicals contained in the IRIS and CERCLA data bases has received review both by the EPA and external review and is considered to be of the highest quality. For this reason, these data bases were relied upon, particularly for data on carcinogens. The EPA agrees that improvements to the science are being made, such as in the area of pharmacokinetics, but these types of data for specific chemicals are still scarce. When new information for a particular chemical becomes available, the EPA's Carcinogen Risk Assessment Verification Endeavor Work Group (which meets regularly and is responsible for development of unit risk estimates) reviews this information and updates the EPA's findings accordingly. A recent example would be the EPA's revision of the unit risk estimate for methylene chloride.

Typically, new information is released as an addendum to a health assessment document, followed by an update of the IRIS files. Because the IRIS files are updated later, for this analysis the EPA also relied on health assessment documents that have been reviewed by the EPA's Science Advisory Board. It should be noted as well that the EPA maintains a "high hurdle"

for data quality, which is the reason that IRIS files are changed only after thorough review and documentation of new information.

With respect to LMS modeling, the LMS procedure provides a "plausible upper limit" of the risk that is consistent with some proposed mechanisms of carcinogenesis (i.e., nonthreshold response). Such an estimate, however, does not necessarily give a realistic prediction of the true risk which may be as low as zero. In this sense, the commenter is correct in stating that LMS modeling is conservative. However, the EPA believes it has the best, though limited, scientific basis of any of the current mathematical extrapolation models.

With regard to the development of RfC's/RfD's, the quality of the scientific studies is given careful and thorough consideration. In addition, although a limited number of RfC's have been developed, several have already been updated as new information becomes available. If new RfC's/RfD's become available that would indicate a pollutant should be added to or deleted from the high-risk list, the EPA may amend the list.

2.6.1.6 Comment: Two commenters strongly urged the EPA to confine the selection of carcinogens for the high-risk list to consideration of potency and not make use of weight-of-evidence classification. On the other hand, two other commenters (IV-D-30, IV-D-33) recommended that the EPA prioritize the high-risk list using a qualitative rather than a quantitative approach (i.e, use weight of evidence reviews rather than potency factors for identifying substances)(IV-D-23, IV-D-31).

Response: The EPA believes it appropriate for identification of high-risk pollutants to consider both the weight-of-evidence and the carcinogenic potency of a pollutant. The listing of several Group A carcinogens was based primarily on weight-of-evidence because the EPA judged that emissions of Group A carcinogens are of sufficient concern to warrant limitations on offsetting under the Early Reductions provisions. Group A carcinogens are those that are known to be carcinogenic to humans. For other carcinogens on the HAP list (i.e., probable or

possible human carcinogens), the EPA felt that the weight-of-evidence classification alone was insufficient to list the pollutant as high-risk. For these pollutants, the three-tier analysis, which considered both potency and exposure potential, was employed.

2.6.1.7 Comment: Three commenters objected to the addition of four human carcinogens to the list after the pollutants had been excluded by the three-tier selection process. One of these commenters further claimed that data for human carcinogens come primarily from workplace exposure studies conducted prior to 1960, and that these exposures have decreased significantly (IV-D-23, IV-D-30, IV-D-33).

Response: The commenters are correct in noting that four Group A carcinogens were added to the list after they had been excluded by the three-tier process. However, the EPA stands by the decision to list these pollutants as high-risk based on the fact that they are known human carcinogens. The EPA judged that emissions of known human carcinogens are of sufficient concern that offsetting reductions in other less hazardous pollutants under an Early Reductions demonstration should be limited. Three of the pollutants (benzidine, bis(chloromethyl)ether, and chloromethyl methyl ether) are extremely potent carcinogens and were originally excluded from the three-tier process at tier 3. This means that, according to the 1989 TRI, these pollutants were not emitted by any reporting facility in quantities sufficient to exceed the risk benchmark level proposed by the EPA. In spite of this, the EPA felt it prudent to list them as high-risk in case a source's emissions changed in the future.

Since proposal of the high-risk list, the EPA has eliminated tier 3 from the screening analysis. As a result, even if the EPA had decided not to use weight-of-evidence as a criterion, these carcinogens would still be listed as high-risk. Benzene was also included on the list even though the risk benchmark level was not exceeded when a 10 tpy emission rate was modeled. The rationale for this decision was that in addition to being a known human

carcinogen, benzene is a very high volume chemical and emissions in excess of 10 tons per year are not uncommon. The EPA believes that offsetting emissions of this known human carcinogen with less hazardous pollutants should also be limited.

With respect to the comment that data used to classify carcinogens as Group A come primarily from workplace exposures: the source of the data does not alter the conclusion that these pollutants are known human carcinogens. Human exposure data as well as data from animal studies lend further support to the Group A classification.

2.6.1.8 Comment: Two commenters suggested that the EPA revise the criteria to include only known human carcinogens (Group A), probable human carcinogens (Group B1), and noncarcinogens for which chronic human health effects can be expected to occur at extremely low levels of exposure (IV-D-44, IV-D-49).

Response: In selecting pollutants for the high-risk list, the EPA considered weight-of-evidence, potency, and exposure potential of the pollutant. A weight-of-evidence classification of Group A (known human carcinogen) was deemed sufficient to list a pollutant as high-risk. The EPA does not agree with the commenters' suggestion that Group B2 and Group C carcinogens should not be considered for, or included on, the high-risk list. In order to be listed, however, carcinogens other than Group A carcinogens had to pass tier 2 of the analysis, which considered potency and exposure potential. Once the pollutants were initially identified for the high-risk list by the tier screening process, they were assigned a weighting factor. The weighting factor system decided on by the EPA gives additional emphasis to the weight-of-evidence classification of carcinogens. Group C carcinogens are therefore assigned the lowest weights.

The EPA also disagrees with the commenters' suggestion that only chronic human health effects should be considered. Section 112(b) of the CAA describes HAP's as those pollutants that present, or may present, a threat of adverse human health effects including substances that are carcinogenic, mutagenic,

teratogenic, neurotoxic, that cause reproductive dysfunction, or that are acutely or chronically toxic. Thus, the EPA believed it appropriate to assess (and include on the high-risk list, where appropriate) pollutants that are acutely as well as chronically toxic.

2.6.1.9 Comment: Two comment letters questioned the data used to select noncarcinogens for the high-risk list. The commenters maintain that RfCs and RfDs can be based on different health endpoints and that the values do not reflect the severity of the health effects. Similarly, the lowest observed effect level (LOEL) (used to screen noncarcinogens that do not have an RfC or RfD) may not necessarily be an adverse or toxic effect. Also, a chemical may be extremely hazardous upon high level, short-term exposure, but be essentially nontoxic at very low levels of exposure. The commenters recommend that health effects be grouped according to severity at anticipated levels of exposure in order to differentiate between noncancer effects (IV-D-30, IV-D-33).

Response: In developing the high-risk list, the EPA considered several health effects endpoints, including carcinogenicity, reproductive and developmental toxicity, acute lethality, and systemic effects other than acute lethality (e.g., neurologic disorders). The commenters are correct in noting that the selection of noncarcinogens for the high-risk list was based on different health endpoints. The EPA feels this approach is necessary, however, because of the large number of noncarcinogens on the HAP list and the variety of noncancer health effects they can potentially cause. The EPA did not feel it was appropriate to judge whether one health endpoint was more severe than another, e.g., whether a reproductive effect is "worse" than a systemic effect.

It is true that the LOEL may not necessarily be an adverse or toxic effect. If a pollutant's LOEL was low enough to cause the pollutant to be listed as high-risk, the EPA reviewed the critical study for scientific quality. The EPA found, in all

cases, that the study was flawed and, in fact, did not list any pollutants on the basis of a LOEL. By comparison, the inhalation RfC's are typically based on the lowest observed adverse effect level. In establishing the RfC, the EPA has made a judgment that the observed health effect is sufficiently severe to be considered adverse. Thus, the selection of several noncarcinogens for the high-risk list was based on inhalation RfC's rather than LOEL's.

The commenters' suggestion that health effects be grouped according to anticipated levels of exposure in order to differentiate between noncancer effects is interesting, but unworkable for the Early Reductions Program. The facilities eligible to participate in the Early Reductions Program represent all types and sizes of source categories that could emit any number of HAP's at a variety of emission rates. For this reason, the EPA is unable to anticipate exposure levels.

2.6.1.10 Comment: One comment letter suggested that all HAP's having potentially serious health effects other than cancer be listed as high-risk. The commenter suggested using facility-specific information to determine whether a health-effects threshold would be exceeded. The weighting factor could then be customized for that facility by relating the weighting factor to the degree to which a health-effects threshold is exceeded. The commenter believes this approach would emphasize reductions in cases where health-effects thresholds may be exceeded and assigns less weight to high-risk pollutants in cases where the health-effects threshold is not likely to be exceeded (IV-D-31).

Response: The high-risk list includes several pollutants that cause health effects other than cancer. The listing criteria that the EPA devised were meant to select a subset of pollutants from the list of 189 HAP's in Section 112(b), that the EPA judged to be toxic enough in small quantities to warrant being listed as high-risk. The EPA believes these criteria were used appropriately to identify the high-risk noncarcinogens. There are several reasons why the EPA prefers that weighting

factors not be customized for each participating facility. The primary reason is that the weighting factors reflect the differences in the toxicity of the pollutants regardless of emission rates. For example, if facility X emits 50 tons of benzidine, a 1,000-to-1 trade is necessary with a HAP not on the high-risk list. If facility Y emits 1 ton of benzidine, a 1,000-to-1 offset is also required. The EPA recognizes this is a conservative approach, but believes it will serve to always emphasize reductions in the high-risk pollutants even if these emissions are small.

In addition, participation in the Early Reductions Program is available to all facilities throughout the Nation. For consistency in program implementation, the EPA prefers the weighting factors for the high-risk pollutants not be customized for each participating facility. In addition, some facilities and also the reviewing agencies may not have the expertise or resources to either perform or review site-specific modeling analyses and determine appropriate weighting factors.

2.6.1.11 Comment: Two commenters requested documentation regarding the selection of the critical study for HAP's that do not have an RfC or RfD (IV-D-30, IV-D-33).

Response: The critical study selected was the study that documented an LC_{50} for methyl isocyanate and phosgene. Since proposal, diazomethane, hexachlorocyclopentadiene, phosphine, and parathion have also been added to the list on the basis of an LC_{50} (LD_{50} in the case of parathion). The critical studies may be found in a memorandum to the docket entitled "Background Information for Noncarcinogens Recommended for Inclusion on the High-Risk List Since Proposal" (Docket No. A-90-47, Item No. IV-B-8).[10]

2.6.1.12 Comment: The comment letter stated that relying on cancer potency factors to weight toxicity and screen unacceptable risk resulted in some illogical choices for the high-risk list. For example, benzene, a Group A carcinogen emitted in large amounts, did not make the list (it was added on even though it

failed the screening criteria). In contrast, chlordane, a Group B2 carcinogen with lower emissions did make the list. Also, compounds such as carbon tetrachloride, chloroform, and methylene chloride, which are B2 carcinogens, have noncancer effects, and are emitted in significant quantities, did not make the list. Comment letter IV-D-30 also stated that the selection of high-risk carcinogens should include consideration of cancer classification in selecting the pollutants and in their weighting (IV-D-26).

Response: In screening the list of 189 HAP's, the weight-of-evidence of a carcinogen was a criterion to the extent that Group A carcinogens were added to the list. The EPA added Group A carcinogens to the list to ensure that exposure to these compounds would be limited to the extent possible. Since proposal of the high-risk list, the EPA has revised the weighting system in such a way that the weight-of-evidence classification is given greater emphasis. Carcinogens such as those mentioned in comment letter IV-D-26 that were not listed on the basis of carcinogenicity were also evaluated for effects other than cancer. The specific chemicals mentioned by the commenter did not meet the screening criteria for these effects.

2.6.2. Comments Concerning Tier 2 (Exposure Modeling)

2.6.2.1 Comment: Five commenters recommended that the EPA not include tiers 2 or 3 of the screening analysis. These commenters felt that selection of high-risk pollutants should be based only on toxicity (IV-D-14, IV-D-22, IV-D-31, IV-D-39, IV-D-46).

Response: In selecting the high-risk pollutants, health effects data were examined first to rank the pollutants on the basis of health effects. Consideration of health effects alone however, was judged insufficient to address Section 112(i)(5)(E), which describes high-risk pollutants as those for which high risks of adverse public health effects may be associated with exposure to small quantities. Accordingly, tier 2 of the analysis was exposure modeling. The EPA believes this step of the analysis to be appropriate. However, after reconsideration,

the EPA has decided to drop tier 3 from the analysis (this tier considered emissions data as a criterion for listing).

2.6.2.2 Comment: Many comments were received concerning the parameters chosen for the tier 2 exposure analysis (IV-D-14, IV-D-16, IV-D-22, IV-D-33, IV-D-39, IV-D-47, IV-D-61). Several commenters felt that the exposure assumptions were not conservative for several reasons, including the meteorological data, the stack parameters, and the limitations of the HEM. (Comments received concerning the presumptive risk benchmark level are addressed separately below [IV-D-14, IV-D-16, IV-D-22, IV-D-33, IV-D-39, IV-D-47].)

One commenter was of the opinion that 1 year of meteorological data is not representative and downwash was not considered (IV-D-47). Two commenters suggested a 3.5-meter stack height and a 20-meter distance to the nearest residence (IV-D-39 and IV-D-47). According to one commenter, the modeling should have used more realistic assumptions about pollutants and emission sources (IV-D-16). Another commenter felt that the HEM is too simplistic because it does not consider actual exposure, short-term exposures, or population activity patterns (IV-D-33). On the other hand, two commenters felt the 500-meter distance to the nearest residence was too close (IV-D-42, IV-D-61). One commenter recommended a 3,000-meter distance and a 10-year population residence time (rather than the 70-year lifetime exposure associated with the cancer potency factor) (IV-D-61).

Response: The second tier of the screening analysis to select the high-risk pollutants was a generic exposure modeling exercise. The EPA intended that the modeling results be used to determine which pollutants merited further analysis based on exposure potential. The EPA did not use the modeling results to estimate actual risk levels, but did use the modeling results to differentiate between pollutants.

The EPA still considers the use of generic modeling parameters appropriate for this analysis because a wide range of emission release and exposure scenarios across many varied source

categories are anticipated under the Early Reductions Program.

The HEM was used to estimate a theoretical downwind concentration of a typical HAP. Because the pollutants are released from various types of sources with variable stack parameters (stack height, emission velocity, distance to nearest residence, etc.), no attempt was made to model site-specific conditions. Meteorological data used were representative of between 2 and 10 years of data from the selected meteorological station. A 10-meter stack height was chosen to represent a chemical plant. For the proposed rule, the modeling parameters also assumed a 70-year continuous exposure and a 500-meter distance to the nearest residence. Upon re-evaluation, the EPA has made changes to these two parameters.

First, the 70-year period over which exposure to a pollutant was assumed to occur continuously has been changed for the purposes of this rulemaking to a 33-year period. Thirty-three years represents the 95th percentile for the number of years an individual would remain at the same residence, based on population mobility and mortality data. The 33-year period was selected for use in this analysis as representative of a reasonable worst-case approach to assessing exposure duration.

Second, the EPA reconsidered the choice of 500 meters to the nearest residence and has revised the analysis using a 200-meter distance. The 200-meter distance to the nearest residence is the distance that has been most often used by the EPA for analyses estimating exposure to emissions from point sources. This distance represents a reasonable worst case for facilities that are anticipated to participate in the Early Reductions Program. The net impact of these changes was the addition of hexachlorocyclopentadiene, phosphine, parathion, and manganese compounds to the list.

2.6.2.3 Comment: One commenter stated that the EPA modeled emissions (hydrazine in particular) as if emitted from point releases rather than as fugitive releases, which resulted in higher predicted concentrations (IV-D-42).

Response: The EPA's screening model does not address fugitive or dispersed releases. The EPA agrees that modeling fugitive emissions as a point source release will generally result in higher predicted concentrations. On the other hand, for this analysis, the EPA used a 10-meter stack. If a lower stack height such as 3.5 meters had been modeled to account for fugitive ground level releases, the predicted concentration would have probably been higher than that predicted by modeling a point release from a height of 10 meters. The generic modeling parameters chosen by the EPA for this analysis are believed to represent the majority of facilities that are anticipated to participate in the Early Reductions Program and the dispersion and emission characteristics of most pollutants.

2.6.2.4 Comment: Two commenters questioned the benchmarks chosen for health effects other than cancer. These commenters felt that neither the LOEL divided by a safety factor of 100 nor the LC_{50} divided by a safety factor of 1,000 were conservative enough. The commenters also thought that using a value one order of magnitude above the RfC was not conservative enough (IV-D-22, IV-D-39).

Response: As stated in the preamble to the proposed rule, uncertainty factors were applied to the health effects benchmarks because the LOEL and LC_{50} values represent levels at which health effects are known to occur. These uncertainty factors were meant to account for variables such as interspecies variations and sensitive subpopulations, but did not incorporate all the factors typically used in developing RfC's. The uncertainty factors used to develop an RfC are typically applied to a lowest observed adverse effect level (LOAEL) or a no observed adverse effects level (NOAEL). The resulting RfC represents a level below which the potential for adverse public health effects is considered to be negligible. However, the purpose of this analysis was to identify pollutants whose emissions could potentially present a high risk, not a de minimis risk. Therefore, the uncertainty factors used in this analysis were not meant to account for all

the factors typically used in developing an RfC. For this analysis, the EPA made a judgment that if a source's emissions were such that a LOEL or LC_{50} could potentially be exceeded (after application of the uncertainty factors and under the modeling scenario used), then the pollutant could be considered high-risk. In this application, the EPA believes uncertainty factors of 100 and 1,000 to be appropriate. Similarly, with respect to using a value one order of magnitude above the RfC, the EPA believes this to be an appropriate estimate of a level at which health effects could potentially be significant enough to be regarded as high-risk.

2.6.3 Comments on One in Ten Thousand Risk Benchmark

2.6.3.1 Comment: Four comment letters were received that stated that the one in one thousand presumptive risk benchmark was not conservative enough (IV-D-16, IV-D-22, IV-D-39, IV-D-47). Commenter IV-D-47 recommended that the EPA include every carcinogen with a potency factor greater than 1.35 X $10^{-8}[(ug/m3)^{-1}]$ based on modeling a 3.5-meter stack. Commenter IV-D-16 argued that Congress intended that sources with risk levels of one in one million be controlled. On the other hand, one comment letter recommended a risk level of one in 1,000. This commenter believes that the EPA's one in ten thousand risk benchmark is inconsistent with the "Savings Provision" in Section 112(q)(1), where standards promulgated under Section 112 in effect prior to the 1990 amendments are to remain in force unless revised by the EPA (IV-D-33).

Response: The exposure modeling exercise conducted as part of tier 2 of the screening analysis was used as a tool to identify pollutants that could potentially cause a high risk to public health (under the exposure scenario that was modeled). The EPA has decided that for carcinogens a one in ten thousand presumptive risk level is appropriate for this analysis. This decision is based primarily on guidance concerning acceptable risk discussed in the NESHAP for benzene promulgated on September 14, 1989 (54 FR 38044).[11]

In the preamble to the benzene decision, the use of the one in ten thousand benchmark is described:

> "EPA will consider the extent of the estimated risk were an individual exposed to the maximum level of pollutant for a lifetime. The EPA will generally presume that if the risk to that individual is no higher than approximately one in ten thousand that risk level is considered acceptable and the EPA then considers the other health and risk factors to complete an overall judgement on acceptability. The presumptive level provides a benchmark for judging the acceptability of maximum individual risk, but does not constitute a rigid line for making that determination."

In the case of the screening analysis for high-risk pollutants under the Early Reductions provisions, the EPA believes the one in ten thousand presumptive risk level has been used appropriately. The commenters are reminded that the generic exposure analysis was not meant to estimate the actual risk from any one type of source category; rather it was used to differentiate between pollutants based on relative toxicities. The EPA recognizes that other modeling assumptions could have been used that would have resulted in either more or fewer pollutants exceeding the presumptive risk level. However, the EPA does not agree with the commenter's suggestion that every carcinogen with a potency factor greater than 1.35×10^{-8} $[(ug/m3)^{-1}]$ should be considered high risk.

With respect to the comment that Congress intended that sources posing risks of one in one million be controlled, the commenter is referring to Section 112(f)(A), the so-called "residual risk" provision. In this provision, it is stipulated that additional emission standards must be promulgated if a source's emissions pose a risk greater than one in one million after application of control technology [as stipulated in Section 112(d)]. The commenter is reminded that the Early Reductions Program provides an extension of the compliance time for applying control technology that is stipulated by standards promulgated under Section 112(d). After the compliance time extension, facilities participating in the Program must still

apply the required technology if their emissions exceed specified levels. In addition, facilities that participate in the Early Reductions Program are not exempted from a residual risk test under Section 112(f), so the commenter's contention that the intent of Congress is not being fulfilled is unwarranted.

With respect to the Savings Provision of Section 112(q)(1), the commenter is reminded that the Early Reductions Program is not an emissions standard. The use of the presumptive risk benchmark of 1 in 10,000 in the screening analysis for selecting high-risk pollutants has no bearing on NESHAP that have already been promulgated.

2.6.4. Comments on Tier 3

2.6.4.1 Comment: Five comment letters found it inappropriate to eliminate pollutants from the high-risk list based on emissions data, as was done in tier 3 of the screening analysis. The commenters contend that use of the TRI for emissions data is inappropriate because not all pollutants are reported. Only large facilities in the manufacturing sector report to the inventory, and not all types of source categories are covered. The commenters feel that the EPA should not eliminate substances because they are not currently in common use and that the tier 3 screen should be dropped from the analysis (IV-D-14, IV-D-16, IV-D-22, IV-D-33, IV-D-39).

Response: The EPA agrees with the commenters' concerns regarding use of the TRI and has consequently dropped the tier 3 screen from the analysis. The EPA also agrees that chemicals not currently in common use should still be listed as high-risk in case production of that chemical is resumed at a later date. The impact of this decision is that the following pollutants have been added to the high-risk list as a result of dropping tier 3: 2-acetylaminofluorene; 1,2 diphenyl hydrazine; toxaphene; nickel compounds; N-nitrosodimethylamine; ethylenimine (aziridine); dimethylcarbamoyl chloride; phosphorus; and diazomethane.

2.6.5 Comments on Offsetting the High-risk Pollutants

2.6.5.1 Comment: Several commenters believe that the indexed weighting system for the high-risk pollutants conflicts with the CAA because it allows offsetting of high-risk pollutants with non-high-risk pollutants. The commenters state that high-risk pollutants should not be allowed to be offset by pollutants not on the high-risk list, or only be allowed when high-risk pollutants are emitted in trace amounts (IV-D-14, IV-D-16, IV-D-20, IV-D-22, IV-D-57). Other commenters agree with the weighting factor concept and the ability to offset high-risk pollutants (IV-D-24, IV-D-36).

Response: Contrary to several commenters' contentions, the high-risk pollutant strategy does not conflict with Section 112(i)(5)(E). That provision requires the Administrator to limit, by regulation, the use of offsetting reductions of other HAP's in counting towards the 90-percent reduction of high-risk pollutants. The statute does not say or even imply that the regulation must prohibit such offsetting reductions.

In response to the comment that these offsets should only be allowed when these pollutants are emitted in trace amounts, the EPA notes that the weighting system effectively restricts the offsetting of emissions of the high-risk pollutants. The amount of reduction of a pollutant not on the high-risk list needed to offset a high-risk pollutant (up to 10,000 to 1) is so large that only relatively trace amounts could be traded. Even in situations where the pollutant concentrations are relatively large (i.e., not trace amounts), it is appropriate to allow offsetting as long as the weighting factor system is followed. If 1 ton of a hazardous pollutant with a weighting factor of 10 is offset with a 10-ton reduction in a pollutant with a weighting factor of 1, the offset should generally provide an equivalent risk reduction. Consequently, the EPA believes such offsets should not be prohibited. Note that these relative trades deal with decreases in the high-risk pollutants. It is not envisioned that any successful Early Reductions submittal will include any

increase in high-risk pollutants other than incidental trace amounts.

2.6.5.2 Comment: Several comments stated that trading among pollutants with different types of health effects is inappropriate. The commenters recommend using critical health effects and toxic potency information to place the listed pollutants into categories, with trading allowed within a category. Trading across categories would be allowed only for categories based on similar health effects. Weighting factors based on relative potencies would be used in such tradeoffs (IV-D-14, IV-D-20, IV-D-22, IV-D-31, IV-D-39, IV-D-46).

Response: The development of the weighting system and the decision to allow trading between carcinogens and noncarcinogens is intended to provide flexibility to the participating facilities in achieving their emission reduction goals. As such, it is a policy decision and not one based on purely scientific grounds. If trading between pollutants with different health endpoints was restricted, this could potentially exclude some facilities from participating in the Early Reductions Program. The EPA feels that such restrictions would not benefit the goals of the Program as a whole.

2.6.6. Comments on Development of the Weighting Factors

2.6.6.1 Comment: Several comment letters made reference to the development of weighting factors for the high-risk pollutants. One commenter recommended the weighting factors be based on weight-of-evidence classification (IV-D-45). On the other hand, three commenters recommended the weighting factors be based only on potency as described by the cancer potency factor (IV-D-31, IV-D-33, IV-D-44). One commenter further suggested that the cancer potency factor be multiplied by 1 million to arrive at the weighting factor (IV-D-31). Another commenter suggested a combination approach where both weight-of-evidence and potency would be considered. In this approach, pollutants with the same weight-of-evidence classification and having potency factors within an order of magnitude would be grouped together (IV-D-39).

Response: The weighting factor system has been revised slightly since the high-risk list was proposed. In the final rule, carcinogens with a Group C classification (possible human carcinogens) have been assigned a lower weight. Greater uncertainty exists regarding the evidence for a Group C classification than for chemicals classified as Group A (known human carcinogen) or Group B (probably carcinogenic to humans). A Group C classification is defined by positive carcinogenicity in a single experiment, a tumor response of marginal statistical significance, or finding benign tumors only. A Group B classification is defined by carcinogenicity in two or more animal species, strains, or experiments, either with or without limited human evidence. Group A is reserved for known human carcinogens.

The greater uncertainty regarding a Group C classification is reflected in a lower weighting factor. As a result, two Group C carcinogens (1,1,2,2 tetrachloroethane and vinylidene chloride) have been assigned weighting factors of 1 rather than 10 as proposed. The EPA does not feel, however, that Group B carcinogens should necessarily be weighted lower than Group A carcinogens. With respect to Group B chemicals, a sound foundation exists regarding carcinogenicity in animals, but the human data are either inconclusive or of limited value, most likely reflecting the difficulty of obtaining quality epidemiologic data. The EPA is currently revising the cancer classification scheme to account for these data gaps. Therefore, for this weighting system, chemicals classified as Group A or B carcinogens are grouped together and ranked by potency.

For carcinogens, the actual weighting factors are based on the potency of the high-risk carcinogens relative to carcinogens not on the high-risk list. This approach is the same as was proposed. Multiplying the potency factors by one million to calculate weighting factors as one commenter suggested, would result in the same relative ranking of the pollutants, but higher weighting factors. The EPA believes that basing the weighting

factors on the differences between the potency of the high-risk carcinogens and the geometric mean potency of the group of carcinogens not on the high-risk list is more justifiable. The weighting factors for noncarcinogens are discussed below.

2.6.6.2 Comment: Four commenters believe the EPA should establish more weighting factor categories to reflect more accurately the different toxicity levels of the various pollutants (IV-D-22, IV-D-23, IV-D-31, IV-D-44). On the other hand, two commenters believe more pollutants should be grouped together so that there is not such a wide range in weighting factors (IV-D-36, IV-D-45).

Response: The EPA has reviewed the weighting factor categories and still finds four separate categories to be appropriate. As described in the comment above concerning weighting factors, there were some adjustments made to the placement of certain pollutants. However, the general categories with weighting factors of 100,000, 1,000, 100, and 10 are still believed to be appropriate. The difference between the most potent carcinogen and the least potent carcinogen with a weighting factor of 10 is about 35 times (with the exception of one pollutant). The EPA does not feel that this is enough of a difference to warrant another weighting factor category.

2.6.6.3 Comment: One commenter stated that several high-risk pollutants that may be emitted in trace amounts as a byproduct of combustion are given relatively low weights of 10. Because these pollutants are emitted in small quantities, the commenter believes it is reasonable to require a relatively large offset (IV-D-39).

Response: The final weighting factor system does not incorporate consideration of emissions, but was based on a combination of cancer classification (weight-of-evidence) and cancer potency. The EPA believes that requiring a large offset because the pollutant is emitted in trace amounts, without consideration of the relative toxicity of the pollutant, is not justified.

2.6.6.4 Comment: One comment letter stated that the EPA needs to devise a system that requires a certain percentage reduction in the target pollutant (i.e., the high-risk pollutant of concern). A goal of, for example, 75 percent reduction of the target pollutant should be required before offset credits of reductions of other compounds could be used to round the reductions up to the desired 90 percent (IV-D-04).

Response: The EPA carefully considered the merits of this suggestion. However, the EPA has decided that imposing this type of requirement would add significantly to both the administrative burden of reviewing and approving an Early Reductions application and the technological burden of actually achieving the reductions. The EPA believes that the weighting system published in the final rule adequately addresses emissions of the high-risk pollutants and is consistent with the overall goal of achieving early emissions reductions.

2.6.6.5 Comment: One commenter suggested that the EPA include consideration of emissions in determining the weighting factor. This commenter believes that the weight-of-evidence classification and amount of emissions of a compound may give a truer picture of which compounds pose the greatest risk (IV-D-26).

Response: The weighting factors do not incorporate emissions because small amounts of one pollutant may pose a much higher risk than greater emissions of a different pollutant. Also, the Early Reductions determinations will be done on a case-by-case basis. If a weighting factor, which would apply industry-wide, was biased by emissions data, it could lead to inappropriate offsetting at a facility having significant emissions of a very toxic pollutant that had been assigned a low weighting factor on the basis of low nationwide emissions.

2.6.6.6 Comment: Three commenters questioned the EPA's policy decision concerning weighting factors for noncarcinogens. The commenters believe that the EPA must assess many additional factors when ranking the hazards of noncarcinogens. These

factors include the severity of the health effect, its reversibility, and chemical properties such as the half-life of volatile compounds in air, vapor pressure, persistence, and bioaccumulation potential (IV-D-33, IV-D-45, IV-D-47).

Response: In assigning weighting factors to the high-risk pollutants, the EPA attempted to base the factors on the relative toxicity of the compounds. For the carcinogens, the cancer potency factor is a straightforward measure of relative toxicity and was used in conjunction with the weight-of-evidence classification to develop the weighting factors. For the noncarcinogens, however, there is not a comparable measure of toxicity that can be used consistently for pollutants with different health effects. In the absence of such a measure, the EPA decided to assign a weighting factor of 10 to the noncarcinogens on the high-risk list. Many of the carcinogens were also assigned a weighting factor of 10.

The EPA chose a weighting factor of 10 for the noncarcinogens in recognition that noncancer health effects can be as seriously debilitating as the effects of cancer. Another alternative would have been to assign these pollutants a weighting factor of 1 because other indices were not available. The EPA rejected this option because only by assigning a weighting factor greater than 1 is offsetting limited between these noncarcinogens and other pollutants not on the high-risk list.

In the final rule, three noncarcinogens were assigned weighting factors greater than 10. The rationale for increasing the weighting factor from 10 to 100 for mercury is based on consideration of persistence in the environment and bioaccumulation. After a review of the scientific data, two other noncarcinogens (acrolein and 2-chloroacetophenone) have been assigned weighting factors of 100 rather than 10 in the final rule to provide an adequate margin of safety from adverse health effects. This decision is explained fully in a memorandum to the docket entitled "Need for Additional Weighting of Two

Chemicals." (Docket No. A-90-47, Item IV-B-4)12

2.6.7 Comments Concerning Bioaccumulation/Persistence Factor

2.6.7.1 Comment: Four comment letters discussed pollutants that persist in the environment and/or bioaccumulate. These commenters recommended that any pollutants identified as persistent or bioaccumulative be added to the list. Specific chemicals such as polychlorinated biphenyls (PCB's), metals, and some pesticides were specifically recommended for listing. The commenters also recommended that an additional weighting factor of 10 be applied to these pollutants (IV-D-14, IV-D-16, IV-D-39, IV-D-47).

Response: After consideration of public comments, the EPA has decided to adjust the weighting factors for chlordane, heptachlor, hexachlorobenzene, mercury compounds, and toxaphene from 10 to 100 based on persistence in the environment and bioaccumulation. The weighting factors for these particular pollutants were increased based on persistence and bioaccumulation data compiled for the EPA in support of the CAA Great Waters Study.

2.6.8 Comments on Specific Chemicals

2.6.8.1 Comment: One comment urged EPA to add radionuclides to the high-risk list (IV-D-39).

Response: The EPA did not add radionuclides to the high-risk list because radionuclide emissions are measured in terms of activity rather than mass and it would be extremely difficult to equate the two for the purpose of offsetting. The EPA recognizes, however, that radionuclides could potentially be present in trace amounts from some combustion sources. To account for this, language has been added to the final rule that stipulates that if a radionuclide source is included in the emissions pool, the EPA will not allow increases in radionuclide emissions under any post-reduction scenario.

2.6.8.2 Comment: One comment letter questioned why lead is not on the high-risk list (IV-D-26).

Response: Airborne lead emissions are currently regulated by a National Ambient Air Quality Standard (NAAQS). The EPA is currently reviewing the data the NAAQS is based on and expects to propose a revised standard in the near future. Given this and other policy considerations regarding identifying a criteria pollutant as high risk, at this time EPA believes it is appropriate to leave lead compounds off the high-risk list.

2.6.8.3 Comment: One comment letter questioned the development of the inhalation RfC for methylene diphenyl diisocyanate (MDI). The commenter claimed that the EPA should only use the thoracic data (lung effects) and not the extrathoracic data (nasal passage effects) to calculate an RfC for MDI (IV-D-41).

Response: The RfC/RfD Verification Work Group judged that the nasal effects observed in the Reuzel study are of concern with respect to chronic exposure situations. Analysis of the incidence and severity of these lesions at necropsy at 1 and 2 years of exposure indicate that both increased with continuing exposure. In addition, lesions described as degenerative occurred in 3/6 nasal sections at 2 years compared with lesions in 2/6 sections at 1-year examination. Basal cell hyperplasia in the 2-year study also was accompanied by atrophy of the olfactory epithelium. The Work Group considers that the spectrum of effects in the nasal cavity is more extensive than minimal irritation. The increase in severity and incidence suggests that similar and more extensive damage may occur in humans as exposure continues.

The Work Group agrees that MDI exposure in the Reuzel study resulted in adverse lung effects. Accumulation of pigment by macrophage was accompanied by tissue damage in areas where pigment-laden macrophage accumulated. The Work Group considers the lung effects to be biologically significant.

2.6.8.4 Comment: Commenter believes the EPA's use of several uncertainty factors to calculate the RfC for MDI is not warranted (IV-D-41).

Response: The RfC/RfD Verification Work Group has reduced the data base uncertainty factor from 10 to 3 because two species

were evaluated. This action reduced the total uncertainty from 300 to 100, which results in an RfC that is somewhat higher. The data base factor is considered justified since there are no developmental/reproductive studies in animals for MDI and there is only limited information pertaining to human exposures. In any case, the revised RfC is still sufficiently low to meet the high-risk screening criteria.

2.6.8.5 Comment: One commenter stated that the EPA did not take into account the low vapor pressure of MDI in the dispersion modeling performed in tier 2 of the analysis. Also, the commenter subsequently submitted additional data to the EPA that showed that MDI emissions have been over-reported to the TRI. According to the commenter, there are no facilities emitting MDI that exceed the "significant source" benchmark the EPA established in tier 3 of the analysis. (See memorandum to the docket entitled "Diisocyanates as High-Risk Pollutants for the Early Reductions Program - Meeting between the Environmental Protection Agency and the Chemical Manufacturers Association [CMA]." (Docket No. A-90-47, Item No. IV-E-13)[13](IV-D-41).

Response: As discussed above in the response to Comment 2.6.1.1, the EPA has decided to drop tier 3 from the analysis and list pollutants on the basis of the health effects and potential for exposure. Therefore, emissions information no longer has any bearing on the pollutant selection process. The EPA agrees with the commenter that MDI has a low vapor pressure and is a solid at ambient temperatures. However, the EPA still believes that the dispersion model used was appropriate for MDI even if it were to be emitted as an aerosol. It is likely that MDI is emitted at temperatures higher than ambient and so would disperse much like any other pollutant.

2.6.8.6 Comment: One comment letter questioned the RfC developed for 2,4 toluene diisocyanate (TDI). The commenter asserts that developmental and reproductive studies are available for TDI, so that an uncertainty factor of 3 is not warranted. In addition the commenter claims that existing data indicate that

the NOAEL for TDI is above the value used by the EPA. The commenter submitted data in support of these comments (IV-D-66).

Response: As a result of additional data becoming available, the EPA has decided to revise the RfC for TDI. As a result, TDI is no longer listed on the high-risk list. Responses to the commenter's specific concerns are addressed below.

The EPA RfD/RfC Verification Work Group agreed at its December 1990 meeting that an uncertainty factor of 3 is not needed for developmental and reproductive effects because experimental data indicate that little material reaches the bloodstream. The Tyl (1988)[14] and Tyl and Bradley (1989)[15] studies are being evaluated and discussion has been incorporated into a revised coversheet. Because the study results are negative, it is reasonable to expect that an uncertainty factor for these endpoints will not appear in the final coversheet.

With respect to the NOAEL for TDI, at the December 1990 meeting of the Work Group, the study by Diem et al. (1982)[16] was selected as the critical study and chronic pulmonary function loss was selected as the critical effect. At the time of these deliberations, neither the Bugler et al. (1991)[17] nor the Jones et al. (1991)[18] study was available. In spite of study drawbacks (e.g., additions to cohort, lack of exposure characterization in the first 2 years, and the cumulative exposure characterization), the Work Group agreed that the Diem et al. (1982)[16] study was well-conducted, the lung deficits were biologically significant, and the data were extensive enough to identify a conservative LOAEL. The question of whether time-weighted-average (TWA) levels or peak levels of exposure were appropriate for exposure characterization was extensively discussed. The Work Group, after consultation with two consultants and one of the authors of the study, felt that TWA measurements were more appropriate. There is no a priori information to suggest that peak exposures, in spite of high correlation with lung deficits, are better measures of exposure than TWA levels, which also show high correlation. It was agreed that instantaneous measurements below

5 parts per billion (ppb) are unreliable because of methodological considerations. However, TWA levels derived from many measurements offer more reliable data. For this reason, TWA levels were selected to characterize the group that experienced lung function decrements.

Decrements were noted in only the high-cumulative-exposure group of 21 never-smokers. Although the job categories for this high group had a geometric mean TWA of 4.5 ppb, the exposures of these 21 individuals were not identified in the study findings. Thus, it is possible that their true TWA may have approximated more closely the TWA of the low-cumulative-exposure category, a geometric mean of 1.1 ppb. In the absence of exposure data and pre-study exposure history for these 21 individuals, the Work Group felt it prudent and conservative to select 1.1 ppb as a "minimal" LOAEL for lung function decrements and no NOAEL was identified. It is acknowledged by the Work Group that this LOAEL is equivocal and may actually be higher. Studies by Peters[19,20,21,23], Wegman[22,23,24], and Musk[25,26] suggested that effects observed by Diem and colleagues were real and the studies together provide supportive evidence of a concentration-response relationship.

The analytical techniques used in the Diem et al. (1982)[16] study involved state-of-the-art technology, a technology (paper tape personal monitors) that was used also in the Jones et al. (1991)[18] and Bugler et al. (1991)[17] studies of TDI-exposed individuals. The limitations of this technology were recognized by Diem and colleagues and their use of personal monitors is considered to accurately reflect breathing zone concentrations of TDI vapors.

The revisions to the RfC coversheet will also include an evaluation of the recently available Bugler et al. (1991)[17] study. It is anticipated that a discussion of the Jones et al. (1991)[18] study will also be included in the coversheet revised by the EPA for TDI, assuming that publication of this study will take place in a timely manner. The summary of the

findings of the Jones et al. (1991)[18] study included in the commenter's submission appears to lack the level of detail for proper evaluation. Data from the Bugler et al. (1991)[17] and Jones et al. (1991)[18] studies may necessitate modifications to the confidence statement in the RfC coversheet with respect to the database. Thus, the final RfC may be different.

2.6.8.7 Comment: Two commenters stated that chromium compounds [chromium IV] should be listed only as hexavalent chromium compounds [chromium IV] because it has been shown that trivalent chromium does not pose the same risk as hexavalent chromium. According to the commenters, trivalent chromium is not a carcinogen. The EPA's 1984 Health Assessment Document[27] concludes that trivalent chromium is not reported to be carcinogenic by any route of administration. Within the last year, IARC has concluded that "metallic chromium and chromium (III) compounds are not classifiable as to their carcinogenicity to humans (Group 3)." The U. S. Department of Health and Human Services also concluded that there is "inadequate evidence" for carcinogenicity of chromium compounds other than hexavalent chromium (IV). According to the commenters, concentrations of chromium (III) 20 to 50 times higher than chromium (IV) are needed to cause an allergic skin reaction. In addition, the 1989 ATSDR Toxicologic Profile for Chromium[28] only calculates adverse human exposure levels with regard to the inhalation of chromium (IV) and not chromium (III) (IV-D-03, IV-D-17).

Response: The EPA reviewed health data on chromium in a 1990 Federal Register (55 FR 650)[29] denying a petition to exempt chrome antimony titanium buff rutile (CATBR) from reporting requirements under Section 313 of the Emergency Planning and Community Right-to-Know Act of 1988. The Federal Register notice provided information on both carcinogenic and noncarcinogenic health effects. On carcinogenicity, the notice indicates that:

> "If CATBR, which is a chromium compound, is retained in the lungs and made available to the cells, then it is of carcinogenic concern by inhalation....The National

> Toxicology Program (NTP) in their 1985 Fourth Annual Report concluded that "if any chromium compounds are carcinogenic, then all compounds containing chromium are potentially carcinogenic."...chromium (III) is believed to be the ultimate carcinogenic form of chromium (VI) after its entry into target cells and subsequent intracellular metabolic reduction."

For these reasons, chromium compounds as a group will continue to be listed as high risk.

The commenter also noted data on noncancer effects. The selection of chromium for inclusion as a high-risk pollutant, however, was based on chromium as a carcinogen.

2.6.8.8 Comment: One comment letter stated that listing chloroprene as a high-risk pollutant is inappropriate because its toxicological properties are well-defined and do not suggest that the material is extremely hazardous. According to the commenter, the approximate lethal concentrations of chloroprene vapor for rats and hamsters suggest only mild to moderate acute toxicity. There is no evidence of mutagenicity in in vivo tests in rats at concentrations up to 100 ppm. Chloroprene does not induce dominant lethal mutations in either rats or mice. Epidemiological studies have demonstrated that chloroprene is not carcinogenic to man. A study of active chloroprene workers at a Du Pont Company plant provided no evidence of biochemical or hematologic effects (IV-D-18).

Response: In the final rule, chloroprene has been deleted from the high-risk list. The focus of the testing referred to by the commenter was on the carcinogenicity and mutagenicity of chloroprene, not noncancer effects. The EPA believes that any determination of the cancer potential of chloroprene must be contingent upon the inhalation study now underway by the NTP. However, a recently-completed NTP subchronic study[30] indicated damage to nasal tissue. Assuming that the RfC Verification Work Group selects this study as the critical study for RfC development, it is still very unlikely that the resultant RfC would warrant listing chloroprene as high-risk.

The proposal of chloroprene as high-risk was based on results of a study that reported effects on reproductive parameters at exceedingly low concentrations (see Docket No. A-90-47, Item No. II-B-4).[10] After further review, the EPA has judged this study to be flawed because of the lack of detailed chemical information, contaminants, and storage conditions. This is especially critical for this compound, as some evidence suggests that toxic materials are generated in chloroprene stored under oxidative conditions and it may be these products that caused the effects seen in the study.

2.6.8.9 Comment: One comment letter stated that the proposed dioxin multiplier should be reevaluated in light of new research. According to the commenter, recent research suggests that dioxin poses far less (if any) risk to human health than previously thought (IV-D-35).

Response: The EPA's Office of Research and Development has begun a comprehensive new assessment of the toxicity of dioxin. This assessment will incorporate information from new epidemiologic investigations and laboratory studies and will reflect the thinking that is emerging from recent scientific discussions. The assessment will include a quantitative dose-response analysis. The commenter is incorrect, however, in asserting that the new assessment is being done because dioxin "poses far less (if any) risk ... than previously thought." This statement is speculative and does not characterize the full body of data that is being evaluated. The EPA has not yet reached any conclusions. In the meantime, the EPA's present characterization will be used. It would be premature and contrary to the EPA's policy to change the dioxin multiplier at this time.

2.6.8.10 Comment: One comment letter claimed that studies of smelter communities have failed to support the hypothesis that arsenic in smelter emissions is responsible for any higher incidence of lung cancer. The commenter also questioned the appropriateness of the weighting factors for arsenic and cadmium. The commenter submitted supporting data (IV-D-38).

Response: The commenter believes that the epidemiology studies of smelter communities by Greaves et al.[31] and Rom et al.[32] raise a question as to the appropriateness of the weighting factors for arsenic and cadmium. The study by Rom et al.,[32] which was addressed in the EPA's 1984 "Health Assessment Document on Arsenic",[27] found no association between cases of lung cancer and distance from a nonferrous smelter. The authors were unable to control for such critical factors as smoking, occupation, and migration, however, and were unable to obtain environmental measurements over most of the years studied. The study by Greaves et al.[31] also found no association between having lung cancer and distance from a smelter. Again, however, the authors were unable to control for such factors as smoking, occupation, and migration and had no environmental data to evaluate exposure other than distance from the smelter.

Even had Greaves et al.[31] and Rom et al.[32] addressed the factors mentioned above, however, the lack of a community effect would not necessarily be inconsistent with the current lung cancer dose-response estimate for inhaled arsenic. The EPA's unit risk estimate of 4.3×10^{-3} $[(ug/m3)^{-1}]$ is a lifetime risk estimate that assumes a lifetime of exposure. To adequately evaluate this estimate in community studies would require detailed knowledge of amount and length of exposure to the individuals in the study.

The lack of an association between distance from the smelters and having lung cancer has no impact on the unit risk estimate. Neither study was designed to evaluate the risk estimate, and both studies have limitations that make it difficult to evaluate, even in a qualitative manner, whether or not an elevated lung cancer risk exists in communities surrounding smelters.

The designation of arsenic and cadmium as high-risk and the subsequent assignment weighting factors were based on the EPA-approved cancer potency factors and consideration of the weight-of-evidence that these compounds cause cancer. The EPA

believes that this designation and the weighting factors are appropriate.

2.6.8.11 Comment: One commenter suggested that chemicals such as phosgene and methyl isocyanate, which pose potential severe, acute hazards should not be included because they are generally not emitted over long durations, nor do they demonstrate a potential for chronic health hazards from lifetime exposure. They do, however, pose an acute hazard under the conditions of a catastrophic accident or large release, and should be handled under Section 112(r) (IV-D-44).

Response: Section 112(i)(5)(E) specifies that the Administrator shall limit the use of offsetting reductions in emissions of other HAP's from the source as counting toward the 90-percent reduction in such high-risk pollutants qualifying for an alternative emissions limitation. No provision is made in this mandate for distinguishing between pollutants producing effects from acute exposure and those producing effects from chronic exposure.

2.6.8.12 Comment: One commenter questioned the EPA's cancer unit risk estimate for 1,3 butadiene. The comments had a number of aspects, including an inventory and analysis of new health data available since the EPA's 1985 assessment, and reconsideration of known issues or areas of uncertainty related to butadiene. Part of the comments also referenced ongoing assessment and regulatory activity by the Occupational Safety and Health Administration. The commenter took issue with the use of the data from a mouse bioassay rather than data from a rat bioassay. The commenter claims the rat is a more appropriate model and that the EPA neglected to consider all available metabolic and species differences when developing the unit risk estimate. Therefore, the commenter believes the unit risk estimate for butadiene greatly overestimates the potential risk to humans (IV-D-43).

Response: There has been new information on butadiene since 1985 in several areas including short- and long-term animal test

systems, evidence from human studies, and some information on metabolic/pharmicokinetic considerations. For these reasons, the 1985 EPA risk characterization (as reflected in the IRIS file) is outdated relative to information now available. This should not be taken to mean, a priori, that the 1985 assessment findings are inferior, but rather that the EPA's risk characterization warrants updating.

The public comments largely assert that the EPA's risk characterization should be revised according to the perspective of the commenter and with a different perspective for some fundamental assumptions. The specific merits of these assertions and critique of the EPA's past evaluations cannot be addressed until the EPA can initiate and complete it's own evaluation of the newer data. The completion of a new evaluation by the EPA is 12 to 18 months in the future according to current plans.

The question of how the unit risk estimate might change given new data or other considerations cannot be estimated. The question is not whether butadiene is carcinogenic in animals, it is how to extrapolate the animal data to humans with appropriate knowledge of species-specific considerations and a host of dosimetry considerations. If the human data base now provides a more robust set of data for quantitative risk analysis, this would also be a new factor relative to the 1985 assessment. In the meantime, however, the EPA's present characterization of 1,3 butadiene will be used. Therefore, 1,3 butadiene remains on the high-risk list.

2.6.8.13 Comment: One commenter submitted extensive comments and supporting data regarding acrylic acid. The commenter took issue with the RfC that has been developed for acrylic acid and upon which the high-risk listing is based (IV-D-40).

Response: The EPA does not believe that the RfC for acrylic acid is in error. Therefore, acrylic acid continues to be listed as a high-risk pollutant. Responses to the commenter's specific concerns about the acrylic acid RfC are addressed separately below.

2.6.8.14 Comment: The IRIS RfC for acrylic acid is based on a 90-day inhalation study in mice reporting a "very slight" focal degeneration of the nasal mucosa at an exposure concentration of 5 ppm. Other researchers have reported that mammalian olfactory epithelia completely regenerate if the basal cell layer remains intact. Thus, the slight focal degeneration is considered a reversible lesion (IV-D-40).

Response: Regarding the discussion of the possible reversibility of the nasal lesions due to acrylic acid exposure, there is some evidence that nasal epithelial lesions are reversible to some extent after cessation of the insult. However, the RfC is designed to be protective for a lifetime exposure. There is no evidence that these lesions are reversible with a continuing exposure, therefore the proposition that the lesions are reversible following a suitable recovery period is not relevant to the derivation of the RfC. Additionally, in a study of chronic exposure of rats to butyl acrylate, nasal lesions similar to those found after acrylic acid exposure persisted after a 6-month recovery period following a 2-year exposure (Reininghaus et al. 1991, Fd. Chem. Toxicol. 29:329-339).[33] In the Miller et al. (1985) study,[34] cited by the commenter, rats and mice exposed to ethyl acrylate for 6 months followed by a 21-month recovery period showed nasal lesions. These studies suggest that the lesion is not necessarily reversible.

2.6.8.15 Comment: The EPA classified acrylic acid as a high-risk air pollutant by rounding the RfC value in the IRIS data base to one decimal place. The actual RfC value as listed in IRIS is 0.33 ug/m^3, not 0.3 ug/m^3 (IV-D-40).

Response: The commenter is in error in stating that the actual RfC value listed in IRIS is 0.33 ug/m^3 The RfC's are generally presented to only one significant figure in recognition of the interpretation and definition of the RfC as an estimate with precision to an order-of-magnitude. When data are available that mitigate the need for a full uncertainty factor of 10 for a

particular area of uncertainty, such as for extrapolation from a LOAEL to a NOAEL, a reduced uncertainty factor is applied. The reduced uncertainty factor is typically the geometric half of the normal factor of 10, which is the square root of 10. This is represented as a 3 to avoid the implication of precision beyond a single significant figure. Thus, the use of a factor of 3 for two areas of uncertainty results in a composite uncertainty factor of 10. The correct uncertainty factor for the acrylic acid RfC derivation on IRIS is 1,000. The correct RfC is 0.3 ug/m^3.

2.6.8.16 Comment: The adverse effect upon which the acrylic acid RfC is based is a very slight, localized, reversible sign of upper respiratory tract irritation. A threshold-dependent effect such as this certainly does not warrant the excessive conservatism employed in this classification process (IV-D-40).

Response: The nasal epithelial lesion on which the acrylic acid RfC is based is degeneration of the epithelial tissues of the nose, which occurred in 40 percent of the exposed animals at the LOAEL. The incidence of the effect increases in an exposure-concentration-related manner and the severity of the effect increases at increasing concentrations. These factors led the EPA RfD/RfC Work Group to the conclusion that the effect is adverse. The EPA agrees that the effect is of minimal severity, and this is reflected in a reduction in the uncertainty factor for extrapolation from a LOAEL to a NOAEL (i.e., an uncertainty factor of 3 rather than 10 was used here). Because a NOAEL was not demonstrated, some uncertainty remains regarding the amount of reduction necessary to reach a level that is not likely to produce the effect. Therefore, an uncertainty factor is applied for extrapolation from a level producing an adverse effect to a presumed NOAEL. The EPA does not believe that the derivation of the RfC for acrylic acid employs "excessive conservatism."

2.6.8.17 Comment: Available chronic inhalation studies for methyl acrylate, ethyl acrylate, and butyl acrylate should be considered as supporting data. Data from these chronic

inhalation studies of acrylate esters, when combined with uptake and hydrolysis data from the rat upper respiratory tract, are directly applicable to the determination of potential effects from chronic inhalation of acrylic acid (IV-D-40).

Response: The chronic studies on acrylate ester were not reviewed during the development of the RfC for acrylic acid. As indicated by the commenter, the nasal lesions produced by acrylic acid and by several acrylate and methacrylate esters are very similar. The studies on acrylate ester may therefore provide relevant information on the toxicity of acrylic acid. Acrylate esters are deposited in the nose and metabolized to acrylic acid and the corresponding alcohol. Acrylic acid is likely to be the toxic metabolite for methyl acrylate, ethyl acrylate, and butyl acrylate. Acrylic acid is deposited directly in the nasal epithelium and does not require metabolic activation. Because of this difference in the mechanism of dose delivery, the acrylate esters cannot be directly used to evaluate acrylic acid toxicity quantitatively.

The chronic studies of methyl acrylate and butyl acrylate show adverse nasal effects in rats at 15 ppm, the lowest concentration tested. The chronic study of ethyl acrylate shows effects in the nasal epithelium at 25 ppm in a high percentage of the exposed animals, and no effect at 5 ppm. The occurrence of an effect at lower concentrations of acrylic acid than of the acrylate esters could reasonably be expected to result from differences in delivered dose resulting from differences in solubility, deposition, or distribution of the chemicals.

The studies of the acrylate esters may provide information on the extrapolation of subchronic to chronic data, as suggested by the commenter. Only subchronic data are available for acrylic acid, and uncertainty exists as to the extent of progression of the lesion leading to increased incidence and/or severity of the lesion with a chronic or lifetime exposure. Comparison of the subchronic acrylic acid study directly with the chronic studies on acrylate esters, as suggested by the commenter, is not

appropriate because the comparison is confounded by differences in dosimetry. However, a comparison of the subchronic and chronic studies on the acrylate esters might provide information on the extent of the progression of the lesion that could be extrapolated to acrylic acid because of the similarity of the lesions. The results of subchronic studies of methyl acrylate and butyl acrylate done by BASF and on ethyl acrylate by the Dow Chemical Company are not available to the EPA at this time.

2.6.8.18 Comment: In chronic studies of acrylate esters, the esters caused no injury to internal organs. No tumors developed in the nasal turbinates with any of the esters; thus, the lesions cannot be considered preneoplastic. Furthermore, there was no evidence of a carcinogenic effect in any organ system or tissue (IV-D-40).

Response: The RfC derivation employs an uncertainty factor for lack of a two-generation reproductive toxicity study. It is the practice of the RfD/RfC Work Group to require reproductive and developmental toxicity studies because functional effects may occur in the absence of any tissue damage that would be seen in a typical subchronic or chronic toxicity study. The absence of either a developmental toxicity or a two-generation reproductive toxicity study is an area of uncertainty that requires application of an uncertainty factor. This uncertainty may be reduced if a reproductive toxicity study were available on any of the acrylate esters showing reproductive toxicity endpoints to be less sensitive than the respiratory tract effect. At this time, the EPA is unaware of any two-generation reproductive toxicity study on acrylic acid or on methyl acrylate, ethyl acrylate, or butyl acrylate.

2.6.8.19 Comment: The incorporation of data from chronic inhalation studies for acrylate esters eliminates the need for the uncertainty factor of 10 for extrapolation from subchronic to chronic studies. Furthermore, these studies complement the studies already cited in the IRIS data base and should

significantly increase the confidence in the inhalation data base from "MEDIUM" to "HIGH" (IV-D-40).

Response: The commenter is in error in stating that the RfC on IRIS uses an uncertainty factor of 10 for extrapolation for subchronic to chronic exposure. The IRIS text states that: "A factor of 10 is used for extrapolation from subchronic to chronic and for limited reproductive studies." As discussed above, the data available to the EPA at this time are not sufficient to reduce or eliminate these areas of concern. However, data might be available that would cause the EPA to re-assess the RfC for acrylic acid. Such data would have to be submitted through the IRIS Submission Desk for consideration.

The minimum data base for high confidence in the RfC data base is two chronic inhalation bioassays in different mammalian species, two developmental studies in different mammalian species, and a two-generation reproductive study. The confidence in the acrylic acid data base is medium due to the lack of reproductive studies and chronic studies. Because of the dosimetric difference described above, and the lack of reproductive studies for any of the acrylate esters, the analogy of acrylic acid with acrylate esters is not sufficient to raise the confidence in the RfC.

2.6.8.20 Comment: Two long-term acrylic acid drinking water studies have been conducted in rats. Decrements in drinking water consumption and body weight gain were the only effects noted. When these studies are included in IRIS, the present oral RfD value of 80 mg/kg/day should be increased by a factor of 10 because the extrapolation from subchronic to chronic studies will no longer be applicable (IV-D-40).

Response: The EPA agrees that the data submitted on oral exposures to acrylic acid should be reviewed and incorporated into the RfD file. However, this review would not change the classification of acrylic acid as high-risk because the high-risk designation is based on the RfC.

2.6.8.21 Comment: Extensive comments concerning vinylidene chloride (VDC) were received from two commenters. The commenters' primary contention lies in the designation of VDC as a carcinogen. (Vinylidene chloride has previously been designated as a Group C [possible human carcinogen] by the EPA.) The letters included comments regarding metabolism and pharmacokinetics and possible species variations, as well as comments about the "large number of 'negative' studies" compared to the number of "positive" studies. The commenters believe that Group C carcinogens should be treated differently than Group A or Group B carcinogens-similar to the treatment of Group C carcinogens by the EPA's corrective action program for solid waste management units. The commenters maintain that by failing to consider distinctions in cancer classification in the tier analysis, the EPA acted contrary to its own guidance as set forth in the "Guidelines for Carcinogen Risk Assessment"[35] and the information presented in the 1985 "Health Assessment Document for VDC."[36] The commenters also questioned the specific study by Maltoni et al.,[37] which is the basis for the unit risk estimate for VDC (IV-D-49, IV-D-55).

Response: In response to public comment, the EPA has revised the weighting factor system in such a way that cancer classification and not just cancer potency is given consideration. As a result, Group C carcinogens that were proposed for the high-risk list have now been assigned a weighting factor of 1. This decision affects VDC and 1,1,2,2 tetrachloroethane. The commenters' concerns about the cancer classification of VDC are addressed below.

The EPA has classified VDC as a Group C carcinogen based on animal data. This classification is based primarily on the finding of kidney adenocarcinomas in male mice, as well as other considerations that contribute to placing VDC into Group C. Although a number of studies have been conducted in different strains and species that might provide information on the potential carcinogenicity of VDC, many of these studies were not

designed as cancer bioassays, or they were flawed in some ways that lessened their usefulness in determining the carcinogenic potential of the chemical. Vinylidene chloride was administered by different routes in different studies--by inhalation, orally by gavage and in drinking water, and by skin application and subcutaneous injection.

Unfortunately, most of these studies were not adequate for proper and conclusive evaluation of cancer-causing activity because of a number of factors, including less-than-lifetime or otherwise inadequate exposure regimens, insufficient numbers of animals used in the studies, and/or inadequate number of dose/exposure levels. Only some of the studies were actually designed and conducted as cancer bioassays. Therefore, the fact that increases in tumor incidence were not observed in most of the studies referred to by the two commenters does not weigh nearly as heavily in the overall weight-of-evidence determination as their comments imply.

There were positive findings in the studies conducted by Maltoni et al., in spite of certain shortcomings. Kidney adenocarcinomas, a rare tumor in mice, were induced in male mice exposed by inhalation. This data set was the one used to calculate an upper-bound risk estimate for VDC. In addition to the kidney adenocarcinomas, there were statistically significant increases in mammary carcinomas observed in female mice and pulmonary adenomas in mice of both sexes, although there was not a dose-response relationship. In a two-stage skin bioassay, there was some evidence that the chemical acted as an initiator.

2.6.8.22 Comment: One comment letter was received concerning ethylene oxide (EO). The commenter's contention is that the EPA's 1985 Health Assessment Document (HAD) (EPA-600/8-84-009F)[38] on EO is out of date because: (1) it fails to consider the array of new epidemiological data, (2) the endpoints observed in animal studies are not necessarily relevant to humans, and (3) the cancer potency factor used is dated and inadequate to represent the potential risk to humans (IV-D-61).

Response: The commenter's submission cites four recent epidemiology studies: Steenland et al.(1991);[39] Greenberg et al. (1990);[40] Gardner et al. (1990);[41] and Kisselbach et al. (1988)[42] in support of the commenter's claim. These studies plus additional studies by Hogstedt et al. (1986);[43] Hogstedt (1988);[44] Bisanti et al. (1988)[45] and two unpublished reports (Stolley et al. [1988][46] and Hagmar et al. [1986][47]) form the basis of response.

The Hogstedt (1986, 1988)[43,44] studies showed significant increases in mortality from both digestive system cancers and leukemia. This confirmed the results of their earlier paper cited in the 1985 HAD. Stolley et al. (1988)[46] reported a statistically significant increase in female breast cancer among EO sterilant workers. The cohort had limited latency and power. A small increase in lymphatic and hematopoietic cancer was noted also but the results were not significant. Hagmar et al. (1986)[47] reported a statistically significant increase in the incidence of malignant lymphoma and myelomatosis in male workers exposed to EO at a chemical factory.

The Steenland (1991)[39] study of 18,254 workers in 14 U. S. plants is by far the largest of the four studies submitted by the commenter. Although there were no significant increases in mortality from any cause in this cohort, there was an excess of hematopoietic cancers in male workers, especially among workers in the longest latency category. This was not observed in females. The report concludes, and the commenter concurs although with a different emphasis, that the results are inconclusive with respect to human carcinogenicity at workplace exposure levels.

The Gardner (1989)[41] study reported slight increases in deaths from leukemia (3 observed versus 2.09 expected) in men who were not exposed to leukemogens other than EO. Additionally, there was an increase in deaths due to non-Hodgkin's lymphoma (4 observed versus 1.62 expected). There were no increases in deaths due to stomach cancer (5 observed versus 5.95 expected).

Overall, the authors report only a slight increase in cancer mortality over the expected. Although they state that differences in exposure levels may explain the discrepancies with the literature results, they conclude that their findings do not exclude the possibility that EO is a human carcinogen.

The third study, Greenberg et al.(1990)[40] was a retrospective cohort study of 2,174 men who either produced or used EO. While there was increased mortality from leukemia and pancreatic cancer, the authors attributed these to exposures from the chlorohydrin department, where EO exposures were considered low.

The Kiesselbach (1988)[42] study reported on the mortality of 2,658 subjects from eight different plants exposed to EO for 1 year (no exposure level was given). Of the 63 cancer deaths reported, only 2 were from leukemia (2.35 expected), while deaths from esophageal and stomach cancers were higher but not significantly so.

In response to the commenter's second point, the EPA's guidelines for carcinogen risk assessment hold that site concordance for tumors between animal and human studies adds to the weight of evidence, but some known human carcinogens, e.g., arsenic, benzene, chromium, have not shown site concordance. Therefore, lack of concordance should not detract from the weight of evidence.

To support the claim that the rat tumor response was an inappropriate model for human risks, the commenter referenced the work of Dr. Leon Goldberg (1986),[48] which contains his analysis as well as those of Drs. Susan Austin and Robert Sielkin. This book, in report form, was submitted by the commenter to the EPA's Science Advisory Board in its 1984 review of the draft HAD.[49] Therefore, this material has already been reviewed and the appropriate parts incorporated into the June 1985 Final Report. Additionally, in its currant submission, the commenter failed to note the existence or significance of a major inhalation study in mice conducted by the National Toxicology Program (Toxicology and

Carcinogenesis studies of EO, NTP TR 326, NIH #88-2582).49 The results of this study showed clear evidence of carcinogenic activity in B6C3F mice. The EPA's use of total number of animals with at least one EO-caused tumor site would lead to a revised cancer potency factor very close to, if not higher, than the current value.

In summary, the commenter's conclusion that EO should not be designated a high-risk pollutant is not supported by the health data submitted. While it is quite possible that new pharmacokinetic data will aid in a reassessment, the submission does not justify waiting for those data to become available before listing EO as high-risk.

2.6.8.23 Comment: The weighting factor for hydrazine should be changed from 100 to 10 because the potency factor for hydrazine is only a factor of 2 greater than the highest potency of other chemicals with a weighting factor of 10. Also, the commenter feels the short half-life of hydrazine (a few minutes to a few hours, depending on ambient concentrations of other reactive species) is inconsistent with a weighting factor of 100. The EPA's exposure model did not account for the short half-life (IV-D-42).

Response: In the final rule, the weighting factor for hydrazine remains at 100. The commenter is correct in stating that the exposure model used does not take into account the volatility of pollutants. The half-life of hydrazine is greatly influenced by the presence of ozone, the hydroxyl ion, and other reactive species in the ambient air. As a result, hydrazine is likely to degrade faster in polluted areas where ozone and hydroxyl ion levels are higher. Depending on these conditions, it is estimated that the half-life of hydrazine ranges up to several hours. The EPA believes this would be ample time for hydrazine to be present in the ambient air at a distance 200 meters from the emission point. The commenter submitted information on the distances to the nearest residence from the

largest hydrazine producers, which showed that residences were further away than 200 meters. However, other types of facilities that emit hydrazine may also participate in the Early Reductions Program and could be closer to residences. Therefore, no adjustment to the weighting factor was made on this basis.

The weighting factor of 100 for hydrazine is based on the potency of hydrazine relative to the geometric mean potency of the group of carcinogens not on the high-risk list. By this method of comparison, hydrazine is about 200 times more potent than carcinogens not on the high-risk list. Because the EPA had previously decided that rather than establish unique weighting factors for each pollutant it would be appropriate to combine pollutants of similar relative toxicities in groups that differ by an order of magnitude, hydrazine was assigned a weighting factor of 100.

2.6.8.24 Comment: One comment letter concerned the scientific study used as the basis of the potency factor for hydrazine. The potency value for hydrazine was calculated on the basis of results of the MacEwen et al. (1981)[50] study. The commenter maintains there are several problems with the study, including (1) the animals may have been compromised by a disease state, (2) the animals were probably exposed to higher concentrations of hydrazine than the measured amounts, (3) higher concentrations led to an underestimate of the NOAEL, resulting in an overestimate of the cancer potency, and (4) the rat may not be an appropriate model for humans (IV-D-42).

Response: While the number of rats showing an inflammatory response increased somewhat at the lowest dose, tumors were not observed in this group. Moreover, most of the incidences of inflammatory response were in the trachea and larynx, while tumors in the high dose animals were mostly in the nasal region. There was little increase in the numbers of animals showing inflammatory response in the 0.25 and 1.0 ppm dose groups even though the latter group did show an increased number of animals with tumors. Finally, respiratory tract tumors were seen in

hamsters with little evidence for inflammation, suggesting that inflammation was not necessary for the tumorigenic response. For these reasons, the acute inflammatory response seen in the lowest exposure group is not considered to be a significant factor influencing responses at the two highest dose groups.

The possibility that there were errors in the concentration measurements cannot be considered at this time. The results were published in a peer-reviewed journal and are considered valid unless there is definitive evidence to the contrary. If an Air Force reanalysis of this study indicates significant errors and the degree of error can be determined, the EPA will then consider adjusting cancer potency factors. Also, any potential error in dose and, therefore, the NOAEL does not affect the estimation of cancer potency because the latter value is based on tumor incidence and not noncancer endpoints.

The data are inadequate to show that the rat is more sensitive to inhaled hydrazine than other laboratory species or humans. Adenomatous polyps were seen in exposed hamsters, even though this species is considered to be quite resistant to the induction of respiratory tract tumors. While mice gave only a marginal response at 1 ppm, they were not exposed to 5 ppm, as were rats and hamsters. While the rat may be quite sensitive to the irritating effects of hydrazine, adenomatous polyps developed in the hamster without apparent inflammation.

2.6.8.25 Comment: The cancer potency of hydrazine has been overestimated by the inhalation route (IV-D-42).

Response: Although tumors have been induced by hydrazine at a variety of sites, the upper respiratory tract is the most sensitive. Potency by one route may be much different than potency by another route because of pharmacokinetic factors. Therefore, low potency by the oral route does not necessarily mean low potency by the inhalation route.

2.6.8.26 Comment: Epidemiology studies show that hydrazine is not a human carcinogen (IV-D-42).

Response: The EPA has determined that the human epidemiological data are inadequate to refute or demonstrate a carcinogenic hazard. Hydrazine has been classified as a Group B carcinogen (probable human carcinogen) based on evidence of animal carcinogenicity.

2.6.9 Miscellaneous

2.6.9.1 Comment: Commenter requested that five or so optional spaces be included on the list for State agencies to add compounds that are of high priority for reduction in their States (IV-D-26).

Response: The authority to designate high-risk pollutants has not been delegated to the States. Section 112(i)(5)(E) stipulates that the EPA Administrator shall, by rule, designate high-risk pollutants under the Early Reductions Program.

2.6.9.2 Comment: One letter urged the EPA to drop the inorganic grouping concept for such pollutants as arsenic, asbestos, beryllium, cadmium, chromium, and mercury, and develop an alternative based on individual toxicity (IV-D-51).

Response: At the current time, the EPA does not plan to split the pollutant groups specified by Congress into individual pollutants. However, in Section 112(b)(3), individual pollutants within pollutant groups will be considered for deletion from the list of HAP's if a petitioner can make a showing that the unique chemical substance meets the deletion requirements of Section 112 (b)(3)(C). Exceptions to this are the compound groups of polycyclic organic matter, mineral fibers, and coke oven emissions.

2.6.9.3 Comment: One commenter was of the opinion that sources should be encouraged to reduce the amount of any high-risk pollutant released (IV-D-25).

Response: The EPA agrees fully with the commenter. Nothing in this rule should be construed to discourage control of high-risk pollutants. The purpose of establishing the high-risk list was to ensure that in achieving the required emission reductions under the Early Reductions Program, high-risk

pollutants would be adequately controlled.

2.6.9.4 Comment: When pollutants are added to the high-risk pollutant list, a source should not be exempt from further reducing those pollutants, but the source should be given up to 3 years to adjust its emissions to continue to qualify for an Early Reductions extension or comply with Section 112(d) standards (IV-D-16, IV-D-25). Other commenters believe that changes to the high-risk pollutant list should not affect the status of a previously submitted commitment or application (IV-D-19, IV-D-30, IV-D-34, IV-D-47).

Response: The EPA has decided that sources with an approved enforceable commitment or an approved permit specifying an alternative emission limit will not be affected when a HAP is either added to the list in Section 112(b) or is newly-designated as a high-risk pollutant. The EPA expects to update the list of high-risk pollutants as the science requires. It is conceivable that a source would have to revise a post-reduction demonstration with each revision of the list. This requirement could add significantly to the administrative burden for both the source and the reviewing agency. Given that the source will be in full compliance with the emission standards under Section 112(d) at the end of the 6-year extension, the EPA feels this additional administrative burden is unnecessary.

2.6.9.5 Comment: The proposed regulation does not provide a means of addressing high-risk HAP's if the facility chooses to use the weighted average approach for reducing gaseous and particulate emissions (IV-D-06).

Response: According to Section 63.74(g), the applicant may demonstrate that the total base year emissions adjusted for high-risk pollutants have been reduced by at least 90 (95) percent or a combined weighted percentage between 90 (95) percent for sources emitting both gaseous and particulate HAP. The equation for calculating the weighted percent is provided in paragraph 63.74(f) of the regulation. The same weighted percent will be used for comparison with the total base year reductions

and with the total base year adjusted for high-risk pollutants.

2.7 STATE AUTHORITY

2.7.1 Comment: One commenter suggests that States be consulted during early permit approvals and have the authority to require greater than 90 (95) percent reduction to protect public health even when the EPA is the reviewing Agency (IV-D-04). Several commenters suggested the EPA consult States during early review and receive firm commitments from the States that the 90 (95) percent reduction is acceptable and that new State air toxics requirements will not burden facilities with additional requirements after Early Reductions requirements have been met. The EPA should also discourage States from requiring greater than 90 (95) percent reduction (IV-D-12, IV-D-19, IV-D-30, IV-D-44). Another commenter suggested that the EPA require each State to make a determination on the percentage reduction that it will accept, and establish a deadline for making this determination (IV-D-38, IV-D-64).

Response: The CAA states in Section 112(i)(5)(A) that: "Nothing in this paragraph shall preclude a State from requiring reductions in excess of those specified in this subparagraph as a condition of granting the extension..." Although not specifically stated, it is implied that the excess reductions can only be required as a condition of the State granting the extension. The CAA, therefore, implies that when the State is the permitting authority, the State may require greater than 90 (95) percent reduction as a condition for granting the extension. As long as the EPA (administered through the Region) remains the permitting authority, the CAA specifies 90 (95) percent reduction.

2.7.2 Comment: The regulation itself should provide for coordination with the States prior to the State having permitting authority (IV-D-22).

Response: The EPA intends to coordinate all efforts with State agencies. The amount of involvement for the States may vary depending on the interest and knowledge of the State

concerning a specific source, or the resources available to a State for the Early Reductions Program. The EPA is committed to State participation, and will include States in the review and approval of permits and enforceable commitments. It is not necessary to put implementation details such as these in the regulation.

2.7.3 Comment: The commenter suggests that States receive all copies of permit applications, not just base year emissions evaluations. States may have valuable information about the source that can affect Early Reductions proposals (IV-D-52).

Response: The regulation does not specify any of the review and disposition requirements of permit applications because these requirements will be contained in Part 71 regulations. The regulation does state that the EPA Regional offices will closely coordinate with States concerning all submittals prior to the States being delegated permitting authority.

2.7.4 Comment: State and local agencies need guidance and training prior to submittal of applications (IV-D-06).

Response: The EPA has worked closely with State and local agencies in the development of the Early Reductions regulations. The EPA has conducted and will continue to conduct training to assist State and local agencies whenever requested in the implementation of the Early Reductions Program. Through this training and independent mailings, the EPA has provided State and regional offices with a draft of the Enabling Document, which will be updated according to the final regulation. The EPA has also compiled a question-and-answer document based on questions raised by regulatory agencies and industry representatives. In accordance with the schedule of source categories, the EPA will identify references to assist State and local agencies with the review of calculated emissions. The EPA will continue to provide support and guidance as necessary to State and local agencies.

2.7.5 Comment: A number of commenters suggests delegating approval authority for the Early Reductions Program to the States independently of approval for State permit programs under Title V

(IV-D-02, IV-D-10, IV-D-14, IV-D-16, IV-D-20, IV-D-25, IV-D-26, IV-D-28, IV-D-31, IV-D-46, IV-D-47, IV-D-57, IV-D-59). One of these commenters (IV-D-46) also believes that language in the regulation implies that States will have sign-off authority on all extensions, regardless of whether States are delegated to administer the Program. Several other commenters suggest that the EPA retain responsibility for approving enforceable commitments and permit applications until the States have an approved Program. States already have an enormous burden in developing an approvable Title V permit program (IV-D-08, IV-D-19, IV-D-28, IV-D-32).

Response: The EPA specifically solicited comment on whether this Program should be delegated to the States. Based on the comments received, the EPA is proceeding to establish the criteria for delegating the Early Reductions Program to those States that seek delegation authority even in advance of a State having a Title V operating permit program.

Section 112(l) of the CAA authorizes the Administrator to approve a State program for the implementation and enforcement of the emission standards and other requirements of the section, including partial delegation of the Program. That is, the EPA anticipates that it will, if a State so desires, delegate to a State the authority to develop and implement the Early Reductions Program. The EPA anticipates that it will publish delegation guidance in the near future that will be useful to the States in developing programs for submittal.

Of course, until such time as a State has an approved State program under Title V, it cannot issue a permit [see CAA Section 112(l)(9)]. Therefore, the Administrator cannot delegate his authority to issue a permit establishing an alternative emission limit under Section 112(i)(5) until such time as a State has an approved Title V permit program.

2.7.6 Comment: Several commenters requested that 63.72(f) be deleted. States should not be allowed to require greater than 90 (95) percent reduction (IV-D-02, IV-D-08, IV-D-27).

Response: Section 112(i)(5)(A) of the CAA Amendments specifically allows States to require reductions greater than 90 (95) percent. It is clear from the language of the CAA that Congress intended States to have the power to promulgate and enforce stricter standards.

2.7.7 Comment: States should have the option of not allowing facilities in their State to participate in the Early Reductions Program (IV-D-14, IV-D-22).

Response: The Early Reductions Program is a national Program mandated by Congress through the CAA and States do not have the authority to disallow participation. However, States do have the power to require additional or stricter State standards or require greater than 90 (95) percent reduction under their Title V State permitting program.

2.8 INTERFACE WITH TITLE V PERMITS

2.8.1 Comment: EPA should establish a policy for dealing with applications under review during the time that States receive the final approval of a State Title V permitting program. Commenter suggests that the reviewing agency remain the same throughout the review and issuance of the permit (IV-D-13).

Response: The EPA generally agrees with the commenter that Title V permit applications undergoing review by the EPA for an Early Reductions demonstration and alternative emission limits should not have to be reviewed twice--once by the EPA and then by the State. In most cases, this should not occur. However, there may be some situations where a State has received approval of its Title V permitting program during the time that the EPA is reviewing a permit application submitted by a source to the EPA for an Early Reductions demonstration. The EPA will address this situation in an upcoming Federal Register notice that will describe a specialty permit rule for the Early Reductions Program.

Briefly, the EPA does not believe that permit issuance would be substantially delayed as a result of the transition to State responsibility for permitting. Owners or operators must know in

a timely fashion whether their sources will be granted a compliance extension. If an extension denial occurs, the source will have to meet the applicable Section 112(d) standard on schedule, and if substantial delays occur, it will mean less time for the source to meet the 112(d) standard.

The anticipated Early Reductions specialty permit rule will address when the EPA will retain permit issuance even after a State receives approval for its comprehensive Title V permit program, as well as when such review and specialty permit issuance will be transferred to the State after submittal to the EPA by the source owner or operator. It is envisioned that in the event of such transfer, the State will adhere as closely as possible to the original review timetable established by the EPA.

2.8.2 Comment: Most applications for early reductions will be submitted before State programs are approved. Commenters would like language added to the regulation and/or assurance that any Early Reductions application that is approved by the EPA (versus the State) will be included in any future operating permit without further negotiation (IV-D-02, IV-D-38, IV-F-1a).

Response: Once the EPA has issued a Title V operating permit providing for alternative emission limitations for Early Reductions sources, they remain in effect for the duration of the 6-year compliance extension. Because permits must be renewed after 5 years, the State would be the reviewing agency at that point. However, the alternative emission limitations, once granted, continue to be permit conditions until the compliance extension expires, in which case applicable Section 112(d) standards then take effect.

2.8.3 Comment: Permits for the Early Reductions Program should not be revoked for any reason prior to the end of the 6-year extension, even pursuant to Section 112(f) of the CAA (IV-D-29).

Response: Permits issued during the 6-year compliance extension may be revoked only in those circumstances that warrant permit revocation under the Title V permit regulations. If the compliance extension were revoked, then the source would have to

achieve timely compliance with any applicable Section 112 standard. Section 112(i)(5) does not shield a source from standards issued under Section 112(f).

2.8.4 Comment: Sources covered by Section 112(d) standards prior to 1994 will be discouraged from participating in the Program because proposed permit rules will not be completed. The commenter based this comment on the statement in the preamble: "Sources subject to early 112(d) standards but which nonetheless have achieved qualifying reductions before proposal, are not required to submit enforceable commitments to participate in the Early Reductions Program. Such sources need only file a permit application demonstrating that qualifying reductions have been achieved." (56 FR 27356)[51] (IV-D-36).

Response: The Early Reductions Program provides the "enforceable commitment" vehicle to allow participation by sources subject to the Section 112(d) standards expected to be proposed by January 1, 1994. Sources that submit an enforceable commitment may submit a permit application as late as December 1, 1993. Emission reductions do not have to be achieved until January 1, 1994. Sources unable to achieve the required reductions may rescind their commitment by December 1, 1993 without penalty.

The statement quoted by the commenter was not intended to discourage sources from submitting an enforceable commitment but was intended to clarify that sources have the option of achieving emission reductions and submitting a permit application according to the deadlines imposed on sources covered by Section 112(d) standards proposed after January 1, 1994. However, the enforceable commitment option allows sources additional time to achieve reductions, additional time to submit the permit application, and the option of rescinding the commitment without penalty. The enforceable commitment mechanism, along with the permitting program, will give facilities maximum opportunity to participate in the Program.

2.8.5 Comment: The public should only comment during the Title V permit issuance process to reduce the time burden and simplify the process (IV-D-27).

Response: Acceptance of base year emissions is essential to participants in the Early Reductions Program. If base year emissions are accepted by both the EPA and the public, facilities will know how to proceed in achieving the actual reductions. In many cases, facilities will need to devote resources to installing control equipment. Therefore, industry will have the benefit of a complete base year review prior to making pollution control expenditures and prior to submission of the permit application. Any necessary changes or adjustments can be made following base year review, therefore facilitating participation in the Program.

Submittal of base year emissions for early review is optional where the reductions are made before proposal. Any source that believes that this submittal is burdensome may simply submit a permit application according to the guidelines in the regulation. It is, however, in industry's best interest to submit base year emissions for early review and to have the public review the emissions.

It should be noted that acceptance of base year emissions does not provide an absolute shield against changes required during subsequent permit review. However, these changes should be minimal.

2.8.6 Comment: Items (b) and (c) in Section 63.77 need to be clarified. Does the "additional information" refer only to a defined source (IV-D-52)?

Response: All permit applications will require the information outlined in Section 63.74 of the regulation. The "additional information" wording in the regulation refers to the information required specifically by the permitting agency over and above that needed to demonstrate early reductions. The information required to complete a permit application will be

specified in the Part 70 and Part 71 permitting regulations (when issued).

2.8.7 Comment: Commenter believes that the "Alternative Emissions Limitation" permit should be a separate permit that is not included on regular Title V operating permits because of conflicting requirements of the two programs. If the permits were separate, the alternative emission limit permit could be written for a 6-year period, thereby eliminating the unnecessary review after 5 years (IV-D-13).

Response: The CAA specifically requires that an Early Reductions alternative emission limitation be established by permit under Title V. Section 112(i)(5)(D) specifies that this permit be issued under Title V by stating: "For each source granted an alternative emission limitation under this paragraph there shall be established by permit issued pursuant to Title V an enforceable emission limitation..."

2.8.8 Comment: Using a Title V permit for a source that is less than an entire facility is inappropriate. A separate means of tracking legally enforceable commitments and reductions is necessary. The reductions may then be worked into the plantwide Title V permit (IV-D-26).

Response: Title V permits apply to an entire facility. All parts of the permit, however, do not have to be issued at the same time. The Early Reductions regulation specifies that a permit will be issued upon approval of the application. Although the permit for the alternative emission limitation will be part of the Title V permit for the entire facility, each part may be issued as it is approved.

2.8.9 Comment: Fees should be collected for the Early Reductions Program or the Title V permit program but not both. Language in the proposed rule should be changed to state that the review fees would be covered under the Title V fee program (IV-D-30). Another commenter also suggests that it would be unfair to collect permit fees for pollutants covered by two permitting programs. Because companies not participating in the

Early Reductions Program and complying with Section 112(d) will only pay one permitting fee, companies participating in the Early Reductions Program should also pay only one permit fee (IV-D-45).

Response: The CAA under Section 112(i)(5) does not establish a separate fee collection system for the Early Reductions Program. However, the CAA states that the Early Reductions Program will be administered by the Title V program and according to Section 502(B) of the CAA, the permitting authority will collect fees under the Title V program. Therefore, fees will be collected but only as prescribed by the Title V program. Applicants who submit enforceable commitments will not be subject to fees until the source applies for a permit.

2.8.10 Comment: One commenter suggests eliminating the base year review for enforceable commitments but requiring submittal of permit applications by January 1, 1993 so that permits may be issued by January 1, 1994. The base year review is truncated and will inappropriately stress the capabilities of the EPA and State personnel. A permit is required to enforce the reduction achieved by January 1, 1994 (IV-D-39).

Response: Base year review will expedite the permit review and assist industry in making "acceptable" reductions. Early review of base year emissions is essential before a source commits the resources to reduce emissions. This review will provide assurance of acceptable base year prior to major expenditures.

2.8.11 Comment: The EPA must provide consistency between the operating permit program and the Early Reductions Program. The EPA needs to give applicants at least 30 days to correct deficiencies with Early Reductions applications (IV-D-45, IV-D-52).

Response: The Early Reductions Program will be administered by the Title V permitting program. Therefore, Early Reductions permit applications are for a Title V permit and the same deadlines and requirements, including the deadlines for

correcting deficiencies, apply. The Early Reductions regulations do not specify these deadlines because these will be specified in the final permitting regulations (i.e., Part 70 and Part 71). Enforceable commitments are given 90 days to correct deficiencies.

2.8.12 Comment: The commenter is concerned about the provision that a compliance extension be in the form of a Title V permit. The regulations for operating permits will not be finalized until the first set of Section 112(d) standards are proposed and it would be too late to apply for the compliance extension for all sources covered by the proposed Section 112(d) standards. The commenter suggests allowing entry into the compliance extension program within 3 months after issuance of the final rule on operating permits (IV-D-48).

Response: The regulation allows sources covered by standards proposed prior to January 1, 1994 to submit an enforceable commitment prior to proposal of the standard. The source is then allowed until January 1, 1994 to achieve the reductions and may submit a permit application as late as December 1, 1993. Sources that have already achieved the required reduction prior to proposal of an applicable Section 112(d) standard must submit a permit application containing the reduction demonstration prior to such proposal; or if a Federal or State permitting program is not yet in place, the permit application for the Early Reductions source may be submitted up to 120 days after promulgation of Federal permitting regulations or 120 days after approval of a State permitting program under Title V, whichever comes first. In the latter situation, even though the permit application would have to be submitted after proposal, the source owner or operator must still document that the required early reductions were achieved prior to proposal of the applicable Section 112(d) standard. In the event that such documentation cannot be provided, the source's Early Reductions demonstration would be disallowed and the source would have to meet the Section 112(d) standard.

It has become apparent recently that no comprehensive Title V permitting mechanism, either a federal rule for issuing Title V permits or an approved State program, will be available in time to process permit applications for enforceable commitments that are due by December 1, 1993. In addition, it may be some time before any source achieving reductions prior to proposal of an early Section 112(d) standard could submit a permit application. In both cases the owner or operator may not know if he would be granted a compliance extension in time enough to meet the Section 112(d) standard if their Early Reductions demonstration were disapproved. Therefore, the EPA is considering options to deal with this developing problem.

One option is for the EPA to promulgate quickly a rule for interim federal issuance of Title V specialty permits. The rule would apply only to Early Reductions permit applications that could not be processed due to lack of an applicable comprehensive Title V program. Permits issued under the specialty program would encompass only the Early Reductions source at a facility and only the hazardous air pollutant emissions from that source. All other Clean Air Act requirements applicable to the Early Reductions source would be handled through the comprehensive Title V permitting process as it becomes available. A future Federal Register notice will describe EPA's proposed action on this matter.

2.8.13 Comment: There may be a gap between the time that an application is approved and the time a Title V permit is issued. Reductions made under the Early Reductions Program should be considered federally enforceable immediately upon approval of the application, regardless of whether a Title V permit program exists (IV-D-27).

Response: Permits do not have separate approval and issuance dates. When the draft permit is signed by the appropriate officials for approval, the permit is considered valid at that time. Therefore, the date of approval and date of issuance are the same and there is no time gap.

2.9 INTERFACE WITH SECTION 112(g) MODIFICATIONS

2.9.1 Comment: In addition to allowing excess offsets under Section 173(a)(1)(A) to be creditable for the Early Reductions Program, the commenter would like the EPA to address "offset" provisions under Section 112(g) of the CAA (IV-D-24).

Response: The EPA recognizes that the availability of Early Reductions credits for use as offsets for emission increases under Section 112(g) is an important issue. The EPA is developing regulations to implement Section 112(g) of the CAA. The issue of offsetting emission increases with Early Reductions credits has not been resolved and will be addressed in the upcoming regulations governing Section 112(g) modifications. However, the EPA recognizes that there are disadvantages in allowing Early Reductions credits to be used to offset Section 112(g) emission increases.

Section 112(i)(5) was designed to bring about a substantial reduction in air toxic emissions from sources prior to the actual issuance of standards governing such sources. In exchange, those sources would receive a limited compliance extension from the emission limitations established pursuant to Section 112 of the CAA. Section 112(g) is a mechanism to allow owners or operators of facilities to make physical or operational changes to their facilities without triggering MACT requirements. A "major source" is considered not to have undergone a modification if any increase (greater than a de minimis increase) as a result of physical or operational changes is offset "by an equal or greater decrease in the quantity of emissions of another hazardous air pollutant (or pollutants) from such source which is deemed more hazardous..." The EPA believes that the intent of Section 112(i)(5) would be undermined by allowing the Early Reductions credits to be used under Section 112(g).

This is best illustrated by example. If Company A submits an enforceable commitment to reduce its emissions by 90 percent at one-half of its facility (and that portion of the facility meets the definition of source in Section 63.73) it will achieve

those reductions (for example, from 100 tpy to 10 tpy) in exchange for an alternative emission limit for the first 6 years beyond the otherwise applicable compliance date. Later, the company wants to undertake a physical change at the other half of the facility that would result in an increase in emissions of 90 tpy of a HAP. If, under Section 112(g), the owner or operator is allowed to use as an offset credit those 90 tpy of reductions from the Early Reductions Program, the major source overall will emit the exact same level of HAP's as it did prior to making early reductions (i.e., 100 tpy); Section 112(d) requirements will be avoided on one-half the facility, and the other half of the facility will have received a 6-year extension from an otherwise applicable Section 112(d) standard.

2.10 INTERFACE WITH TITLE I PROVISIONS

2.10.1 Comment: The commenters believe that emission reductions under the Early Reductions Program should be able to be used as credits for offsets and netting. The Program is voluntary and, therefore, the emission reductions are not "required" (IV-D-27, IV-D-45, IV-F-1).

Response: Most of the HAP's emitted by sources participating in the Early Reductions Program are either VOC or particulate matter and, therefore, subject to other requirements under the CAA. For such situations, questions have surfaced over the interaction between the Early Reductions Program and the other CAA requirements. Specifically, a frequent question from interested companies concerns whether reductions made under the Early Reductions Program can be considered creditable reductions for purposes of New Source Review (NSR) permitting under Parts C and D of Title I of the CAA. The preamble to the proposed Early Reductions rule described the way early reductions would be treated in situations involving offsets under Part D NSR requirements but did not discuss "netting" transactions. The promulgation preamble reiterates the proposal preamble discussion regarding use of early reductions as offsets and adds the EPA's policy regarding netting transactions:

a. Offsets. Emission reductions of HAP's for the purpose of obtaining an alternative emission limitation under Section 112(i)(5) of the CAA are not creditable for the purpose of meeting an offset requirement under Section 173(a)(1) of the CAA. A source in a nonattainment area (an area where a national ambient air quality standard is exceeded) or an ozone transport region may need to obtain offsets for emission increases from planned new construction or modification of existing facilities. The HAP reductions are not allowed as offsets in this instance because Section 173(c)(2) of the CAA states: "Emission reductions otherwise required by this Act shall not be creditable as emissions reductions for purposes of any such offset requirement." A source successfully participating in the Early Reductions Program will be granted an alternative emissions limitation (for the duration of the compliance extension period) in lieu of a Section 112(d) emission standard. Therefore, the reduction of HAP emissions under the Early Reductions Program is a substitute for the reduction of HAP emissions that would otherwise be required of the source under Section 112(d).

However, a source owner or operator may use as offsets any reductions in HAP emissions in excess of those required to qualify for an extension under the Early Reductions Program or reductions in nonHAP emissions that are coincidentally obtained through use of the HAP reduction measures, if such reductions are not required by any other provision of the CAA and meet any other requirements for offsets under NSR rules. These reductions are allowed as offsets pursuant to Section 173(c)(2) of the CAA, which further states: "Incidental emission reductions which are not otherwise required by the CAA shall be creditable as emission reductions for such purposes...."

b. Netting. In general, an owner or operator considering a physical or operational change at a major stationary source (as defined in the NSR rules) will be subject to (1) the requirements of Section 173(a) [e.g., offsets, application of LAER] in nonattainment areas or ozone transport regions or (2) the

requirements for Prevention of Significant Deterioration (PSD) [e.g., application of BACT] in attainment or unclassifiable areas, unless the changes will not cause a "significant net emissions increase" in pollutants subject to NSR. To determine the net emissions increase for NSR purposes, the owner or operator is allowed to sum the emissions increase from the proposed change with any creditable increases and decreases elsewhere at the plant.

The NSR rules and the EPA's "Emissions Trading Policy Statement" (ETPS) (51 FR 43823; December 4, 1986)[52] limit the creditability of some decreases in emissions for this "netting" procedure. For example, the NSR rules for nonattainment areas state that a decrease in emissions is creditable only to the extent that "...the reviewing authority has not relied on it in issuing any permit under regulations approved pursuant to 40 CFR Part 51 Subpart I or the State has not relied on it in demonstrating attainment or reasonable further progress;..." [40 CFR 51.165(a)(1)(vi)(E)]. The PSD rules contain similar language. Essentially what this restriction does is prevent sources from obtaining two credits for one reduction, where the credits are related to the same air quality objective (which in this case is the attainment/maintenance of NAAQS). Thus, as an example, a source cannot use an emissions reduction to meet reasonable further progress requirements and as a reduction credit in netting calculations.

However, under the ETPS, HAP decreases credited under the Early Reductions Program also may be credited for purposes of determining the net emissions increase for a plant change proposed at a later time for NSR purposes, provided of course that the reduced HAP's also are pollutants subject to the NSR rules and that the decreases meet all other requirements for netting. In such situations, the HAP decreases produce benefits for two different air quality objectives and one credit can be given toward each; the HAP credit is associated with the air toxics reduction objectives of Section 112 of the CAA and the NSR

credit is associated with the attainment/maintenance of NAAQS and PSD. The amount of the HAP reduction creditable in these situations will be limited if the netting calculations involve HAP emissions increases. Specifically, the creditable HAP reductions from the Early Reductions Program will be reduced by the amount of any increase in HAP emissions involved in the netting calculations. If no HAP increases are involved, the entire HAP reduction is creditable.

The principle behind this policy limitation is similar to the one behind the netting restriction in the NSR rule mentioned above, namely that a reduction should not receive two benefits or credits (double counting) for the same air pollution control objective. The objective of the Early Reductions Program under Section 112 of the CAA is to achieve significant reductions of HAP's at existing facilities. Sources that achieve such HAP reductions in accordance with the rules promulgated today receive credit for the reductions in the form of a 6-year compliance extension for applicable Section 112(d) standards. If the reductions also were allowed to be used as netting reduction credits for physical or operational changes involving increases in HAP's, then the reductions in effect would be promoting HAP increases elsewhere at the plant site by helping such facilities net out of NSR control requirements. Under such a scenario, an owner or operator could receive a 6-year compliance extension to Section 112(d) standards for some portion of the plant, net out of NSR control requirements, and have overall HAP emissions equal to preexisting levels. Clearly this is not a result consistent with the objectives of the CAA.

To illustrate the effect of this policy, consider a plant site in which a portion of the facility (e.g., a process unit) participates in the Early Reductions Program and achieves a 50 tpy reduction of particulate HAP's. Later, the owner or operator proposes a physical or operational change at another section of the plant that would increase particulate emissions by 75 tpy, but none of the emissions increase would be HAP's. In this case,

the owner or operator can use all of the HAP reductions from the Early Reductions Program to net against the particulate emissions increase because no HAP increases are involved. However, if 30 tpy of the proposed 75 ton increase are HAP's, then only 20 tpy of the HAP reductions under the Early Reductions Program could be used as reduction credits in any netting calculations (20 tpy is the amount by which the HAP reduction exceeds the proposed HAP increase). Finally, if 50 tpy or more of the proposed 75 ton increase would be HAP emissions, then none of the HAP reductions from the Early Reductions Program could be used to net against the particulate emissions increase (because the HAP increase from the proposed modification is equal to or greater than the HAP reductions from the Early Reductions Program).

It should be noted that this netting policy for HAP reductions is applicable only for NSR programs. Under Section 112(g) of the CAA, the EPA must promulgate separate requirements for modification of HAP sources. The provisions to implement Section 112(g) are under development but will not become effective in a State until the State has obtained approval of a Title V permitting program.

2.10.2 Comment: The definition of contiguous facility should not mirror the PSD program, where emission points under common ownership within 25 miles have been considered part of the contiguous facility (IV-D-47).

Response: The Early Reductions Program differs from the PSD program in that a source must be part of a contiguous area under common ownership or control. The PSD program considers both contiguous areas and adjacent areas in the source definition. Therefore, the Early Reductions Program is more limited when attempting to combine emission points in the source definition.

2.10.3 Comment: Sources that achieve a 90-percent reduction from base year emissions should be granted the same 6-year extension from complying with reasonably available control technology (RACT) requirements under Title I as received from Section 112(d) standards under Title III (IV-D-45).

Response: Section 112(i)(5) of the CAA authorizes the Administrator (or a State operating pursuant to an authorized Title V permit program) to grant a 6-year extension from compliance with an emission standard promulgated under Section 112(d) that would otherwise be applicable to that source, provided the source satisfies certain conditions. Nothing in Section 112(i)(5) or any other provision of the CAA authorizes the Administrator to grant extension of any RACT requirement that might be required under other sections of the CAA. As a practical matter, however, the EPA anticipates that many of the methods or technologies adopted to reduce a source's HAP by 90 (95) percent for purposes of obtaining a compliance extension from a Section 112(d) standard may also constitute compliance with RACT requirements under other provisions of the CAA.

Although sources successfully participating in the Early Reductions Program will be granted an alternative emission limitation in lieu of meeting an application Section 112(d) standard, the source still is responsible for complying with other applicable requirements of the CAA. For example, sources located in areas designated nonattainment for the criteria pollutant ozone are subject to other emission reduction requirements. State implementation plans (SIP's) for these nonattainment areas (plans for attaining the criteria pollutant ambient air quality standards) must contain requirements for application of RACT requirements for stationary sources of VOC. The RACT is required for sources (1) for which the EPA has published--or will publish--a control techniques guideline document, and (2) that are "major", as defined in the CAA.

State implementation plans also must provide for other emission reductions sufficient to demonstrate attainment by specified deadlines and to meet interim reasonable further progress requirements. States may obtain reductions from any VOC emission source in the inventory, which means that they may eventually require additional emission reductions from sources participating in the Early Reductions Program. (It should be

noted that VOC emission reductions resulting from compliance with HAP rules, including those under the Early Reductions Program, are creditable toward the Program requirements to the extent that they were not required prior to enactment of the CAA Amendments of 1990 and are consistent with creditability requirements under the CAA.)

The interaction between the Early Reductions Program and other requirements for the attainment of NAAQS causes concern in that the prospect of later application of additional requirements to sources that make early reductions would effectively limit the attractiveness of, and therefore participation in, the Program. Therefore, with respect to the percentage reduction requirements, reasonable further progress, and attainment demonstration requirements, the EPA has established a policy to reduce the amount of uncertainty for sources that choose to participate in the Early Reductions Program. This guidance should further encourage possible applicants to participate in the Early Reductions Program. Briefly, the policy regarding RACT and reasonable further progress requirements for sources making early reductions states that:

- The source must meet any applicable existing RACT requirements (including RACT that is required but has not been adopted by the State, i.e., RACT fixups);
- The EPA encourages States to favorably consider the reductions made under the Early Reductions Program in their analysis of any future RACT requirements for the source; and
- The EPA encourages States to seek any additional reductions (beyond those under the Early Reductions Program) needed to make reasonable further progress first from sources not participating in the Early Reductions Program.

The intent of the policy is to require compliance with existing RACT requirements, but also potentially give sources some breathing room with respect to future RACT or reasonable

further progress requirements, in recognition of the fact that substantial (90 [95] percent) reductions already have been made at the source. This policy is appropriate because, in most cases, a 90 (95) percent reduction of HAP's from the sources will produce comparable reductions in criteria pollutants or criteria pollutant precursors (i.e., VOC). For example, nearly all HAP's emitted as gases also are VOC.

However, it is possible that an Early Reductions demonstration will not produce a criteria pollutant reduction. A creditable HAP emission reduction may be achieved by substituting a nonHAP compound for the HAP. If, for example, both compounds are VOC, then there is no VOC reduction, although the HAP has been eliminated. In such cases, it would not be appropriate to apply this policy.

2.11 TEST METHODS AND PROCEDURES

2.11.1. General

2.11.1.1 Comment: The EPA should establish de minimis concentrations for all HAP's for Method 301. This would be the lowest concentration for which the test methods would have to be validated (IV-D-21, IV-D-31, IV-D-50).

Response: It is beyond the scope of Method 301 to specify de minimis levels. Method 301 does provide specific procedures for the determination of the limit of quantitation. In addition, Method 301 requires that the data and the proposed method be validated for the concentration(s) of HAP's in the waste stream(s).

2.11.1.2 Comment

Method 301 should contain a procedure for calculating the concentration range for which a method would be considered validated (IV-D-21).

Response: Method 301 advocates that the proposed test methodology be validated over the range of expected HAP concentrations either in the field or through laboratory testing utilizing the ruggedness test procedures. In addition, a procedure is offered for determining the limit of quantitation.

Such procedures would establish the concentration range.

2.11.1.3 Comment: Method 301 does not specify under which process conditions the validation testing should be conducted (IV-D-33).

Response: The choice of operating conditions depends upon the end use(s) of the data. Considerations in structuring the validation test should include: sample matrix complexity in regard to future applicability of the proposed method, sample analyte concentration(s) in the sample waste stream and of the applicable emission standard, and representativeness of the process conditions in regard to establishing actual annual emissions.

2.11.1.4 Comment: If applicants choose to use the weighted average approach to determine the required percent reduction, they should be required to state the temperature and pressure ranges used to determine the mass emission rates (because gaseous emissions may condense into liquid droplets under atmospheric conditions) (IV-D-59).

Response: The EPA agrees that temperature and pressure information is necessary to determine the emission rate. Expressing emissions at standard conditions is not the same as changing the sampling conditions.

2.11.1.5 Comment: The final rule should include a definition of "particulate" (IV-D-50).

Response: The definition of particulate matter is dependent upon the test method involved. The requirements of the applicable regulation, SIP, or Federal regulation should be reviewed first for applicable definition(s). The problem exists for emissions that can be in either a particulate or gaseous phase. If there is a question, the applicant should consult with the EPA to arrive at a resolution.

2.11.1.6 Comment: Method 25A should be accepted for the determination of base year and post-reduction emissions. The commenter suggests a circumstance that would allow for such use of a total hydrocarbon analysis on a continuous basis: when the

gas stream is principally comprised of the HAP of concern and the HAP contribution to the total hydrocarbon concentration can be documented. The commenter also points out that continuous measurements would be more appropriate for batch processes (IV-D-33).

Response: The EPA believes that application of Method 25A to a single HAP in a sample matrix containing no other hydrocarbons would prove acceptable, assuming the detector is calibrated using that HAP. Total emissions of the HAP would then be determined using the emission value integrated for the entire test run. Application of Method 25A to more complex gas streams would need to be examined on a case-by-case basis. Use of continuous mass spectrometric techniques where the HAP could be speciated may be more likely to succeed.

Method 301 addresses composite sampling techniques and the EPA believes that procedures similar to those specified for a composite sampling test method could be applied to the measurement of emissions from a batch process.

2.11.1.7 Comment: Use of the validation protocol in Method 301 will increase the cost of testing and the time required to complete a test. The commenter requests that the EPA not be required to pre-review the validation report before the test method can be used (IV-D-33, IV-D-47).

Response: The EPA agrees that the validation of data obtained by the proposed method can be conducted concurrently with other testing in order to combine the validation step with the source test. This is encouraged, where appropriate, and was an intent of Method 301. Note that the source owner or operator incurs some risk in that the proposed method may not meet the Method 301 validation criteria and the emissions data may not be applicable for compliance determination. Well-substantiated validation reporting should keep this risk to a minimum.

2.11.1.8 Comment: The cost of validating the data obtained by a proposed method may be prohibitive for many sources (IV-D-47).

Response: The EPA agrees that the development and testing of a method, even the limited validation approach of Method 301, can be expensive; however, the cost is necessary for ensuring data of quality sufficient for the intended purposes.

2.11.1.9 Comment: The optional procedures of Method 301 (Sections 7, 8, and 9) will increase the cost of validating a method (IV-D-47).

Response: Although these procedures are not required in all situations, the EPA agrees that there will be additional costs incurred when these optional procedures are conducted.

2.11.1.10 Comment: The commenter urges the EPA to publish a guidance document outlining source testing methods as soon as possible (IV-D-58).

Response: The EPA has prepared an initial list of validated methods. This list may be obtained from the Emission Measurement Technical Information Center (EMTIC), U. S. Environmental Protection Agency (MD-19), Research Triangle Park, North Carolina 27711. Updates to the list of validated methods will be made available on a periodic basis. The EMTIC may be contacted at any time to review the current list at (919) 541-0200.

2.11.1.11 Comment: The commenters identified several typographical errors, as well as grammatical inconsistencies (IV-D-21, IV-D-31, IV-D-47).

Response: These have been corrected.

2.11.2 Method Applicability

2.11.2.1 Comment: A hierarchy should be established for identifying the appropriate validation procedure to use (IV-D-21).

Response: The EPA agrees that such guidance would be appropriate in Method 301 and has reworded Sections 5.1 through 5.3 to define this hierarchy.

2.11.2.2 Comment: Method 301 should allow proposed methods to be validated using any of the three procedures. We do not agree that a proposed method should be demonstrated against a validated method, if a validated method for a particular application is

recognized (IV-D-33).

Response: The EPA does not agree. See response to Comment 2.11.2.1.

2.11.2.3 Comment: Method 301 should provide a less rigorous validation procedure for the early stages of method development (IV-D-31).

Response: The EPA agrees that an overall test method development program will be more extensive than a single application of Method 301. Method 301 is specifically a field validation protocol. Responsible method development and evaluation should provide an indication that the proposed method has a sufficient probability of performing within the criteria of Method 301 during field validation testing.

2.11.2.4 Comment: Method 301 may adversely affect State toxic screening programs that have incorporated less precise emission measurement techniques (IV-D-31).

Response: Method 301 is applicable to source owners or operators wishing to comply with a Federal requirement using a test method that has not yet been validated. Because a source emissions screening and ranking process for use in the development of a State toxics strategy is not subject to specific Federal requirements, Method 301 should not affect this type of program.

2.11.2.5 Comment: The commenter raises an important consideration in preparing for a field validation involving comparison of the proposed method against a validated method (Section 5.2). If the emission concentrations are highly variable over time, as in the case of a batch process such as coking operations, the method precision calculated using Equation 301-7 can be disproportionately influenced by large absolute differences (IV-D-31).

Response: If paired rather than quadruplet samples are used for procedures under Section 5.2, each test run of the validation testing should be conducted over the entire process cycle.

2.11.2.6 Comment: Method 301 does not address the direct interface or dilution interface sampling options of Method 18 (IV-D-33).

Response: Method 301 may be applied to the direct and dilution interface sampling options of Method 18. However, the validation cannot be conducted without quadruplicate sampling and analytical systems, which the EPA considered excessively burdensome. For the other sampling options of Method 18, such as container and absorption tube sampling, validation field testing should be conducted using Method 301.

2.11.3 Bias Criteria and Calculation

2.11.3.1 Comment: The bias criterion for validation of the data obtained by a proposed method compared to a validated method is too restrictive (IV-D-31).

Response: For pollutants and sources for which validated method(s) are available, Method 301 requires alternative methods to have a similar precision and a reasonable bias (±10 percent) compared to the validated method(s). The EPA believes that these criteria are not too restrictive and allow for innovative method development.

2.11.3.2 Comment: Method 301 does not explain the bias correction limits (IV-D-33).

Response: References in Method 301 that document that the levels selected are typical for those demonstrated in the process of emission test method development.

2.11.3.3 Comment: Method 301 requires an excessive number of samples for the determination of bias and precision. The commenter suggests that reducing the number of test runs by half would only result in a difference of less than 11 percent of the t-statistic at an 80 percent confidence level, but would cut the time, effort, and cost in half. (IV-D-33).

Response: The decision level specified in the comment is incorrect and should be 0.05. The difference in the t-statistic resulting from reducing the number of samples by 50

percent is 17 percent rather than 11 percent. This difference is not acceptable to the EPA.

2.11.3.4 Comment: Section 6.1.5 does not indicate the acceptance criteria for the correction factor calculated in Equation 301-5. Further, this correction factor may be inappropriate for methods that employ isotopic spiking (e.g., EPA Method 23 surrogate standards) where values are not corrected as long as the recovery is within 30 percent (IV-D-31).

Response: The acceptance criteria for the correction factor calculated in Equation 301-5 is specified in Section 1.2.1 of the Method. Isotopic spiking with surrogate standards as specified in Method 23 is conducted as a quality assurance check of breakthrough of the analytes on the sorbent. The isotopic spiking specified in Method 301 is used to assess method bias. The two are not mutually exclusive. Where a significant bias is identified (Section 6.1.4) using the spike, the correction factor (Section 6.1.5) is calculated. The correction factor is evaluated by the criteria in Section 1.2.1 and the data are either corrected or the data and procedure to obtain the data are rejected.

2.11.3.5 Comment: The commenter expressed concerns about the reasonableness of requiring reference materials at concentrations below a proposed method's detection limit or in concentrations in multiple ranges representative of several emission points at the same facility (IV-D-21).

Response: Validation of a proposed method requires that the method be capable of measuring in the applicable range of emission concentrations. A method with a detection limit above the emission concentration at a particular emission source could not be validated for that source. Method 301 does provide for ruggedness testing, which allows a proposed method to be validated for testing at multiple concentrations without requiring multiple field validation tests. Whether ruggedness testing or field validation is used to validate the method for the appropriate concentrations, it will be necessary to obtain

reference materials in the applicable ranges.

2.11.3.6 Comment: The commenter suggests rephrasing Sections 5.1.2.1 and 5.1.2.2 to require sampling the reference material at a concentration close to the "expected" concentration in the source rather than equal to the emission standard (IV-D-21).

Response: The EPA agrees and has revised these sections accordingly.

2.11.4 Precision Criteria and Calculation

2.11.4.1 Comment: The criterion for precision specified in Method 301 of 50 percent relative standard deviation was too high, even though nine sampling runs are needed to show compliance. The commenter suggested that the relative standard deviation should be reduced to 15 percent or less so that only three sampling periods are needed to show compliance (IV-D-47).

Response: The method criteria for precision and followup testing provide maximum flexibility in method development and application while achieving high-quality results. They also serve indirectly as an incentive in method development; that is, the better the method precision, the less effort is required during followup testing using the validated method.

2.11.4.2 Comment: The commenter recommends that more explicit terminology be used in Sections 6.2.1.3 and 6.2.2.3 regarding the F-test, which tests the significance of the proposed method variance to that of the validated method (IV-D-31).

Response: The intent of these sections is to perform a comparison of the variances of the two methods. Method 301 has been revised to include both the F-test and simple comparison of variances, demonstrating that the variance of the proposed method is less than or equal to that of the validated method, as suggested by the commenter.

2.11.4.3 Comment: Sections 6.1.2.4 and 6.2.2.4 should be revised to calculate the "standard deviation of the differences" rather than the "standard deviation of the mean of the differences" (IV-D-31).

Response: The EPA agrees with the concerns regarding Sections 6.2.1.4 and 6.2.2.4 and has made the appropriate changes.

2.11.4.4 Comment: Section 6.3.2 does not specify calculation of the relative standard deviation for the spiked samples (as is specified for the unspiked samples in Section 6.3.6). It is not clear which relative standard deviation must meet the ±50 percent criterion in Section 1.2.2 (IV-D-31).

Response: Section 6.3.2 has been revised to parallel Section 6.3.6. The method has also been revised to specify the 50 percent relative standard deviation criterion for both the spiked and unspiked samples.

2.11.4.5 Comment: Equation 301-13 should incorporate the standard deviation of the unspiked samples as well as that of the spiked samples (IV-D-31).

Response: The EPA agrees with the commenter's suggested revisions to the calculation and has incorporated them into the Method.

2.11.4.6 Comment: An error was identified in Equation 301-7 (IV-D-31).

Response: This has been corrected.

2.11.5 Sample Stability

2.11.5.1 Comment: The commenter requests additional guidance in Section 8 on appropriate data analysis techniques (IV-D-31).

Response: The procedures provided are sufficient. The analyst has flexibility to determine the applicable data analysis techniques for the specific sample stability study.

2.11.5.2 Comment: The commenter requests additional guidance in Section 8.2.1 regarding sample stability studies for impinger sampling systems that require sample extraction or digestion (IV-D-31).

Response: Section 8.2.1 has been revised to include guidance for samples requiring extraction or digestion.

2.11.5.3 Comment: Sections 8.2.2 and 8.2.3 should be clarified to specify whether spiked or unspiked samples (Section 5.3)

should be used to study sample stability (IV-D-31).

Response: The study should include equal numbers of spiked and unspiked samples. Specific stability interpretations should be made with the spiked samples. The unspiked samples are included to allow the analyst to assess the application of the spiked sample findings. Sections 8.2.2 and 8.2.3 have been revised to clarify this point.

2.11.5.4 Comment: The commenter requested additional guidance and clarification on appropriate techniques. For example, Section 8.2.4 should specify that half the samples analyzed at the minimum and maximum storage times should be from the validated method and half from the proposed method. It should also address procedures for samples that require extraction or digestion (IV-D-31).

Response: Several wording clarifications have been made. Section 8.2.4 has been revised to specify that equal numbers of samples from the proposed and validated methods be analyzed. The procedures for samples requiring extraction or digestion should parallel those described in Section 8.2.2.

2.11.6 Practical Limit of Quantification

2.11.6.1 Comment: Section 9 on calculating the practical limit of quantitation should provide procedures for cases where there is a non-zero intercept on the calibration curve (IV-D-31).

Response: The procedure provided is applicable to this case.

2.11.6.2 Comment: Section 9.3.5 should provide the calculation method for s_0 at zero concentration (IV-D-31).

Response: The procedure provided is applicable to this case.

2.11.7 Followup Testing

2.11.7.1 Comment: Method 301 should include additional quality assurance requirements for follow-up testing (IV-D-33).

Response: Quality assurance is the goal of applying Method 301. Quality control is a general requirement of any compliance test, but is beyond the scope of Method 301. We suggest that the

general procedures of the Quality Assurance Handbook for Air Pollution Measurement Systems, Volume III, Stationary Source Specific Methods, EPA-600/4-77-027b[53], be followed.

2.11.8 Waivers/Extending Method Applicability

2.11.8.1 Comment: A State wishes to have its future methods approved as either "documented" or "conditional" (IV-D-31).

Response: State methods approved through a Federal approval process would have "conditional" status.

2.11.8.2 Comment: "Documented" methods (Section 12.1.2 of Method 301), such as National Institute of Occupational Safety and Health, American Standards and Testing Materials, and Occupational Safety and Health Administration methods should be considered validated methods (IV-D-47).

Response: The application for a waiver under Section 12.2 should demonstrate the applicability of the "documented" method to the particular source to be measured. The validation procedure and documentation for that particular source would be reviewed with respect to Method 301 requirements.

2.11.8.3 Comment: The Method 301 requirements in Section 12.1.1 for extending applicability of a method to "similar" sources are burdensome. There should be a more reasonable requirement than conducting a ruggedness test and applying to the EPA for a waiver (IV-D-33).

Response: Section 12.1.1 states applicability to other sources may be demonstrated by conducting ruggedness testing. The EPA agrees with the commenter that ruggedness testing is not always necessary, depending upon the similarity of the sample matrices. In addition, validation of the proposed method on a complex sample matrix may be sufficient to demonstrate that the method is applicable to a similar source with an emission matrix of less complexity. In every case, the requester must apply for a waiver to extend the applicability.

2.11.8.4 Comment: Method 301 does not specify acceptable deviations in method procedures after validation (IV-D-33).

Response: Once validation of a method has been completed and the data used to meet a Federal or State requirement, modifications to the method cannot be made without approval of the responsible agency or validation through application of Method 301. Any modification must be fully explained and documented with supporting data such as that from a ruggedness test. The primary consideration in acceptance of a modification will be its effect on the results obtained by the previously validated method.

2.11.8.5 Comment: A State is concerned that the validation of a method at one source will be inappropriately interpreted as a validation for all applications (IV-D-31).

Response: The field validation procedure of Method 301 is appropriate for validating emissions data only from the source and at the levels for which the method was validated. Optional procedures are provided and must be applied to extend applicability of the methodology beyond the specific emission source and concentration levels at which the validation was conducted.

2.12 MISCELLANEOUS COMMENTS

2.12.1 Comment: The commenter believes that the Early Reductions Program offers an incentive to sources only if the Section 112(d) standard is greater than 90 (95) percent. To increase the incentive to make early reductions, the commenter suggests reducing emission fees from sources participating in the Program based on the difference between the required Section 112(d) reduction and the 90 (95) percent reduction. For example, if emission fees would have been $100,000 per year and a Section 112(d) standard of 98 percent is promulgated then the source would have to pay $100,000. If a 112(d) standard of 90 (95) percent is promulgated, the source would have to pay $0. If a Section 112(d) standard somewhere in between were promulgated, the fee would be linearly proportional (IV-D-02).

Response: There is nothing in the CAA that allows Federal regulations to tie emissions reductions to a fee-based incentive

program. Fees are only allowed as part of a SIP in order to allow States to recover the cost of a Title V permitting program, and are based on residual emissions. Specific State regulations governing fee schedules would have to be changed to address this comment.

2.12.2 Comment: The EPA should provide other incentives such as preferred government procurement status, tax incentives, and a greater certainty of future control requirements to entice industry to make voluntary reductions (IV-D-07).

Response: Incentives such as those suggested by the commenter go beyond the authority of the CAA. The EPA believes that regulatory relief from compliance with a Section 112(d) standard provides the necessary incentives for voluntary reductionc. The EPA is making every possible effort to communicate the benefits of early reductions. In addition, the EPA will keep industry informed regarding the development of control requirements under Section 112(d) standards.

2.12.3 Comment: Two commenters suggest that the EPA establish a question-and-answer hotline (IV-D-33, IV-D-45). One commenter further suggests developing an ongoing question-and-answer document available that provides several seed questions (IV-D-33).

Response: The EPA has developed a question-and-answer document based on specific questions raised by Regions, State and local agencies, and industry. The document will continue to evolve throughout the course of the Early Reductions Program and should provide consistent answers to often-encountered problems. The EPA is also available as necessary to provide support and guidance to State and local agencies.

2.12.4 Comment: One commenter was concerned that facilities participating in the Early Reductions Program would have to: (1) install controls to meet the 90 (95) percent requirement, (2) install additional control to meet Section 112(d) standards at the end of the extension period (if the applicable Section 112(d) standard is greater than 90 [95] percent), and (3) then install

controls to meet any residual risk 112(f) standard. In addition, the State may require additional control at any time in the process.

The commenter does not believe this provides incentive to participate in the Program and, therefore, recommends the following options to increase the incentive: (1) allow the control strategy used to achieve the 90 (95) percent reduction to be defined as the Section 112(d) standard (i.e., rather than extend compliance with the Section 112(d) standard, let 90 (95) percent reduction replace the requirement of the standard), (2) the source may determine what it believes the applicable Section 112(d) standard will be and use these controls to achieve the 90 (95) percent or higher reduction; if the Section 112(d) standard is determined to be something else, the source will not be punished for its "good faith" determination and will receive an indefinite compliance variance from the applicable Section 112(d) standard, or (3) the EPA will commit to complete "residual risk analyses" 2 years prior to the delayed compliance deadline (this would allow facilities to directly install residual risk control strategies only rather than meet the Section 112(d) standard and then residual risk requirements (IV-D-07).

Response: The first two suggestions offered by the commenter are not allowed by the CAA. Standards established by Section 112(d) of the CAA will be based on technological considerations. Regarding the residual risk standards, the provisions of the CAA will result in Section 112(f) standards being promulgated prior to the expiration of the Early Reductions extensions or, in the worst case, just as the extension expires. Facilities will not be faced with the possibility of installing unnecessary controls to meet Section 112(d) and Section 112(f) standards sequentially.

2.12.5 Comment: Facilities that achieved 90 (95) percent reduction under the "Nine CEO's Voluntary Emission Reduction Program" should be automatically exempted for 6 years from

compliance with the Section 112(d) standards without going through the extension application process (IV-D-05).

Response: Facilities that participated in the "Nine CEO's Voluntary Emission Reduction Program" must submit an application or enforceable commitment according to the same procedures as facilities that did not participate in the CEO program. The process will allow the owner or operator to describe which portion of a facility will be defined as the "source." The application process also allows for review and public comment, which the CEO program did not. Recent activity and documentation by the CEO participants should make an Early Reductions submittal easier to develop.

2.12.6 Comment: The rule should specify how relatively new facilities may participate in the Program when actual base year emissions are yet to be established (IV-D-30).

Response: It may be very difficult for sources built just prior to proposal of an applicable Section 112(d) standard to participate in the Program. First, the regulations require that actual and verifiable base year emissions be established. This means that a representative operating history is required prior to proposal of Section 112(d) standards. Additionally, most States require a reasonably high level of control for HAP emissions from new sources as part of new source permitting. Although possible, it will be difficult to achieve 90 (95) percent reduction above the level of control required.

2.12.7 Comment: The EPA should reduce requirements for application submission and supporting documentation, and agency review times should be shortened (IV-D-27).

Response: The requirements for application submission, supporting documentation, and allowances for review time are judged to be the minimum requirements necessary to ensure that the Early Reductions Program is successful. This information is needed to verify that emissions reductions are actual reductions, and not "paper" reductions. Any reduction of agency review time would not ensure adequate review of the applications.

2.12.8 Comment: Sections 63.75(d) and 63.77(f) should provide consistent deadlines for submittal of late test data: 180 days. The only exception should be enforceable commitments, which should be provided by March 31, 1994 (IV-D-33).

Response: The test data referred to under Section 63.75(d) supports base year data for enforceable commitments. Sources making enforceable commitments may need to act quickly to submit the commitment prior to proposal of a Section 112(d) standard. In this instance, sources will have very little time to obtain accurate test data. Therefore, the EPA has granted a reasonable time period of 180 days after proposal of an applicable Section 112(d) standard for sources to conduct necessary testing to support enforceable commitments.

The test data referred to under Section 63.77(f) supports post-reduction emissions for permit applications. In this case, the EPA proposed allowing only 90 days for submission of test data. Because sources planning to submit a permit application will have sufficient lead time before applying, less additional time is needed than for submittal of supporting data for the enforceable commitment to produce necessary test data.

The EPA has modified the Early Reductions regulation to make consistent the deadline for post-reduction emissions test data to support the reduction demonstration for enforceable commitments and permit applications. Section 63.77(f) of the proposed rule allowed sources with enforceable commitments 120 days (i.e., from December 1, 1993 until March 31, 1994) after the permit application deadline to submit test data but required other permit applicants to submit the same type data within 90 days. The 90-day deadline has now been changed to require test data within 120-days after the deadline for submittal of the permit application.

2.12.9 Comment: The alternative emission limitation should not be required for each emission point within a source but as a single annual average, source-wide emission limit reflecting the required reductions (IV-D-27).

Response: Any alternative emission limitation must be enforceable. The alternative emission limitation could be written for a single emission point, a group of emission points, or the entire source. The specific requirements will depend on the definition of source and what the permitting authority considers to be enforceable. At a minimum, the alternative emission limitation must reflect continuing compliance with 90 (95) reduction. If an applicable Section 112(d) standard has been proposed, the alternative emission limitation may parallel the requirements of the standard.

2.12.10 Comment: The commenter states that the CAA does not specify that numerical limits be set for alternative limits. Therefore, the commenter urges the EPA to specify in the final rule that the permitting authority has discretion in defining alternative emission limitations, and is not required to use numerical limits whenever possible (IV-D-38).

Response: Section 112 of the CAA requires that numerical standards be specified wherever possible. However, any format is acceptable as long as it is enforceable and ensures continued 90 (95) percent reduction as required by the Early Reductions Program.

2.12.11 Comment: Regarding Section 63.72, should the words "permitting authority" be used instead of "state acting pursuant to a permitting..."? The current wording implies that only the State has permitting authority (IV-D-52).

Response: The regulation has been changed to incorporate this comment. Section 63.72 of the regulation describes the general provisions of the Early Reductions Program. During the course of the Program, the authority to review and issue permits will shift from the EPA to the States. The wording in the proposed regulation limited the provisions to States. The term "permitting authority" refers to States or the EPA and is, therefore, the more appropriate term in this context.

2.12.12 Comment: The definition of responsible official in the proposed rule is too complicated. A corporate officer or

delegated official should have the authority to sign. The "financial test" in the rule should be deleted (IV-D-29, IV-D-38). Another commenter suggested the definition of responsible official be consistent with the definition used in the Title V permit regulations (IV-D-45).

Response: The definition of responsible official is consistent with the definition presented in the Part 70 regulations.

2.12.13 Comment: The EPA should publish as quickly as possible the intended regulation proposal dates. In addition, a list of source categories for which Section 112(d) standards are under development should be published from time to time, with names and telephone numbers of contacts with whom sources could discuss the progress of the Section 112(d) standards (IV-D-27, IV-D-34 - should be published in the Federal Register at least 90 days prior to proposal; IV-D-38 - at least 1 year prior to proposal).

Response: The EPA published its source category list in the Federal Register on July 16, 1992 (57 FR 31576)[54], for which it intends to develop Section 112(d) standards and a draft schedule for proposing those standards (57 FR 44147; September 24, 1992)[55]. In addition, every 6 months, the EPA publishes a regulatory agenda that identifies the regulations currently under development, with the names and phone numbers of the appropriate contacts. These published lists should keep industry and the public adequately informed with regard to specific proposal dates.

2.12.14 Comment: The EPA should allow certain process information to be submitted as confidential on a case-by-case basis. Specifically, the following types of data should be shielded: (1) concentration of specific chemicals in process vents, (2) boiler and process design capacities, (3) hourly maximum design rates, (4) release temperatures, (5) release velocities, and (6) specific chemical emission rates (IV-D-28, IV-D-30, IV-D-33, IV-D-35, IV-D-45).

Response: According to the CAA, "emissions data" cannot be considered confidential. A recent Federal Register notice specified categories of data that qualify as "emissions data" and are therefore, not confidential (56 FR 7042, February 21, 1991).[56] Such data include but are not limited to

> "...identification of facility and emission points, emission types (type of release point and specific pollutants), emission rates, release heights, descriptions of terrain and surrounding structures, stack and vent diameters at the point of emission release, release velocities, release temperatures, frequency of releases, duration of releases, concentrations, densities of emission streams or average molecular weights, boiler or process design capacities, emission estimation methods, percent space heat, and hourly maximum design rates."

The EPA will continue to follow these regulations while implementing the Early Reductions Program.

Other information not classified as emission data may be determined to be confidential on a case-by-case basis at the request of the submitter. The EPA has strict guidelines and procedures for handling confidential data to protect its confidentiality.

2.12.15 Comment: This commenter wants assurance that time periods can be extended when confidential data are in issue (IV-D-39).

Response: Data initially identified by the submitter as confidential but later determined nonconfidential will be afforded the full review time provided in the rule.

2.12.16 Comment: The EPA should clarify the rule so as to make the 1 year extension under Section 112(i)(3)(B) available to an Early Reductions source at the end of the 6-year compliance extension, if needed to install controls (IV-D-38).

Response: The extension provision given in the CAA [Section 112(i)(3)(B)] only applies to sources impacted by individual Section 112(d) standards. The Early Reductions Program already provides a 6-year extension from complying with any Section 112(d) standard. Sources participating in the Early Reductions Program should have ample time to plan and install

necessary control technology to meet these standards.

2.12.17 Comment: The commenter feels the regulation should emphasize the importance of pollution reduction, not participation by industry and gives specific examples where the emphasis on participation may lead to increased emissions (IV-D-39).

Response: The legislative history indicates that Congress wanted the EPA to encourage participation in the Early Reductions Program. The EPA believes that greater participation will lead to more early reductions and, hence, more overall benefit to the environment. The overall goal of the regulation is to reduce pollution. In order to achieve this goal, sources must participate in the Program.

2.12.18 Comment: The commenter proposed that the EPA allow a 6-month extension for companies to comply with Section 112(d) standards if they make a genuine effort to participate in the Early Reductions Program but are forced to withdraw prior to December 1, 1993 (IV-D-48).

Response: Under Section 112(i)(3)(B) of the CAA, the Administrator (or a State with a program approved under Title V) may issue a permit that allows a source up to 1 additional year to comply with a Section 112(d) standard if such an additional period is necessary for the installation of controls. If the source needs extra time to install controls because of participation in the Early Reductions Program, the source may apply for this 1 year extension. An additional extension is not authorized by the CAA.

2.12.19 Comment: The commenter suggests clarifying the regulation to state that Section 112(d) reductions apply to base year emissions and not to emissions remaining after reductions made for the Early Reductions Program. Clarification is also needed in how to define base year and the Section 112(d) standard if the Section 112(d) source and the early reductions defined source are not the same (IV-D-02, IV-D-08).

Response: Section 112(d) standards will be specific to each source category and may assume several formats, including percent reduction, concentration limits, mass limits, etc. If a percent reduction is selected, for example 98 percent for MACT, the 90 percent reduction for Early Reductions generally will count toward the required Section 112(d) reduction.

2.12.20 Comment: Clarify that Section 63.81 "Rule for special situations," should be clarified to indicate that a company must make an enforceable commitment or achieve reductions before the first Section 112(d) standard is proposed for the "source" that will receive the extension, not before the first Section 112(d) standard applicable to the facility is proposed (VI-D-08, IV-D-19).

Response: Section 63.81 already states that the Section 112(d) standard must be applicable to a source as defined under Section 63.73. Thus, the regulation clearly indicates that only emission points included in the Early Reductions source determine the appropriate submittal date. To clarify the provisions of this section of the regulation, a permit application or enforceable commitment must be submitted prior to proposal of the earliest Section 112(d) standard that applies to any emission point in the Early Reductions source definition. The extension for compliance, however, begins on the compliance date of the Section 112(d) standard applicable to the emission point. This will lead to different compliance extension expiration dates for different emission points in a source subject to more than one Section 112(d) standard proposed at different times. Emission points not included in the Early Reductions source must comply with any applicable Section 112(d) standard according to the schedule in Section 112(e). At a later date, the source owner or operator may reapply with a different definition of source as long as no Section 112(d) standard has been proposed that applies to any part of the "new" source.

2.12.21 Comment: The emphasis on post-control emissions should be removed (i.e, it should focus on post-reduction emissions)

(IV-D-12, IV-F-1b).

Response: The EPA recognizes that there are many methods to reduce emissions other than applying a control device. Any emphasis on using a control device versus other methods of emission reduction was unintentional and, in fact, the EPA encourages pollution prevention and recycling methods in preference to add-on controls. All references in the proposed regulation to post-control emissions have been replaced with post-reduction emissions.

2.12.22 Comment: The situation in which more than one Section 112(d) standard affects a source should be clarified. The current regulation could be interpreted to mean that all of the source must be in compliance with the applicable Section 112(d) at the end of the 6-year extension, when in reality only the portion of the source affected by the standard must comply (IV-D-27).

Response: If several Section 112(d) standards apply to a source under the Early Reductions Program, the source owner or operator must submit a permit application or enforceable commitment prior to the proposal of the earliest Section 112(d) standard that applies to any emission point in the defined source. The extension for compliance, however, begins on the compliance date of the Section 112(d) standard applicable to each specific emission point or type emission point. Thus, source compliance extensions for various emission points may begin and end at different times. Emission points not included in the Early Reductions source must comply with any applicable Section 112(d) standard according to the schedule in Section 112(e).

2.12.23 Comment: In the preamble to the proposed rule, the statement (on page 27360) "If the application is denied, the source will be subject to applicable MACT standards" is misleading. The EPA should clarify the statement to reflect that the source will be subject to Section 112(d) standards on the timetable specified in Section 112(e) (IV-D-30).

Response: The regulation in Section 63.80(d) states that the source must comply with an "applicable standard issued under Section 112(d) of the CAA by the compliance date specified in such standard." Therefore, the regulation clearly indicates that the source must not immediately be in compliance with the standard as soon as the permit is disapproved but must adhere to the same compliance schedule as sources that did not apply for a compliance extension.

2.12.24 Comment: The commenter requests clarification of the procedures and requirements of the proposed rule with respect to question 1 under paragraph F: "Permit Application and Permits" of the preamble (page 27630) (IV-D-30).

Response: The procedures and requirements for emission tests are stated in Sections 63.74(d)(3) and 63.74(i). The questions in Section F1 of the proposal preamble are reminders to the reviewer to ensure these requirements are met.

2.12.25 Comment: The commenter suggests that the word "train" be substituted for "unit" in the list of definitions. The commenter feels that the term "unit" describes an independent piece of equipment, while a "train" better describes a group of equipment linked together for the purposes of producing a product or performing a function. The commenter also suggests that the EPA include a definition for "emission point" to describe the affected source where the enforceable emission limitations apply (IV-D-39).

Response: Because it does not appear elsewhere in the regulation, the term "process or production unit" has been removed from the regulation under the definition of source and under Section 63.72, "Definitions."

2.12.26 Comment: There is no definition of "facility" in the regulation (IV-D-52).

Response: The term "facility" has been replaced throughout the regulation with "plant site," which is a "contiguous area under common ownership or control." The only reference to facility that remains is related to Sections 63.73(a)(1) and (3),

both of which list "a building structure, facility, or installation." In both instances, the definition of facility will remain the same as that intended by Section 111(a) of the CAA.

2.12.27 Comment: The proposed rule should emphasize that companies that make good-faith efforts will not be subject to enforcement action if errors or mistakes in the enforceable commitment are discovered by the company or the EPA (IV-D-35).

Response: The EPA will use its enforcement discretion for cases where companies make an honest mistake in their estimation of the base year emission data or supporting materials. In such instances, companies may be required to revise their base year and make additional reductions in order to achieve 90 (95) percent emission reductions. Alternatively, companies may rescind their commitment without penalty prior to December 1, 1993. Sources found submitting false or fraudulent information in their commitment for early reductions, even after initial approval of their base year submission, shall be subject to enforcement action under Section 113 of the CAA or other Federal statutes.

2.12.28 Comment: The commenter recommends that the EPA allow facilities that do not meet their enforceable commitments to be subject to applicable Section 112(d) standards only, rather than face possible penalties (IV-D-44).

Response: Sources that make an enforceable commitment to achieve early reductions can revoke the commitment without penalty up to December 1, 1993. These sources would thus be subject only to the applicable Section 112(d) standard. This allows the source a considerable amount of time to attempt to achieve the promised reductions. If the source is unable to achieve those reductions, it may terminate its participation in the Early Reductions Program without sanction, provided it does so by the required deadline. Other participants in the discussions leading up to proposal of this rule expressed the concern that Congress intended that commitments are to be kept,

and that once made, they could never be revoked. To give any meaning to the "enforceable" part of enforceable commitment, there must be something that is enforceable. The EPA believes that, if after given every opportunity to revoke the commitment if necessary, the unrevoked commitment is enforceable. The EPA feels that the suggested compromise between the competing positions is reasonable.

Companies that achieve the committed reductions prior to January 1, 1994, but subsequently increase emissions in violation of their Title V permit conditions (or in violation of the enforceable commitment if the permit has not yet been issued), would not have to revert to meeting the Section 112(d) standard. The companies would be subject to an appropriate penalty, but would continue to maintain the considerable benefits of continuing in the Early Reductions Program. Likewise, the companies that indicate that they are continuing in the Program by not revoking their commitment prior to December 1, 1993, but who fail in their performance by not achieving the reductions committed to prior to January 1, 1994, will likewise be subject to an appropriate penalty. The EPA will use enforcement discretion to determine the severity of penalties, based on the efforts made to achieve the reductions.

2.13 REFERENCES

1. 126 Congressional Record, S16927, October 27, 1990.
2. Federal Register, Volume 57, page 31576, July 16, 1992.
3. Federal Register, Volume 56, page 9318, March 6, 1991.
4. Federal Register, Volume 51, page 43814, December 4, 1986.
5. House of Representatives Report Number 101-490, May 17, 1990.
6. Protocols for Generating Unit Specific Emission Estimates for Equipment Leaks of VOC and VHAP. United States Environmental Protection Agency. Research Triangle Park, NC. Publication No. EPA-450/3-88-010. October 1988.
7. Federal Register, Volume 56, page 9315, March 6, 1991.
8. Enabling Document for Regulations Governing Compliance for Early Reductions of Hazardous Air Pollutants. United States

Environmental Protection Agency. Research Triangle Park, NC. Publication No. EPA-450/3-91-013. July 1991.

9. Memorandum from Hassett-Sipple, B., Pollutant Assessment Branch, Environmental Protection Agency, to Early Reductions Docket A-90-47. May 30, 1991. Revised Criteria for Selecting High Risk Pollutants for the Purposes of Clean Air Act Section (i)(5)(E).

10. Memorandum from Keating, M.H., Pollutant Assessment Branch, Environmental Protection Agency, to Early Reductions Docket A-90-47. May 8, 1991. Background Information for Noncarcinogens Recommended for Inclusion of the High-Risk List Since Proposal.

11. Federal Register, Volume 54, page 38044, September 14, 1989.

12. Memorandum from Shoaf, C., Environmental Protection Agency Office of Criteria and Assessment, to A. Vasu, EPA:ESD. January 13, 1992. Need for Additional Weighting of Two Chemicals.

13. Memorandum from Keating, M.H., Pollutant Assessment Branch, Environmental Protection Agency, to Early Reductions Docket A-90-47. January 31, 1992. Diisocyanates as High-Risk Pollutants for the Early Reductions Program - Meeting between the Environmental Protection Agency and the Chemical Manufacturers Association (CMA).

14. Developmental Toxicity Study of Inhaled Toluene Diisocyanate Vapor in CD® (Sprague-Dawley) Rats. R.W. Tyl. Bushy Run Research Center Project Report 50-592. 1988.

15. Two-generation Reproduction Study of Inhaled Toluene Diisocyanate in CD® (Sprague-Dawley) Rats. R.W. Tyl and T.L. Neeper-Bradley. Bushy Run Research Center Project Report 51-576. 1989.

16. Five-year Longitudinal Study of Workers Employed in a New Toluene Diisocyanate Manufacturing Plant. J.E. Diem, et al. Am. Rev. Respir. Dis., 1982. pp. 420 thru 428.

17. The Acute and Long-Term Respiratory Effects of Aromatic Diisocyanates; a Five-Year Longitudinal Study of Polyurethane Foam Workers. J. Bugler, et al. Report distributed to the British Rubber Manufacturers' Association, the International Isocyanate Institute, and the Health and Safety Executive Council. May 7, 1991.

18. Abnormal Lung Function in Polyurethane Foam Producers: Weak Relationship to Measured TDI Exposures (abstract). R.N. Jones et al. American Review of Respiratory Diseases 143:A440 (International Conference Supplement). 1991.

19. Acute Respiratory Effects in Workers Exposed to Low Levels of Toluene Diisocyanate (TDI). J. M. Peters et al. Arch Environ Health--Vol. 16, May 1968. pp 642 thru 647.

20. Studies of Isocyanate Toxicity. J.M. Peters. Proc. Roy. Soc. Med. Volume 63, April 1970. pp 372 thru 374.

21. The Relationship of Acute Pulmonary Effect of Organic Materials to Chronic Pulmonary Effects. J.M. Peters. Reprinted from Annals of the New York Academy of Sciences, Volume 221, February 28, 1974. pp 44 thru 49.

22. A Dose-Response Relationship in TDI Workers. D.H. Wegman, et al. Journal of Occupational Medicine, Vol. 16, No. 4, April 1974. pp 258 thru 260.

23. Epidemiology of Toluene Diiosocyanate (TDI)-Induced Respiratory Disease. J.M. Peters and D.H. Wegman. Environmental Health Perspectives, Vol. 11, June 1975. pp. 97 thru 100.

24. Chronic Pulmonary Function Loss from Exposure to Toluene Diisocyanate. D.H. Wegman, et al. British Journal of Industrial Medicine, Vol. 34, 1977. pp. 196 thru 200.

25. Absence of Respiratory Effects in Subjects Exposed to Low Concentrations of TDI and MDI: A Reevaluation. A.W. Musk, et al. Journal of Occupational Medicine, Vol. 27, No. 12, December 1985. pp. 917 thru 920.

26. Isocyanates and Respiratory Disease: Current Status. A.W. Musk, et al. American Journal of Industrial Medicine, 1988. pp. 331 thru 349.

27. Health Assessment Document for Chromium. Final Report. D. Basu et al. EPA-600/8-83-014F, U. S. Environmental Protection Agency, Research Triangle Park, North Carolina, 1984. (NTIS PB85-115905).

28. U. S. Agency for Toxic Substances and Disease Registry. Toxicological Profile for Chromium. Oak Ridge National Laboratory, 1989. (NTIS PB89-236665).

29. Federal Register. Volume 55, page 650, January 8, 1990.

30. National Toxicology Program Study (three reports).
a) Subchronic Inhalation Toxicity Study of Chloroprene in Rats (Contract #NO1-ES-5515).
b) Subchronic Inhalation Toxicity Study of Chloroprene in Mice (Contract #NO1-ES-5515).
c) Pathology Working Group Chairpersons Report. 1988. 13-week Subchronic Toxicity Test by Inhalation of Chloroprene in Fischer 344 Rats and B6C3F1 Mice.

31. Relationship Between Lung Cancer and Distance of Residence from Nonferrous Smelter Stack Effluent. W.M. Greaves, et al. American Journal of Industrial Medicine 2:15-23. 1981.

32. Lung Cancer Mortality Among Residents Living Near the El Paso Smelter. W.N. Rom et al. British Journal of Industrial Medicine 39:269-272. 1982.

33. Chronic Toxicity and Oncogenicity of Inhaled Methyl Methacrylate and n-Butyl Acrylate in Sprague-Dawley Rats. Reininghaus, et al. Fd. Chem Toxicol 29:329-339. 1991.

34. Chronic Toxicity and Oncogenicity Bioassay of Inhaled Ethyl Acrylate in Fisher 344 Rats and B6C3F1 Mice. R.R. Miller et al. Drug. Chem. Toxicol. 8:1-42. 1985.

35. Federal Register, Volume 51, No. 185, September 24, 1986, Guidelines for Carcinogen Risk Assessment.

36. Health Assessment Document for VDC. Final Report. EPA-600/8-83-031F, U. S. Environmental Protection Agency, Office of Health and Environmental Assessment, Washington, D.C., 1985.

37. Carcinogenicity Bioassays of Vinylidene Chloride - Research Plan and Early Results. C. Maltoni et al. La Medicinia del Lavoro 68:240-262. 1977.

38. Health Assessment Document for Ethylene Oxide. Final Report. D.A. Gray et al. EPA-600/8-84-009F, U. S. Environmental Protection Agency, Office of Health and Environmental Assessment, Washington, D.C., 1985. (NTIS PB86-102597).

39. Mortality Among Workers Exposed to Ethylene Oxide. K. Steenland et al. New England Journal of Medicine 324:1402, May 16, 1991.

40. A Mortality Study of Men Assigned to Ethylene Oxide Production or Other Ethylene Oxide Related Chemical Manufacturing. H.L. Greenberg et al. In press, Brit. J. Ind. Med. 1989.

41. A Cohort Study of Industrial and Hospital Workers Exposed to Ethylene Oxide. M.J. Gardner et al. Presented at the Sixth International Symposium in Epidemiology in Occupational Health, Stockholm, Sweden. August 15-18. Brit. J. Ind. Med. December, 1989.

42. Final Report on a Multicentral Epidemiological Study on Ethylene Oxide. N. Kiesselbach et al. Presented at the Sixth International Symposium in Epidemiology in Occupational Health, Stockholm, Sweden. August 15-18, 1988.

43. Epidemiologic Support for Ethylene Oxide as a Cancer Causing Agent. C. Hogstedt et al. Journal of the American Medical Association 255:1575-8. 1986.

44. Epidemiologic Studies on Ethylene Oxide and Cancer: An Update, In: Bartsch, H., Hemminiki, K., O'Neill, I., eds, Methods for Detecting DNA Damaging Agents in Humans: Applications in Cancer Epidemiology and Prevention. C. Hogstedt. IARC Scientific Publication No. 89. New York: Oxford University Press 1988:265-70.

45. A Cohort Study on Cancer Mortality of Ethylene-Oxide Workers. L. Bisanti et al. Presented at the Sixth International Symposium in Epidemiology in Occupational Health, Stockholm, Sweden. August 15-18, 1988.

46. A Preliminary Report of Cancer Incidence in a Group of Workers Potentially Exposed to Ethylene Oxide. P.D. Stolley, Clinical Epidemiology Unit, University of Pennsylvania Hospital. Unpublished Report. April 25, 1986.

47. Mortality and Cancer Morbidity Among Workers in a Chemical Factory. L. Hagmar et al. Scand. J. Environ. Health 12: 545-551, 1986.

48. Hazard Assessment of Ethylene Oxide. L. Goldberg. Ethylene Oxide Industry Council, CRC Press, Boca Raton, Florida. 1986.

49. U. S. National Toxicology Program. NTP Technical Report on the Toxicology and Carcinogenesis Studies of Ethylene Oxide (CAS no. 75-21-8) in B6C3F1 Mice (inhalation studies). NTP, U. S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Research Triangle Park, North Carolina. 1987.

50. Chronic Inhalation Toxicity of Hydrazine: Oncogenic Effects. J.D. MacEwen et al. Report Number AFAMRL-TR-81-56, Air Force Aerospace Medical Research Laboratory, Wright-Patterson Air Force Base, Ohio. 1981.

51. Federal Register. Volume 56, page 27356, June 13, 1991.

52. Federal Register. Volume 51, page 43823, December 4, 1986.

53. Quality Assurance Handbook for Air Pollution Measurement Systems, Volume III, Stationary Source Specific Methods, EPA-600/4-77-027b.

54. Federal Register. Volume 57, page 31576, July 16, 1992.

55. Federal Register. Volume 57, page 44147, September 24, 1992.

56. Federal Register. Volume 56, page 7042, February 21, 1991.

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16. ABSTRACT

Regulations govening compliance extensions for early reductions of hazardous air pollutants are promulgated under the authority of section (612)(i)(5) of the Clean Air Act (CAA). These rules would apply to sources that seek compliance extensions from standards promulgated under section (112)(d) of the CAA. This document contains summaries of public comments received on the proposed rule (56 FR 27338, June 13, 1991), EPA responses and a summary of changes since proposal.

17. KEY WORDS AND DOCUMENT ANALYSIS

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