

**PROPOSED LISTING FOR THE NATIONAL EMISSION STANDARD FOR
HAZARDOUS AIR POLLUTANTS: RESEARCH AND DEVELOPMENT
FACILITIES**

**Summary of
Public Comments**

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

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1.0 INTRODUCTION

On May 12, 1997, the United States Environmental Protection Agency (EPA) submitted an Advance Notice of Proposed Rulemaking (ANPR) for the National Emission Standard for Hazardous Air Pollutant (NESHAP): Source Category List (62 FR 25877). The notice provided advance notice that the EPA was considering whether to list research and development (R&D) facilities.

Public comments and information were requested on the best way to list and regulate such sources. Comment letters were received from industry and academic representatives, and governmental entities. A total of 110 comments were submitted during the comment period, including 51 from industry, 14 from trade associations, 35 from academic institutions, and 9 from Federal and State agencies. Table 1-1 presents a listing of all persons that submitted written comments, their affiliation, and their docket item number. A public hearing was not requested.

The written comments that were submitted on the ANPR have been summarized. The EPA responses to these comments are not included in this version of the document. At the present time, the EPA does not have sufficient information to formulate responses. Once the additional data gathering effort is complete, the EPA will respond to these comments. The summary of comments and responses will be one part of the basis for the EPA's decision whether to list R&D facilities as a source category of hazardous air pollutants (HAP).

The comment summaries are presented in the following sections:

- 2.0 Comments Related to Whether the EPA should list R&D as a Source Category of HAP
- 3.0 Comments on the Regulatory Burden of Listing R&D
- 4.0 Comments on R&D Listing Options

- 5.0 Comments on R&D Regulations
- 6.0 Comments on Potential to Emit Issues
- 7.0 Information Provided in Comments about Actual R&D Emissions
- 8.0 Information Provided in Comments about University R&D
- 9.0 Information Provided in Comments about Control Costs and Options
- 10.0 Information Provided in Comments about R&D Facilities
- 11.0 Other Comments

TABLE 1-1. LIST OF COMMENTERS ON ADVANCED NOTICE OF PROPOSED RULEMAKING FOR RESEARCH AND DEVELOPMENT NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS

Air Docket A-97-11 Item Number	Commenter and Affiliation
II-D-01	N.M. Smith, Corporate EHS Manager, Life Technologies, Grand Island, NY
II-D-02	D.W. Gustafson, Env. & Health Reg. Affairs/T.A. Threet, Counsel, The Dow Chemical Company, Midland, MI
II-D-03	T.J. Ryan CIH, CSP, RBP, Director/Risk Manager, University of Houston, TX
II-D-04	R.E. Brown, Jr., Director - Health, Safety, and Environment, Dexter Aerospace Materials Adhesives Division, Pittsburgh, CA
II-D-05	A. Deshmukh, Environmental Specialist, Occidental Chemical Corporation, Dallas, TX
II-D-06	T.J. Hmeil, Corporate Ecology and Safety Air Team Leader, BASF Corporation, Monaca, PA
II-D-07	A.E. Slesinger, Director, Environmental Affairs & Safety, Boehringer Ingelheim, Pharmaceuticals, Inc., Ridgefield, CT
II-D-08	G.A. Clark, Environmental Administrator, Research & Development Division, The Babcock and Wilcox Company, Alliance, OH

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II-D-09	M. Blair, Air Pollution Control Division, Colorado Department of Public Health and Environment, Denver, CO
II-D-10	G.W. Bonsell, Armstrong World Industries, Inc., Lancaster, PA
II-D-11	V. Jones, Government Relations Manager, The Clorox Company, Oakland, CA
II-D-12	D.L. Buhaly, Program Manager, ORNL Site Manager, Department of Energy, Oak Ridge, TN
II-D-13	C. Cardounel, Air Quality Engineer, Corporate Environmental Quality, Reynolds Metals Company, Richmond, VA
II-D-14	H.D. Baier, Director, Occupational Safety & Environmental Health, University of Michigan, Ann Arbor, MI
II-D-15	P. Stavola, Environmental and Regulatory Counsel, Novartis Crop Protection, Inc., Greensboro, NC
II-D-16	E.A. Praschan, Regulatory Liaison Manager, American Automobile Manufacturers Association, Washington, DC
II-D-17	M.D. Finucane, CIH, Director, Office of Environmental Health and Radiation Safety, University of Pennsylvania

Air Docket A-97-11 Item Number	Commenter and Affiliation
II-D-18	J.D. Parmer, Director, Office of Radiation, Chemical and Biological Safety, Michigan State University
II-D-19	K.A. VanDusen, Director, Environmental Health & Safety, University of Washington
II-D-20	J.B. Blatz, Corporate Director, Environmental Affairs, The Dexter Corporation
II-D-21	G.A. Brier, Environmental Manager, PPC US Air Programs, Pharmacia and Upjohn, Kalamazoo, MI
II-D-22	V.W. Kennedy, Senior Vice President - Business and Finance, Oakland, CA
II-D-23	P.E. Wyszowski, Manager, Environmental Management Dept., Lucent Technologies
II-D-24	M.B. Stokes, Manager, Environmental Affairs & Services, Sara Lee Sock Company, High Point, NC
II-D-25	V.W. Kennedy, Senior Vice President - Business and Finance, University of California, Oakland, CA
II-D-26	Norman L. Morrow, Exxon Chemical Americas, Houston, TX
II-D-27	Deborah L. Chapin, Kodak Park Environmental Services, Health, Safety, and Environment, Eastman Kodak Company, Rochester, NY

Air Docket A-97-11 Item Number	Commenter and Affiliation
II-D-28	Craig S. Moody, CPH, University of Minnesota, Department of Environmental Health and Safety, Integrated Waste Management Facility, Minneapolis, MN
II-D-29	Lou Diberardinis, CIH, CSP, Associate Director, Environmental Medical Service, Massachusetts Institute of Technology, Medical Department, Cambridge, MA
II-D-30	William T. Martin, Plant Environment coordinator, Vulcan Chemicals, Birmingham, AL
II-D-31	Steven C. Holland, MS, ARM, Director of Risk Management and Safety, University of Arizona, Tucson, AZ
II-D-32	Leslie S. Ritts, Counsel to NEDA/CARP, National Environmental Development Association, Clean Air Regulatory Project, Washington, DC
II-D-33	Ellen Siegler, Senior Counsel, American Petroleum Institute, Washington, DC
II-D-34	Glynn Roundtree, Director, Environment, Safety, and Health, Aerospace Industries Association, Washington, DC
II-D-35	Paul J. Yaroshack, Acting Deputy Assistant Secretary of the Navy, Department of the Navy, Office of the Assistant Secretary (Installations and Environment), Washington, DC

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II-D-36	Paul Goozh, Environmental Management Division, National Aeronautics Space Administration, Washington, DC
II-D-37	Dorothy Bowers, Vice President, Environmental and Safety Policy, Merck and Company, Inc., Whitehouse Station, NJ
II-D-38	David R. Wefring, Environmental Regulatory Specialist, 3M Environmental Technology and Service, St. Paul, MN
II-D-39	Bernie Paul, Technical Group Leader, Air Program, Environmental Affairs Division, Eli Lilly and Company, Clinton, IN
II-D-40	R.S. Price, Leader, Environment/Product Stewardship, Allied Signal, Inc., Morristown, NJ
II-D-41	Thomas J. Hmeil, Corporate Ecology and Safety Air Team Leader, BASF Corporation, Mount Olive, NJ
II-D-42	D.W. Gustafson, Env. & Health Reg. Affairs/T.A. Threet, Counsel, The Dow Chemical Company, Midland, MI
II-D-43	M.L. Mullins, Vice President, Regulatory Affairs, Chemical Manufacturers Association, Arlington, VA

Air Docket A-97-11 Item Number	Commenter and Affiliation
II-D-44	P.S. Anderson, President, American Chemical Society; P.B. Lederman, Chair, Government Relations Committee, American Institute of Chemical Engineers; Washington, DC
II-D-45	R.W. Rousseau, 1997 Chair, Council for Chemical Research, Inc., Washington, DC
II-D-46	J.C. Hovious, Assistant Director, Environmental Affairs, Union Carbide Corporation, Health, Safety, & Environment, Danbury, CT
II-D-47	Barbara J. Price, Vice President, Phillips Petroleum Company, Health, Environment and Safety, Bartlesville, OK
II-D-48	P.T. Cavanaugh, Vice President and General Manager Federal Relations, Chevron Corporation, Washington, DC
II-D-49	Carolyn Wright, Director, University of Texas System, Office of Environmental Affairs, Austin, TX
II-D-50	Phil Pendergast, DVM, Ph.D, OSHA/Environment Specialist, Office of Research Risks Protection, Ohio State University, Columbus, OH

Air Docket A-97-11 Item Number	Commenter and Affiliation
II-D-51	Thomas X. White, Associate Vice President, Manufacturing and Quality Control, Regulatory and Scientific Affairs, Pharmaceutical Research and Manufacturers of America, Washington, DC
II-D-52	Shannon S. Broome, Counsel and Leader, Air Programs, General Electric Company, Corporate Environmental Programs, Fairfield, CT
II-D-53	Edward Arnett, Chair, Committee on Prudent Practices in the Laboratory, National Research Council, Commission on Physical Sciences, Mathematics, and Applications, Washington, DC
II-D-54	Jim Sell, Senior Counsel, National Paint and Coatings Association, Washington, DC
II-D-55	S.L. Edwards, Director, Public Affairs, Synthetic Organic Chemical Manufacturers Association, Washington, DC
II-D-56	W. Kjonaas, Vice President for Physical Facilities, Purdue University, West Lafayette, IN
II-D-57	S. Bayrakal, Environmental Engineer, Harvard University, Cambridge, MA
II-D-58	A. Deshmukh, Environmental Specialist - Air Quality, Occidental Chemical Corporation, Dallas, TX

Air Docket A-97-11 Item Number	Commenter and Affiliation
II-D-59	S.J. Faiello, President, Research and Development Council of New Jersey, Morris Plains, NJ
II-D-60	J.A. Dege, Manager - Air Programs, Dupont SHE Excellence Center, Wilmington, DE
II-D-61	T.F. Cecich, Vice President Environmental Safety, Glaxo Wellcome Inc., Research Triangle Park, NC
II-D-62	W.H. Hannum, Director, ESH/QA Oversight, Argonne National Laboratory, Argonne, IL
II-D-63	J.M. Wilson, Manager - Environmental Protection Pharmaceutical Group, Bristol-Myers Squibb Company, Syracuse, NY
II-D-64	W.D. Stempel, Deputy General Counsel, Yale University, New Haven, CT
II-D-65	J.A. Lease, Manager, Environment, Health and Safety, Alcoa Technical Center
II-D-66	V. Hinshaw, Dean/Senior Research Officer, University of Wisconsin-Madison
II-D-67	J.A. Buckman, Principal Environmental Engineer, Millennium Petrochemical Inc., Cincinnati, OH
II-D-68	J.D. Erickson, Director of Environment and Energy, Federal Aviation Administration (FAA)

Air Docket A-97-11 Item Number	Commenter and Affiliation
II-D-69	T.A. Kovacic, Associate Air Quality Consultant, Corporate Environmental Affairs, Dow Corning Corporation, Midland, MI
II-D-70	M. Archer, Environmental Compliance Manager/R. Stuart, Environmental Safety Program Manager, The University of Vermont, Burlington, VT
II-D-71	P.M. Zakriski, Manager of Environmental Affairs, BFGoodrich Specialty Chemicals Company, Brecksville, OH
II-D-72	F.J. Kurasiewicz, VP, Research and Development, Best foods, Sommerset, NJ
II-D-73	D.H. Miller, Convener, Laboratory Safety Alliance, San Francisco, CA
II-D-74	L.M. Gibbs, Associate Vice Provost for Environmental Health and Safety, Stanford University, Stanford, CA
II-D-75	D. Issacs, EIA Deputy General Counsel, Director, Environmental Affairs, Electronic Industries Association, Arlington, VA
II-D-76	J.A. McCumber, Director, Environmental Health Office, Syracuse University, Syracuse, NY
II-D-77	L.T. Leasia, Director, Office of Research Safety, Northwestern University, Chicago, IL

Air Docket A-97-11 Item Number	Commenter and Affiliation
II-D-78	M.M. McDougall, Chair, Campus Safety, Health and Environmental Management Association, University of San Diego, LaJolla, CA
II-D-79	Carolyn Wright, Director, University of Texas System, Office of Environmental Affairs, Austin, TX
II-D-80	M.W. St. Clair, CSP, The Ohio State University
II-D-81	E.A. Fraser, Vice President, Environment, Health and Safety, Hoechst Marion Roussel, Inc., Bridgewater, NJ
II-D-82	R. Hardiman, Chief Corporate Counsel, Genetech, Inc., South San Francisco, CA
II-D-83	R.F. Pelletier, Director, Office of Environmental Policy & Assistance, Department of Energy, Washington, DC
II-D-84	R.K. Warland, Director, Division of Air Resources, New York State Department of Environmental Conservation, Albany, NY
II-D-85	V. A. Anderson, Director, Division of Environmental Health and Safety, University of Illinois at Urbana-Champaign, Urbana, IL
II-D-86	R. Bobal, Senior Manager, Corporate Environmental & Safety Affairs, Hoffman LaRoche, Inc.

Air Docket A-97-11 Item Number	Commenter and Affiliation
II-D-87	D. Corti, Environmental Health Director, University of Montana, Missoula, MT
II-D-88	C. Richter. Comments of behalf of Metal Finishing Suppliers Association (MFSA), American Electroplaters and Surface Finishers Society (AESF) and National Association of Metal Finishers (NAMF)
II-D-89	T. Alexander, Director, Indiana University Environmental Health and Safety, Indiana University, Bloomington, IN
II-D-90	J.E. Difazio, Jr., Senior Counsel, Chemical Specialties Manufacturers Association, Washington, DC
II-D-91	W.T. Burkhart, Manager, Environmental Government Relations, North America Health, Safety & Environment, Proctor & Gamble, Cincinnati, OH
II-D-92	K. Davis, Associate General Counsel, Washington University in St. Louis, St. Louis, MO
II-D-93	S.E. Steinbach, General Counsel, American Council on Education, Washington, DC
II-D-94	H.D. Baier, Director, Occupational Safety & Environmental Health, University of Michigan, Ann Arbor, MI
II-D-95	P.E. Wyszowski, Manager, Environmental Management Dept., Lucent Technologies

Air Docket A-97-11 Item Number	Commenter and Affiliation
II-D-96	J.F. Graf, Director, Environmental Science, The Cosmetic, Toiletry, and Fragrance Association, Washington, DC
II-D-97	R.I. Sedlak, Technical Director, The Soap and Detergent Association, New York, NY
II-D-98	F.M. Thompson, Director, Department of Environmental Health and Safety, University of Minnesota, Minneapolis, MN
II-D-99	W.R. Hendee, Senior Associate and Vice President, Medical College of Wisconsin, Milwaukee, WI
II-D-100	S.R. Williams, Staff Environmental Engineer, IBM Almaden Research Center, San Jose, CA
II-D-101	A. Burgos, Jr., University of Southern California
II-D-102	D.M. Friedland, Law Offices of Beveridge & Diamond, Washington, DC
II-D-103	J.J. Cohen, M.D., President, Association of American Medical Colleges, Washington, DC
II-D-104	A. Burgos, Jr., Environmental Safety Specialist, University of Southern California, Los Angeles, CA

Air Docket A-97-11 Item Number	Commenter and Affiliation
II-D-106	A.W. Stelson, Ph.D., Senior Environmental Engineer, Stationary Source Compliance Program, Georgia Department of Natural Resources, Environmental Protection Division, Air Protection Branch, Atlanta, GA
II-D-107	Genetech, Inc. Washington, DC. Comments on behalf of American Council on Education; Chevron; Laboratory Safety Alliance; Proctor and Gamble; American Petroleum Institute; Genetech, Inc.; Pfizer, Inc.; and Stanford University.
II-D-108	L.M. Gibbs, Laboratory Safety Alliance, San Francisco, CA
II-D-109	M.J. Bocchicchio, Assistant Vice President - Facilities Administration, University of California, Oakland, CA
II-D-110	T.H. Moran, Vice President, Business Affairs, University of Southern California, Los Angeles, CA

**2.0 COMMENTS RELATED TO WHETHER THE EPA SHOULD
LIST R&D AS A SOURCE CATEGORY OF HAP**

**2.1 Do Not List R&D as a Source Category of HAP, or List and De-
list R&D Immediately Thereafter**

Comment: Twenty-nine commenters (II-D-03, II-D-10, II-D-12, II-D-15, II-D-30, II-D-33, II-D-39, II-D-40, II-D-43, II-D-45, II-D-47, II-D-48, II-D-51, II-D-52, II-D-55, II-D-57, II-D-58, II-D-59, II-D-60, II-D-67, II-D-69, II-D-73, II-D-74, II-D-75, II-D-79, II-D-88, II-D-100, II-D-102, and II-D-108) stated that the EPA should not list R&D as a source category or should list and then immediately de-list R&D. One commenter (II-D-03) remarked listing is not necessary because the "appropriate controls" described in the ANPR are no controls for R&D facilities. One commenter (II-D-10) believed that there would be little benefit of listing since R&D facilities generally have low actual emissions and are generally covered by State permit requirements, as well as CAA reasonably available control technology (RACT) and Title V. Three commenters (II-D-12, II-D-57, and II-D-79) quoted the EPA's White Paper for Streamlined Development of Part 70 Applications (July 10, 1995), which describes how there is no need for extensively detailing R&D inventories, activities, or emissions in relationship to Title V permitting. One commenter (II-D-15) remarked that regulating R&D at a major source manufacturing facility would be regulating a few "pounds" of emissions in addition to the "tons" emitted by the major source. One commenter (II-D-30) stated that the listing of R&D as a source category would be overly ambitious with disproportionate benefits to the environment. One commenter (II-D-47) stated that listing R&D sources is not sound policy for practical reasons. Three commenters (II-D-52, II-D-55, and II-D-

60) believed that the EPA should not list until the prerequisites to CAA § 112(c)(1) or (c)(3) have been met. One commenter (II-D-57) described their regulation under the Massachusetts Operating Permit program (310 CMR 7.00) and hoped that the EPA will not list R&D sources, thereby not altering the existing permits. One commenter (II-D-69) stated that the EPA should allow the States to continue to have the flexibility to regulate of R&D facilities.

2.2 CAA Section 112 Does Not Require the EPA to List R&D as a Source Category of Hazardous Air Pollutants

Comment: Fifty-seven commenters (II-D-03, II-D-07, II-D-10, II-D-12, II-D-16, II-D-18, II-D-20, II-D-21, II-D-22, II-D-23, II-D-27, II-D-30, II-D-32, II-D-33, II-D-34, II-D-35, II-D-37, II-D-38, II-D-39, II-D-41, II-D-43, II-D-44, II-D-46, II-D-47, II-D-48, II-D-49, II-D-51, II-D-52, II-D-55, II-D-56, II-D-57, II-D-58, II-D-59, II-D-60, II-D-64, II-D-66, II-D-67, II-D-69, II-D-70, II-D-73, II-D-74, II-D-75, II-D-76, II-D-79, II-D-80, II-D-82, II-D-83, II-D-85, II-D-86, II-D-91, II-D-93, II-D-95, II-D-96, II-D-97, II-D-102, II-D-103 and II-D-108) cited CAA § 112, stating that the EPA is not required to list R&D as a source category of HAP. Eight commenters (II-D-21, II-D-33, II-D-34, II-D-37, II-D-39, II-D-51, II-D-55, and II-D-75) stated that they believe the EPA misinterpreted its mandate in stating (in the ANPR) that the EPA has no discretion in whether to list R&D as a source category.

Commenters provided various citations in support of this statement. Nine commenters (II-D-03, II-D-07, II-D-12, II-D-60, II-D-73, II-D-82, II-D-83, II-D-85, and II-D-96) cited lack of evidence supporting the section 112 requirement for a "threat of adverse effects to human health or the environment" as

justification for not listing. Thirty-four commenters (II-D-16, II-D-20, II-D-21, II-D-22, II-D-23, II-D-32, II-D-33, II-D-34, II-D-35, II-D-37, II-D-39, II-D-43, II-D-44, II-D-47, II-D-51, II-D-52, II-D-57, II-D-58, II-D-59, II-D-64, II-D-67, II-D-73, II-D-74, II-D-75, II-D-76, II-D-79, II-D-80, II-D-82, II-D-83, II-D-85, II-D-86, II-D-91, II-D-95, and II-D-102) cited the phrase "as necessary" in §112(c)(7) as providing the EPA the authority to not list R&D. Six commenters (II-D-27, II-D-30, II-D-32, II-D-33, II-D-51, and II-D-52) cited the case of *Alabama Power Co. V. Costle*, 636 F.2d 323, 360-361 (DC cir. 1980) as a precedent that supports this interpretation of section 112. The *Alabama Power* decision dictates that the EPA may avoid "pointless expenditures of effort" when the burden would yield trivial gain. Twenty commenters (II-D-16, II-D-23, II-D-32, II-D-43, II-D-49, II-D-52, II-D-58, II-D-59, II-D-60, II-D-64, II-D-73, II-D-74, II-D-75, II-D-79, II-D-82, II-D-93, II-D-95, II-D-97, II-D-102, and II-D-103) quoted the discussion by Senator Harkin in presenting section 112 (c)(7), to the U.S. Senate or the Senate Committee on Environment and Public Works. Senator Harkin voiced concerns that the unique characteristics of R&D be considered by the EPA if any standards are made (at the administrator's discretion), and R&D facilities not be covered arbitrarily with manufacturing operations. Eight commenters (II-D-22, II-D-27, II-D-38, II-D-73, II-D-79, II-D-83, II-D-93, and II-D-103) cited similar statements that R&D facilities not be covered arbitrarily in rules that cover manufacturing, which were made to the U.S. House of Representatives Committee on Energy and Commerce.

Some commenters provided other statements on this issue. Two commenters (II-D-34 and II-D-51) stated that the EPA is only required to list R&D if listing is necessary for equitable treatment. One commenter (II-D-34) continued by stating the EPA may not be authorized to list if it is not necessary to assure

equitable treatment. Similarly, one commenter (II-D-51) determined that EPA's authority to list and regulate R&D does not come from § 112(c)(7), as this clause only directs the subcategorization for special treatment. Also, on the language of § 112(c)(7), one commenter (II-D-95) stated that if the congressional intent were to mandate the establishment of a R&D subcategory, then they would have omitted the words "as necessary." One commenter (II-D-47) stated that listing is not required because the words "shall list" found in § 112(c)(8) are not included in § 112(c)(7). The commenter (II-D-47) also described how § 112(c)(7) overrides § 112(c)(1) because § 112(c)(7) does not reference § 112(c)(1), as § 112(c)(5) does. Conversely, one commenter (II-D-55) stated that the EPA is mistaken to proceed with listing under § 112(c)(7) without regard to § 112(c)(1) or (3). One commenter (II-D-76) noted the potential to apply § 112(h) by establishing a design, equipment, work practice, or operational standard rather than a maximum achievable control technology (MACT) standard.

2.3 The EPA Has Little Evidence of R&D Major Sources

Comment: Forty-eight commenters (II-D-16, II-D-22, II-D-23, II-D-26, II-D-31, II-D-32, II-D-33, II-D-35, II-D-40, II-D-41, II-D-44, II-D-45, II-D-46, II-D-47, II-D-49, II-D-50, II-D-51, II-D-52, II-D-55, II-D-57, II-D-59, II-D-60, II-D-61, II-D-64, II-D-66, II-D-67, II-D-69, II-D-72, II-D-73, II-D-74, II-D-75, II-D-76, II-D-79, II-D-80, II-D-81, II-D-82, II-D-83, II-D-84, II-D-85, II-D-90, II-D-93, II-D-95, II-D-97, II-D-99, II-D-100, II-D-102, II-D-103, and II-D-104) provided comments that stated the EPA has little or no evidence of R&D major sources or adverse effects on human health and the environment due to R&D source emissions. One commenter (II-D-26) stated that even their

largest R&D operations are not major sources of HAP. Three commenters (II-D-26, II-D-40, and II-D-83) cited the Part 70 rule revision (60 FR 45556) as stating that there is a small likelihood of R&D facilities being major sources. One commenter (II-D-26) stated that State regulations are already in place, and that the EPA should not impose further requirements. Two commenters (II-D-33 and II-D-40) stated that there is no evidence that R&D warrants regulation under § 112(d), and it would be wasted resources to generate that evidence and develop a regulation. One commenter (II-D-41) remarked that the EPA must develop an adequate method for determining potential-to-emit (PTE) HAP before a major source determination could be followed through. Similarly, one commenter (II-D-55) stated that until the PTE methodology was established, all sources should be considered area sources. The commenter cited that, in connection with the promulgation of the initial source category (55 FR 31576, 16 July, 1992), the EPA stated it would list categories where it was reasonably certain that at least one major source existed. However, the EPA does not have the evidence to be consistent with this interpretation. Two commenters (II-D-55 and II-D-69) stated that without evidence of a major source the EPA has no basis under § 112(c)(1) or (3). One commenter (II-D-80) cited the EPA's White Paper for Streamlined Development of Part 70 Applications (July 10, 1995), as stating R&D sources are generally not major sources and are exempt from the requirements of any category that may be created. Contrary to all other comments, one commenter (II-D-84), a State agency, provided R&D emissions for a facility where the emissions were above the major source level.

2.4 The EPA Does Not Have Enough Information Now to List R&D

Comment: Twenty-seven commenters (II-D-16, II-D-21, II-D-27, II-D-32, II-D-37, II-D-41, II-D-46, II-D-49, II-D-51, II-D-52, II-D-57, II-D-60, II-D-64, II-D-67, II-D-69, II-D-73, II-D-76, II-D-77, II-D-79, II-D-83, II-D-89, II-D-93, II-D-94, II-D-101, II-D-102, II-D-103, and II-D-104) stated that the EPA does not have enough information at this time to list R&D. Six commenters (II-D-16, II-D-27, II-D-32, II-D-37, II-D-51, and II-D-67) voiced a concern that if the category is listed without enough information then the rule will not be promulgated in the directed time frame and section 112(j) will be invoked. Moreover, four commenters (II-D-46, II-D-51, II-D-52, and II-D-60) stated that there is not a statutory deadline for when all source categories must be listed, so the EPA should be sure it has enough information before listing. Similarly, six commenters (II-D-21, II-D-32, II-D-41, II-D-51, II-D-52, and II-D-60) stated that the Inspector General's audit report should not dictate the timing of listing, rather the EPA should be sure there is adequate information to insure resources are not wasted.

2.5 Inspector General's Report Does Not Justify Regulating an Entire Industry

Comment: Eighteen commenters (II-D-16, II-D-23, II-D-32, II-D-33, II-D-40, II-D-43, II-D-51, II-D-52, II-D-58, II-D-59, II-D-60, II-D-73, II-D-77, II-D-79, II-D-89, II-D-90, II-D-91, and II-D-94) stated that they do not believe the Inspector General's report justifies listing R&D facilities. These commenters gave various reasons why the Inspector General's report should not justify listing R&D. Twelve commenters (II-D-16, II-D-32, II-D-33, II-D-43, II-D-51, II-D-52, II-D-58, II-D-

60, II-D-77, II-D-79, II-D-89, and II-D-94) stated that the EPA should not list all R&D just to cover a small number of sources that may inappropriately characterize themselves as R&D so as to avoid regulation. Three commenters (II-D-16, II-D-32, and II-D-51) stated that to do so would be inefficient and inconsistent with the "special treatment" language of § 112 (c)(7). Similarly, one commenter (II-D-33) believed that listing R&D as a source category under § 112(c)(7) would not address the problem of inappropriate characterization. Five commenters (II-D-23, II-D-43, II-D-52, II-D-59, and II-D-60) recommended using existing regulatory options or MACT tools (such as defining the scope of activities considered as manufacturing) to resolve the problem. Five commenters (II-D-32, II-D-51, II-D-58, II-D-90, and II-D-91) suggested that the EPA use its CAA authority to investigate how many sources may be inappropriately classifying sources as R&D if it wishes to address this problem, rather than listing R&D as a source category.

2.6 R&D Actual Emissions Are Generally Low, or *de minimis*.

Comment: Forty-four commenters (II-D-04, II-D-07, II-D-10, II-D-12, II-D-16, II-D-17, II-D-23, II-D-24, II-D-26, II-D-28, II-D-30, II-D-33, II-D-34, II-D-39, II-D-40, II-D-44, II-D-46, II-D-48, II-D-49, II-D-51, II-D-52, II-D-54, II-D-55, II-D-57, II-D-58, II-D-59, II-D-60, II-D-61, II-D-62, II-D-65, II-D-66, II-D-69, II-D-70, II-D-71, II-D-73, II-D-76, II-D-79, II-D-83, II-D-85, II-D-86, II-D-88, II-D-93, II-D-95, and II-D-103), stated that R&D emissions are low or *de minimis*. One commenter (II-D-04) remarked that the R&D emissions are very small compared to the already permitted manufacturing emissions. Two commenters (II-D-54 and II-D-69) stated that emissions are low because good laboratory practices are used, such as minimizing quantities used

and keeping storage containers closed. Twelve commenters (II-D-26, II-D-28, II-D-34, II-D-40, II-D-57, II-D-66, II-D-70, II-D-76, II-D-79, II-D-85, II-D-93, and II-D-103) cited that the EPA stated (60 FR 45529/45557) that even large R&D facilities typically have very low emissions.

One commenter (II-D-51) cited the case of *Alabama Power Co. v. Costle*, 636F.2d 323, 360-361 (D.C. Cir. 1980) in their argument for not regulating R&D operations because they are *de minimis* sources. The decision states that the EPA may avoid "pointless expenditures of effort" when the "burdens of regulation [would] yield a gain of trivial or no value." The commenter argued that R&D operations are *de minimis* sources and regulation may be avoided under the *Alabama Power* decision.

2.7 Do Not Regulate R&D until All Other MACT Standards Are Finished

Comment: Ten commenters (II-D-16, II-D-21, II-D-32, II-D-41, II-D-43, II-D-46, II-D-51, II-D-52, II-D-60, and II-D-90) stated that the EPA should not list R&D until the work on all other MACT standards are finished. Seven commenters (II-D-16, II-D-21, II-D-32, II-D-46, II-D-51, II-D-52, and II-D-60) remarked that completing the other source categories first would be good policy considering limited resources and time constraints [thus avoiding the burden of § 112(j)]. Four commenters (II-D-16, II-D-43, II-D-51, and II-D-60) stated that this approach would give the Agency extra time to evaluate the state of existing information or gather more information.

2.8 It Is Difficult to Characterize and Regulate R&D Processes Due to Great Variety among R&D Operations

Comment: Forty-nine commenters (II-D-07, II-D-10, II-D-11, II-D-12, II-D-13, II-D-15, II-D-16, II-D-23, II-D-26, II-D-28, II-D-32, II-D-33, II-D-34, II-D-37, II-D-38, II-D-39, II-D-40, II-D-44, II-D-46, II-D-47, II-D-48, II-D-50, II-D-51, II-D-52, II-D-55, II-D-57, II-D-59, II-D-60, II-D-61, II-D-62, II-D-64, II-D-65, II-D-66, II-D-67, II-D-70, II-D-71, II-D-72, II-D-73, II-D-75, II-D-77, II-D-79, II-D-80, II-D-81, II-D-86, II-D-88, II-D-90, II-D-97, II-D-100, and II-D-101) described how it is difficult to characterize and regulate R&D processes due to great variety among R&D operations. Seventeen commenters (II-D-13, II-D-15, II-D-23, II-D-40, II-D-48, II-D-50, II-D-51, II-D-52, II-D-57, II-D-59, II-D-61, II-D-62, II-D-65, II-D-72, II-D-73, II-D-79, and II-D-101) pointed out that R&D operations are especially difficult to characterize and regulate as compared to less variable manufacturing operations. Twenty-five commenters (II-D-11, II-D-13, II-D-15, II-D-23, II-D-26, II-D-28, II-D-33, II-D-34, II-D-38, II-D-40, II-D-47, II-D-48, II-D-51, II-D-52, II-D-55, II-D-59, II-D-64, II-D-70, II-D-73, II-D-79, II-D-80, II-D-81, II-D-88, II-D-90, and II-D-101) cited the variety or variability in R&D sources, processes, experiments, equipment, type and volumes of chemicals, duration, emissions, controls, or products for the difficulty in characterization and regulation. Four commenters (II-D-13, II-D-60, II-D-73, and II-D-86) remarked that R&D processes are so dynamic that it would be difficult and expensive to justify the use of traditional control methods. One commenter (II-D-33) believed that R&D characterization and regulation will be costly due to the great variety in R&D operations.

Three commenters (II-D-16, II-D-32, and II-D-52) suggested the agency exercise its § 112(d)(1) authority to "distinguish among classes types, and sizes within a category or subcategory in establishing such standards..." so that the rule will better account for the significant variability in R&D facilities. The commenters made an example of the HON rule (59 FR 19402; April 22, 1994). This rule relied on distinguishing characteristics to classify the type of regulation required.

2.9 There Are No Real Health/Environmental Effects Issues Associated with R&D

Comment: Thirty-seven commenters (II-D-03, II-D-07, II-D-12, II-D-16, II-D-21, II-D-22, II-D-29, II-D-32, II-D-34, II-D-46, II-D-47, II-D-48, II-D-49, II-D-50, II-D-51, II-D-52, II-D-55, II-D-57, II-D-60, II-D-64, II-D-66, II-D-72, II-D-73, II-D-74, II-D-75, II-D-79, II-D-81, II-D-82, II-D-83, II-D-85, II-D-86, II-D-90, II-D-93, II-D-99, II-D-102, II-D-103, and II-D-104) stated that there is no evidence of a threat or risk of adverse effect associated with R&D operations or R&D area sources. The "threat of adverse effect" language is taken from § 112(c)(3). One commenter (II-D-29) provided Massachusetts Department of Environmental Protection Regulation 3100 CMR 7.00 which exempts academic and research laboratories because these facilities pose minimal risk. One commenter (II-D-48) stated that studies in their area have shown that even large laboratory complexes pose a risk of less than one in a million. One commenter (II-D-51) provided an example of a member facility the that has over 300 lab hoods, and less than 0.2 tons per year emissions. Using the EPA's SCREEN3 model, the facility would have to increase emissions 100 times the current levels to approach TLV/100 (TLV/100 is a measure of health risk). One commenter (II-D-102)

provided an example of the limited health risks from the report "Risk Assessment Summary of Laboratory Emissions of Toxic Air Contaminants." In this assessment three large California R&D operations, over four years, despite multiple conservative assumptions, found no significant cancer or non-cancer health effects associated with the HAP emissions from the facilities. All three facilities were below the significant effects levels established by California Proposition 65.

A commenter (II-D-55) stated that they support efforts to reduce harmful emissions if such regulation would have significant environmental benefits. The commenter felt, however, that there was no information indicating that R&D facilities present a threat to human health or the environment. The commenter also stated that emission rates are low and reasonably calculating PTE was difficult, resulting in negligible environmental benefits.

A commenter (II-D-75) estimated that emissions from their research center would be 1,500 pounds per year (lb/yr). The commenter based this estimation on purchasing data and the conservative assumption that all purchased chemicals are emitted. The commenter felt that this does not demonstrate a risk to the environment or human health.

Two commenters (II-D-82 and II-D-102) stated that studies of large R&D facilities at Stanford and UCSF-Parnassus indicated that the cancer risks from exposure to emissions from these cities were less than one in a million. The commenter felt that regulating R&D facilities would show minimal human health benefits.

3.0 COMMENTS ON THE REGULATORY BURDEN OF LISTING R&D

3.1 R&D Operations' Need for Flexibility

Comment: Thirty-eight commenters (II-D-10, II-D-13, II-D-16, II-D-20, II-D-23, II-D-26, II-D-27, II-D-28, II-D-30, II-D-34, II-D-37, II-D-38, II-D-39, II-D-40, II-D-46, II-D-48, II-D-51, II-D-52, II-D-54, II-D-55, II-D-57, II-D-59, II-D-60, II-D-61, II-D-64, II-D-65, II-D-66, II-D-67, II-D-71, II-D-73, II-D-75, II-D-76, II-D-79, II-D-82, II-D-86, II-D-96, II-D-100, and II-D-102) expressed a need for flexibility with respect to R&D operations, in part, to meet ever changing needs and new technological developments. Four commenters (II-D-30, II-D-51, II-D-52, and II-D-60) stated that R&D facilities are designed to have inherent flexibility. Two commenters (II-D-10 and II-D-38) felt that innovation in environmentally-improved products and pollution prevention would be stifled. Eight commenters (II-D-13, II-D-26, II-D-27, II-D-28, II-D-40, II-D-52, II-D-60, and II-D-79) felt that limited flexibility would damage US competitiveness. Three commenters (II-D-37, II-D-73, and II-D-86) were concerned that limiting flexibility would restrict the discovery and development of new life-saving drugs or other new products. Three commenters (II-D-23, II-D-59 and II-D-75) indicated that R&D operations are short-term in nature. The commenters noted that research priority dictates the nature and duration of these experiments. One commenter (II-D-102) stated that it is not feasible to change the controls as the research progresses.

Two commenters (II-D-10 and II-D-64) indicated that operational flexibility is necessary to allow experimentation. The commenters felt that R&D personnel need to be allowed to make changes quickly and often. One commenter (II-D-64) requested

that any performance-based standard allow for flexibility and an autonomous laboratory environment.

Sixteen commenters (II-D-13, II-D-16, II-D-27, II-D-39, II-D-40, II-D-46, II-D-51, II-D-52, II-D-54, II-D-55, II-D-60, II-D-67, II-D-71, II-D-73, II-D-82, and II-D-86) stated that flexibility is required to try new processes and develop new products. The commenters mentioned the importance minimizing the time to respond to new ideas and market conditions. Two commenters (II-D-13 and II-D-67) also mentioned the importance of minimizing cost in the R&D process. One commenter (II-D-82) was concerned that, under the proposed regulation, they would be required to go through extensive permitting and emissions testing before any alteration to their R&D facilities. The commenter mentioned that months of permitting would be required before being able to install and utilize such technology.

A commenter (II-D-20) recommended that "modification" of an R&D laboratory be narrowly defined to include only the modification of the emissions points themselves. The commenter felt that "modification" should not include changes in the laboratory scale process equipment used or in the chemical feedstocks. The commenter further stated that scientists must be free to alter the experimental processes without having to consider "significant modifications," as this would limit flexibility.

Five commenters (II-D-27, II-D-28, II-D-57, II-D-79, and II-D-86) stated that rigid R&D control standards could inhibit creativity and innovation. The commenters noted that changes in chemical use, potential emissions, and research activities are necessary to discover new products and improve processes and products. The commenter noted that R&D operations are influenced by regulations to which their production counterparts are subject. Three commenters (II-D-28, II-D-57, and II-D-79) were

concerned about restricting the creativity and productivity of laboratories. Two commenters (II-D-28 and II-D-79) stated that the overall productivity of a laboratory is related to the flexibility of chemical use.

Two commenters (II-D-34 and II-D-65) indicated that it is necessary for R&D facilities to make numerous and necessary changes over a short period of time. The commenters felt that MACT regulations would prevent them from performing efficiently.

A commenter (II-D-54) stated that R&D facilities achieve improvements in technology by having the ability to use a wide range of possible technologies. The commenter recommended that interference with this should be minimized and limited to circumstances that truly warrant it. The commenter was also concerned about eliminating or minimizing the use of certain types of materials as a control strategy.

A commenter (II-D-73) stated that flexibility is essential to conduct research and generate ideas. The equipment must accommodate a variety of users, and must be adjustable. The commenter was concerned that MACT would require the permanent installation of specific control devices. The commenter was also concerned that MACT could require installation of control equipment that would be suitable only for working with specific chemicals.

3.2 Confidentiality Concerns

Comment: Eight commenters (II-D-32, II-D-38, II-D-41, II-D-46, II-D-52, II-D-73, II-D-91, and II-D-97) were concerned about the disclosure of confidential information as a result of the NESHAP development process. Two commenters (II-D-91 and II-D-97) stated that the implications of releasing confidential information directly related to ongoing product R&D needed to be

fully understood. Four commenters (II-D-38, II-D-41, II-D-46, and II-D-52) felt that their competitors would gain an unfair advantage over them as a result of the release of confidential material. Two commenters (II-D-32 and II-D-38) recommended that Agency confidential business information (CBI) policies would have to be revised to properly protect R&D information.

A commenter (II-D-32) stated that under EPA's Freedom of Information Access (FOIA) and enforcement policies, it is clear that once regulated as emissions, compounds and research techniques could not be protected from disclosure to the public. The commenter felt that if such information were disclosed, most research should be slowed. In contrast, one commenter (II-D-38) cited Federal rules [40 CFR 2.301(a)(2)(ii)] that recognize the need to protect the confidentiality of R&D information in the context of environmental compliance.

A commenter (II-D-38) was concerned about loss of patent protection, or trade secrets, loss of sales and market share for new products, and reduced profits. The commenter indicated that knowledge of confidential processes and manufacturing costs would help competitors plan their marketing and pricing strategies.

Four commenters (II-D-38, II-D-41, II-D-46, and II-D-52) were concerned about the sensitivity of specific data due to the possible impact on competitiveness. One commenter (II-D-38) asked that any potential R&D standard not require emission data to be reported.

3.3 Regulation Would Impede Product Innovation or R&D Competitiveness

Comment: Thirty-one commenters (II-D-01, II-D-13, II-D-17, II-D-20, II-D-26, II-D-27, II-D-28, II-D-37, II-D-38, II-D-40, II-D-41, II-D-46, II-D-47, II-D-48, II-D-51, II-D-52, II-D-54,

II-D-60, II-D-61, II-D-63, II-D-71, II-D-73, II-D-74, II-D-75, II-D-79, II-D-81, II-D-82, II-D-88, II-D-91, II-D-97, and II-D-100) were concerned that R&D regulations would negatively affect competition and innovation. Seven commenters (II-D-38, II-D-41, II-D-46, II-D-52, II-D-73, II-D-91 and II-D-97) stated that release of sensitive information would have a negative effect on competitiveness. One commenter (II-D-54) stated that innovation was the chief mechanism by which their competitive position is maintained. One commenter (II-D-100) was concerned that researchers would be unable to use a material in a project for fear of not having the appropriate MACT. The commenter stated that it is not feasible to install every possible control technology for the various HAP that may be used. Therefore, according to the commenter, the types of chemicals that may be used and what researchers do within a research facility would be limited. The commenter also felt that keeping track of different standards for each piece of R&D equipment or activity would be time consuming and detract from creative activities.

Two commenters (II-D-01 and II-D-48) stated that overhead costs brought on by the R&D regulation could result in budgetary constraints that would stunt growth and development, and limit their ability to be innovative and competitive.

Nine commenters (II-D-13, II-D-41, II-D-51, II-D-60, II-D-71, II-D-73, II-D-81, II-D-88, and II-D-100) mentioned that industry competes in global markets in which R&D is a vital component. Five commenters (II-D-13, II-D-41, II-D-51, II-D-60, and II-D-71) were concerned that any competitive edge the U.S. industry currently holds would be lessened by the regulation. Four commenters (II-D-73, II-D-81, II-D-88, and II-D-100) stated that if R&D facilities are subject to MACT regulation, the ability of U.S. companies and institutions to compete in a world marketplace would be reduced. One commenter (II-D-73) mentioned

fierce competition and rapid technological changes in the global market place. The commenter stated that effective R&D is vital to corporate survival. One commenter (II-D-81) indicated that if research becomes too cumbersome in the US, companies will look elsewhere. One commenter (II-D-88) stated that since R&D in the U.S. supports and enhances protection of the environment, the regulation would be contrary to these objectives.

A commenter (II-D-17) stated that if engineering research were delayed until controls were in place, it would have little benefit to the environment, and would lower the competitiveness of U.S. industry.

Six commenters (II-D-20, II-D-37, II-D-61, II-D-74, II-D-79, and II-D-82) felt that the regulation would impede flexibility to develop and research new formulations.

A commenter (II-D-27) was concerned that if the MACT standard limited flexibility, then creativity, innovation, and competitiveness would be limited. The commenter indicated that requiring controls on the R&D process would be costly and would impede competitiveness in the U.S., while the rest of the world would not have such constraints.

Two commenters (II-D-28 and II-D-79) stated that tracking chemical usage for mass balances would be overly burdensome. The commenters felt that this burden would restrict the creativity and productivity of laboratories, and would negatively impact U.S. competitiveness.

A commenter (II-D-38) was concerned that industry specific R&D standards would put them at a competitive disadvantage because their R&D equipment is used for several different industries. The commenter felt that subjecting one type of R&D facility to MACT standards, while exempting another would create competitive disadvantages among R&D facilities. The commenter recommended that any R&D MACT standards should apply to R&D

facilities regardless of whether they are public, governmental, or educational facilities.

A commenter (II-D-46) stated that reduction in cycle time for the R&D process for environmentally friendly processes or products is a source of competitive advantage for the U.S. Chemical Industry. The commenter felt that delays in bringing new products and processes to the marketplace due to impractical requirements would weaken the U.S.'s competitive edge in a global market.

Three commenters (II-D-26, II-D-52, and II-D-75) expressed concern that if R&D operations are not able to be conducted with speed and flexibility, they would be placed at a disadvantage to their competitors.

Two commenters (II-D-73 and II-D-100) stated that complying with an R&D MACT would take resources away from R&D efforts and shift them to compliance activities. The commenters felt that adding controls to R&D would negatively impact the cost of research. The commenters felt that this would lessen productivity in the R&D process. According to the commenters, this would result in less research in areas such as health science, less polluting energy resources, and improvement of manufacturing processes.

A commenter (II-D-100) stated that the goal of R&D is to get ideas to the public and in the marketplace as quickly as possible. The commenter felt that imposing restrictions on these facilities would restrict the information that can be produced, and is of little benefit to the public.

3.4 Regulation Would Be an Administrative Burden

Comment: Forty-three commenters (II-D-03, II-D-07, II-D-12, II-D-15, II-D-16, II-D-18, II-D-19, II-D-20, II-D-26, II-D-27,

II-D-28, II-D-30, II-D-31, II-D-32, II-D-33, II-D-34, II-D-37, II-D-38, II-D-41, II-D-44, II-D-45, II-D-46, II-D-52, II-D-54, II-D-57, II-D-60, II-D-62, II-D-64, II-D-66, II-D-73, II-D-75, II-D-76, II-D-77, II-D-79, II-D-82, II-D-88, II-D-89, II-D-90, II-D-91, II-D-94, II-D-99, II-D-100, and II-D-102) indicated that R&D regulation would be burdensome to R&D facilities.

A commenter (II-D-03) stated that any control based on calculations would result in a paper compliance program, with little value.

Two commenters (II-D-07 and II-D-15) referred to the documentation, recordkeeping, and other commitments that would be required to acquire synthetic minor status. One commenter (II-D-07) stated that these requirements would be burdensome because of the vast array of different materials handled, which are constantly changing. One commenter (II-D-15) stated that small facilities would not have the resources to keep up with the recordkeeping requirements.

Two commenters (II-D-16 and II-D-32) indicated that there is not a methodology for calculating PTE and the cost of developing and implementing numerical emissions limits would outweigh any health and environmental benefits. The commenters suggested that the EPA consider developing a menu of standards from which the sources could choose, depending on their operations.

A commenter (II-D-18) stated that many universities have already incurred burdens under the CAA. Because of their power plant, the commenter was required to perform a survey to identify air emissions sources besides the power plant. The commenter recommended that the EPA review the impact and burden already placed upon colleges and universities. The commenter also recommended that the EPA determine whether such burden constitutes equitable treatment.

Eleven commenters (II-D-19, II-D-20, II-D-26, II-D-31, II-D-32, II-D-44, II-D-77, II-D-79, II-D-89, II-D-94, and II-D-102) referred to the burdens associated with quantifying emissions. According to six commenters (II-D-26, II-D-77, II-D-79, II-D-89, II-D-94, and II-D-102), this is a result of the multitude of very small sources in an R&D facility and the constantly changing experiments. Five commenters (II-D-77, II-D-79, II-D-89, II-D-94, and II-D-102) also felt that PTE calculations could not be performed due to the variability in research. The commenters were also concerned that academic institutions would not be able to prove that they are not significant sources. Therefore, the commenters felt that they would be end up being subject to an R&D regulation that is not, in the their opinion, equitable or reasonable. One commenter (II-D-19) referred to the cost of identifying and quantifying source emissions as being burdensome. One commenter (II-D-20) stated that requiring tracking usage below a *de minimis* threshold would impose burdensome recordkeeping requirements on laboratories that may use several different HAP compounds in small quantities for experimental purposes. One commenter (II-D-31) stated that the level of effort and expense required to perform such estimations is high and not cost-effective, given the small amounts of emissions generated. One commenter (II-D-32) stated that regulating R&D activities would be burdensome and costly given the variability of R&D operations and the impracticability of estimating emissions. The commenter felt that estimating emissions would use resources that would interfere with the research process. One commenter (II-D-44) stated that listing R&D would be costly. The commenter felt that an R&D listing would divert already scarce and declining resources from important research programs.

Three commenters (II-D-28, II-D-79, and II-D-99) referred to the burdens associated with the use of a mass balance method.

Two commenters (II-D-28 and II-D-79) stated that college and university laboratories use a variety of chemicals in small quantities, in different locations, and under the control of different personnel. According to the commenters, the purchasing departments are not centralized, and purchases are not tracked. The commenters felt that mass balances could not be performed due to the thousands of small containers used for storage, waste, etc. The commenters indicated that it would be difficult to estimate the quantity of chemicals used in storage, in reaction products, and in waste mixtures. One commenter (II-D-99) stated that the use of the mass balance method would take a large amount of faculty and staff time to record the purchase and use of chemicals.

A commenter (II-D-37) stated that any R&D regulation would require the development of a large amount of information pertaining to tens of thousands of reagents and mixtures used in R&D operations. According to the commenter, the EPA would have to use this information to develop a rational baseline, emission factors, a method of regulating, and a procedure for managing changes within the R&D facility. The commenter felt that both the EPA and the individual facility would be overwhelmed with the reporting of each "process" change that could affect emissions, since the facilities exist to test different compounds and processes.

Two commenters (II-D-38 and II-D-60) referred to the burden of the multiple source category approach. According to one commenter (II-D-38), industry-specific R&D standards could create overlapping or conflicting standards for a piece of R&D equipment or certain R&D activities. The commenter felt that keeping track of such differing requirements would be complex and time-consuming and would keep R&D personnel from performing research. The commenter stated that thousands of researchers would be

required to keep records. The commenter also stated that traditional permitting, control, and recordkeeping requirements would cause delays, costs and burdens for R&D. The commenter felt that these permitting and recordkeeping impediments would likely arise more frequently in R&D operations than industry operations. One commenter (II-D-60) was concerned that owners/operators of major R&D facilities would require frequent revisions or reopenings of title V permits to incorporate newly promulgated or applicable R&D MACT standards.

Three commenters (II-D-41, II-D-46, and II-D-52) referred to the sensitive nature of data generated by the R&D process. The commenters felt that MACT floor analyses would be particularly burdensome since information is not generally available in the public domain. According to the commenters, the sources would have difficulties in extracting information necessary to perform the MACT floor analysis from their competitors. The commenters stated that the sources would not be able to meet the requirements to conduct an initial MACT floor analysis.

A commenter (II-D-54) recommended that the EPA consider building on the existing recordkeeping system rather than creating a new one. The commenter stated that R&D lab records must be precise and complete to ensure good experimental and R&D results.

A commenter (II-D-62) stated that non-commercial facilities were already subject to a number of regulatory requirements under the CAA. The commenter referred to current requirements, including their permit (which was required because of their NO_x and SO₂ emissions), the NESHAP for Department of Energy (DOE) facilities, and Federal and State rules governing volatile organic compound (VOC) emissions. The commenter remarked that they were subject to the VOC rules as a result of being located in the Chicago severe ozone nonattainment area.

Two commenters (II-D-76 and II-D-77) were concerned that the burdens associated with an R&D MACT could divert resources from educational purposes. One commenter (II-D-76) presented the following as anticipated burdens: (1) the need to collect data concerning HAP emissions from R&D activities; (2) the annual expenses in time, personnel, and capital necessary to quantify and monitor R&D emissions; (3) the possibility that recordkeeping burdens associated with MACT compliance could hinder research activities; and (4) the difficulty in tracking HAP emissions due to the continually changing academic activities and the minimal amounts of chemicals used.

A commenter (II-D-102) stated that Congress and the EPA have recognized that the variability in use and needs R&D facilities experience make it difficult as well as costly and cumbersome to calculate PTE and impose control requirements on R&D facilities. According to the commenter, any MACT standard, whether it is a part of a MACT standard for an industry category or an independent MACT, would be more burdensome for R&D facilities than other regulated facilities. The commenter felt that this would be inequitable.

3.5 Financial Burden Is Not Offset by Environmental Benefits (Cost to Benefit Ratio Is High)

Comment: Fifty-five commenters (II-D-03, II-D-07, II-D-08, II-D-10, II-D-14, II-D-16, II-D-20, II-D-22, II-D-26, II-D-27, II-D-28, II-D-30, II-D-31, II-D-37, II-D-38, II-D-39, II-D-43, II-D-45, II-D-46, II-D-47, II-D-48, II-D-49, II-D-51, II-D-52, II-D-53, II-D-54, II-D-55, II-D-56, II-D-57, II-D-60, II-D-61, II-D-62, II-D-66, II-D-67, II-D-73, II-D-74, II-D-75, II-D-77, II-D-79, II-D-81, II-D-82, II-D-86, II-D-87, II-D-88, II-D-89, II-D-90, II-D-91, II-D-92, II-D-94, II-D-98, II-D-99, II-D-100,

II-D-101, II-D-102, and II-D-104) stated that the financial burden resulting from regulating R&D operations would not be offset by the benefit to the environment.

A commenter (II-D-07) stated that treating exhaust streams with few parts per million of a volatile material is not cost effective.

A commenter (II-D-10) estimated that it would cost over \$20 million per ton of HAP reduced. According to the commenter, this estimate was based on past experience with incinerators, and a worst case emission estimate. The commenter pointed out that the control technology would need to be sized based on PTE, even though actual emissions are much less.

Four commenters (II-D-14, II-D-79, II-D-89, and II-D-94) requested that the EPA review the impact and burden the CAA has placed upon colleges and universities and determine the benefit toward the reduction of air emissions.

Two commenters (II-D-26 and II-D-102) stated that the Executive Order 12866 and the Small Business Regulatory Flexibility Act (SBRFA) must be considered by the EPA before listing R&D source categories, to determine cost impacts and benefits. One commenter (II-D-26) pointed out that many R&D operations are small businesses, subject to special consideration. The commenter stated that delisting a source category of so many facilities would not be possible since it would have to be demonstrated that there is less than one in a million cancer risk for every facility.

A commenter (II-D-28) provided cost estimates for control of HAP from their facilities. The commenter estimated capital costs of \$333 million with an annual cost of \$78 million for the thermal oxidizers. The commenter pointed out that thermal oxidizers generate criteria pollutants. The commenter felt that it does not make sense to create emissions while trying to reduce

emissions. The commenter estimated capital costs of \$12 million with an annual cost of \$42 million for carbon adsorption filters. The commenter stated that hazardous waste would be generated when the spent filters are changed.

Two commenters (II-D-30 and II-D-52) stated that HAP emissions from R&D facilities are low. The commenters felt that any R&D facilities with unacceptable emissions would be subject to State controls that would ensure sufficient protection of the public health. The commenters were concerned about the additional costs of regulating these sources under § 112 with little additional benefit.

A commenter (II-D-31) discussed a facility survey conducted where emissions were estimated from 55 randomly selected laboratories. The commenter stated that the survey involved less than 10 percent of the laboratories and took over four months to complete.

A commenter (II-D-37) was concerned that a MACT standard for R&D sources would result in fewer pollution prevention initiatives during process development, due to increased administrative costs and regulatory requirements. The commenter stated that such a process would continue to generate additional releases and waste. The commenter also stated that increased administrative requirements associated with any MACT rule would result in an increase in costs of bringing new drugs to market. According to the commenter, increases in costs to bring new drugs to the market would translate to fewer drugs entering development.

Three commenters (II-D-27, II-D-38, and II-D-86) were concerned that add-on controls would increase emissions of criteria pollutants. Two commenters (II-D-27 and II-D-38) stated that the secondary pollution could be generated at levels that offset the HAP reductions. One commenter (II-D-38) provided an

example of a thermal oxidizer that controls approximately 3.7 lb/yr of VOC. According to the commenter, this would not be cost-effective, considering the cost of an oxidizer. The commenter further stated that the oxidizer actually emitted 4.6 lb/yr of criteria pollutants (PM₁₀, SO_x, NO_x, and CO), which is more than it controlled. One commenter (II-D-86) indicated that any controls sized for potential emissions would be oversized for R&D operations. The commenter stated that these units would cost millions of dollars and would generate secondary impacts such as increased criteria pollutant emissions from a combustion device, or increased solid waste from spent carbon filters.

A commenter (II-D-46) estimated emissions from one facility's R&D operations to be about 6 tons per year (tpy). The commenter stated that regulation of these emissions would be complex and time consuming while providing little to no environmental benefit.

A commenter (II-D-51) stated that coming up with emissions estimates was labor intensive. The commenter also stated that one of their members operates a facility in which a significant amount of one employee's time is spent doing emissions calculations for 2 of their 3 pilot plants. The commenter further stated that the emissions estimates are not necessarily meaningful. The commenter also provided an example in which an emissions estimate study cost over \$26,000 to estimate average emissions of only 0.1 lb/day of VOC.

Four commenters (II-D-57, II-D-79, II-D-101, and II-D-104) stated that the environmental and public health benefits must be weighed for the implementation of the Operating Permit program against the listing and regulation of R&D facilities. Two commenters (II-D-57 and II-D-79) felt that regulation would cause a delay in issuing operating permits and would cause an increase

in the use of Federal, State, and facility resources required to amend regulations and permit applications. The commenter also felt that the EPA should assume the responsibility for gathering emissions-related data to determine whether R&D facilities constitute a human health or environmental hazard. The commenter would like to see that the finite resources at the Federal, State, and facility level are conserved. Two commenters (II-D-101 and II-D-104) referred to the § 112(g) requirements regarding MACT for new or modified major sources of HAP. The commenters were concerned that if R&D facilities were regulated, implementing § 112(g) would be complex and highly resource intensive with no environmental benefit.

A commenter (II-D-66) stated that listing R&D facilities would be costly to these facilities. The commenter felt that already scarce resources would be diverted from programs that show demonstrable environmental benefits. The commenter suggested that the EPA make a determination of a danger to public health or the environment before engaging in the program.

A commenter (II-D-73) cited the control of insignificant HAP emissions from R&D activities as providing negligible environmental benefits. The commenter also described the administrative documentation requirements as being time-consuming and labor-intensive.

Four commenters (II-D-74, II-D-77, II-D-79, and II-D-100) were concerned that the added cost for administration of requirements would detract from research funding with little environmental benefit.

A commenter (II-D-91) stated that the nature and extent of emissions from R&D facilities make estimation questionable and control expensive.

A commenter (II-D-99) stated that collecting chemical use data from about 1,000 researchers and computing an institutional

total would take thousands of hours of staff time. The commenter felt that resources would be diverted from programs that improve human health.

A commenter (II-D-102) felt that regulating R&D facilities is counter to EPA's new Integrated Air Toxics Strategy. According to the commenter, the Draft Strategy is designed to help the Agency focus its efforts (and limited resources) on those areas in which regulation can have the greatest impact on human health and the environment. The commenter felt that R&D facilities do not present the type of threats the Draft Strategy has been designed to abate. The commenter further stated that R&D facilities easily meet the goal of the Draft Strategy, which is that, by the year 2010, no HAP emission source poses a cancer risk greater than one in ten thousand to the exposed population. The commenter recommended that the EPA not expend its limited resources on a regulation for facilities that already meet the goals that the agency hopes it will meet by the year 2010.

4.0 COMMENTS ON R&D LISTING OPTIONS

4.1 Comments Encouraging Establishment of One, Not Multiple, R&D Rule

Comment: Seven commenters (II-D-09, II-D-27, II-D-32, II-D-38, II-D-44, II-D-52, and II-D-60) endorsed on establishing only one rule for R&D facilities, rather than several individual rules. One commenter (II-D-09) stated that making different standards for different types of industries would be more confusing and less effective. Similarly, one commenter (II-D-32) stated that there is too much diversity in R&D operations to effectively separate them into multiple source categories. One commenter (II-D-38) favored establishment of one category because facilities that have to comply with the standards for several subcategories would be at a competitive disadvantage to facilities that have to comply with only one subcategory standard. One commenter (II-D-44) observed that at some facilities it would be nearly impossible to separate laboratories used for research, teaching, testing, or medical experimentation for the purpose of regulatory subcategorization. Two commenters (II-D-52 and II-D-60) stated that subcategorization may require revisions to title V permits as new subcategories are promulgated or become applicable. The commenters found this to be excessively burdensome.

4.2 Comments Encouraging the Establishment of Multiple, Not One, R&D Rules

Comment: Twelve commenters (II-D-09, II-D-13, II-D-47, II-D-50, II-D-52, II-D-60, II-D-61, II-D-62, II-D-75, II-D-80, II-D-83, and II-D-88) provided comments on establishing multiple rules

for R&D facilities, rather than one rule covering all facilities. Four commenters (II-D-13, II-D-47, II-D-60, and II-D-80) observed that the wide diversity of materials, processes/operations, sources, emissions, controls, and products associated with R&D operations would make treating R&D as one source category inappropriate. One commenter (II-D-88) stated that the same problems with diversity within R&D would also be true within subcategories of R&D. Two industrial commenters (II-D-50 and II-D-62) preferred that educational/non-commercial sources be treated separately from industrial sources. One commenter (II-D-62) remarked that there should be differentiation within the source categories based on emissions. Similarly, one commenter (II-D-09), a State agency, remarked that there should be consideration of both major sources and large area sources, and further differentiation could be based on the varying toxicity levels of HAP. One commenter (II-D-75) stated that the EPA should consider establishing R&D standards on an industry-by-industry basis. One commenter (II-D-80) stated that one all-inclusive category would be unnecessarily restrictive of some types of R&D operations. One commenter (II-D-83) commented that several categories would be more equitable and more protective of human health given the wide differences in emissions from R&D facilities.

4.3 Comments Encouraging the Regulation of R&D Facilities under NESHAP Applying to Corresponding Manufacturing Facilities

Comment: Two commenters (II-D-04 and II-D-80) preferred the regulation of R&D facilities under the NESHAPs applying to corresponding manufacturing facilities. One commenter (II-D-80) stated that this method would recognize the inherent characteristics of a particular R&D operation.

4.4 Comments on Not Aggregating Manufacturing and R&D Emissions for Major Source Determination (Major R&D Facilities Should Be Major in and of Themselves)

Comment: Twenty-two commenters (II-D-04, II-D-15, II-D-16, II-D-20, II-D-21, II-D-26, II-D-32, II-D-34, II-D-35, II-D-39, II-D-40, II-D-41, II-D-50, II-D-51, II-D-52, II-D-55, II-D-56, II-D-60, II-D-65, II-D-71, II-D-86, and II-D-95) believed that manufacturing and R&D emissions should not be aggregated for major source determination. Eight commenters (II-D-04, II-D-15, II-D-20, II-D-26, II-D-35, II-D-51, II-D-86, and II-D-95) explicitly stated that major R&D sources should be major sources of emissions in and of themselves. One commenter (II-D-26) stated that R&D operations are often managed separately from the manufacturing operations. One commenter (II-D-35) stated that considering R&D separately would be more equitable and manageable. One commenter (II-D-41) stated that aggregating emissions would penalize collocated R&D operations, when they are collocated simply for convenience. One commenter (II-D-50), a university commenter, encouraged keeping R&D regulation separate from collocated powerplants. Similarly, one commenter (II-D-95) encouraged exclusion of heating equipment and backup power systems in the determination of major sources.

A number of the commenters also cited legal arguments for not aggregating R&D sources with other collocated sources. Specifically, ten commenters (II-D-15, II-D-16, II-D-26, II-D-32, II-D-34, II-D-35, II-D-39, II-D-52, II-D-60, and II-D-86) stated that the special treatment language of CAA § 112(c)(7) implies that major source determination for R&D operations should be handled independently of other major sources at the same location. In more detail, five commenters (II-D-16, II-D-32, II-D-51, II-D-52, and II-D-60) cited the case of *National Mining*

Association v. EPA, which allows the EPA to consider collocated sources in major source determinations. The commenters do not believe that this precedent should extend to R&D operations because of the special treatment described in CAA § 112(c)(7). One commenter (II-D-36) cited the publicly owned treatment works (POTW) presumptive MACT (P-MACT) as an example of the EPA using the limited applicability approach, as only sources that are major in and of themselves were addressed. Additionally, nine commenters (II-D-16, II-D-32, II-D-35, II-D-41, II-D-52, II-D-55, II-D-56, II-D-60, and II-D-86) discussed the language of the Part 70 operating permits (60 FR 45530, 45558; August 31, 1995), which states that R&D operations should be considered separately when making a major source determination. One commenter (II-D-65) cited the Operating Permit Program Final Rule (July 21, 1992) with a similar discussion of treating R&D separately. Two commenters (II-D-16 and II-D-21) cited CAA § 112(c)(1) in finding that the EPA has not met the requirements of this section until demonstrating the existence of R&D facilities that are in and of themselves major sources. One commenter (II-D-16) stated that the EPA should exercise the authority to distinguish among classes, types and sizes [under CAA §112(d)(1)] to apply MACT to only those facilities that are major sources in and of themselves. Two commenters (II-D-52 and II-D-60) cited 59 FR 12408-09 (March 16, 1994) in arguing that R&D major sources must be major sources in and of themselves. One commenter (II-D-40) cited the NESHAP for the Synthetic Organic Manufacturing Industry (40 CFR Subparts F, G, H) because it exempts R&D facilities that are collocated with the chemical manufacturing unit. The commenter stated that this exemption is evidence that the EPA has acknowledged the congressional directive that R&D source be treated equitably and separately.

5.0 COMMENTS ON R&D REGULATIONS

5.1 *De Minimis* Levels

Comment: Eight commenters (II-D-01, II-D-09, II-D-20, II-D-32, II-D-52, II-D-54, II-D-62, and II-D-87) addressed whether the EPA should include *de minimis* cutoffs in any R&D regulations developed. Two commenters (II-D-32 and II-D-52) opposed the EPA's establishing a definition of the term *de minimis* as used in the R&D definition. The commenters felt that establishing a criteria for the definition of the term *de minimis* would be inappropriate. The commenters also felt that the criteria would not adequately account for the significant variations among R&D facilities. The commenter stated that any MACT standard for R&D facilities should preserve flexibility to interpret the meaning of *de minimis* on an industry or source specific basis.

A commenter (II-D-52) felt that the infeasibility of defining the term *de minimis* was illustrated in the EPA's past efforts to limit the scope of R&D exemption under § 5(h)(3) of the Toxic Substances Control Act (TSCA). In its Final Rule implementing revisions of the TSCA premanufacture notice regulations, the EPA stated that it was "retaining the qualitative approach to defining 'small quantities' solely for research and development" on the basis that "there is no single quantitative limit that would allow for the variety of research taking place in the chemical industry...." [51 FR 15096, 15097 (April 22, 1986)]. The commenter stated that, like the term "small quantities" as referenced in the R&D exemption under TSCA § 5(h)(3), the term *de minimis*, as used in the R&D definition under § 112 (c)(7) of the CAA, does not lend itself to a quantitative definition.

The commenter also felt that it would be inappropriate to limit the meaning of the term *de minimis* through specific dollars or percentages. The commenter stated that in previous MACT standards, the EPA established applicability cutoffs, such that certain sources are exempt from the standard or subject to only minimal requirements. The commenter felt that using these cutoffs would be difficult to apply in the R&D context.

On the other hand, six commenters (II-D-01, II-D-09, II-D-20, II-D-54, II-D-62, and II-D-87) supported the EPA's establishing a *de minimis* cutoff. The commenters suggested specific *de minimis* levels be set. One commenter (II-D-54) stated that the EPA should establish a *de minimis* threshold that would limit the application of any future regulation only to circumstances truly warranting regulation. One commenter (II-D-01) stated that R&D facilities with calculated or demonstrated HAP emissions less than 1 tpy in aggregate, and 2 tpy in combination should be exempt from generally available control technology (GACT) for contiguous area sources. According to the commenter, R&D facilities with small scale operations need an exemption. The exemption is necessary to assure products can be reasonably formulated and brought to market. The commenter felt that it would be economically beneficial for R&D facilities engaged in pilot operations to have a 1 tpy (aggregate) and a 2 tpy (combination) exemption from area source GACT regulations. One commenter (II-D-62) stated that the EPA should set a high threshold level for regulation of emissions to avoid having to address the large variety of low level emissions from R&D facilities. The commenter felt that a realistic MACT could be developed that would apply to the few cases where higher emissions occur.

A commenter (II-D-09) recommended a large area source cutoff be established. For this cutoff, the commenter suggested one-

half of the major source thresholds (i.e., 5 tpy for any single HAP and 12.5 tpy for any combination of HAP). The commenter stated that any source below the large area source cutoff should be exempt from the regulation.

A commenter (II-D-20) stated that R&D laboratories should not be required to track emissions of HAP that are used in the laboratory below a *de minimis* threshold. The commenter suggested a *de minimis* material usage threshold of 1,000 lb/yr. The commenter felt that requiring tracking of usage below the *de minimis* thresholds would impose impossibly burdensome recordkeeping requirements on laboratories that use several different HAP compounds in small quantities.

A commenter (II-D-87) requested that the EPA consider a *de minimis* exemption to the NESHAP for R&D facilities that generate less than 10,000 lb/yr of emissions.

Comment: A commenter (II-D-03) stated that the only acceptable control would be the allowance for filing a one-time exemption as a *de minimis* source, if necessary.

Comment: A commenter (II-D-07) recommended specific equipment be exempted from the R&D regulations. The commenter suggested that "distributed equipment" be exempted from any PTE calculation or deemed "insignificant." The commenter described "distributed equipment" as being a large number of exhaust system hoods serving a low actual emission rate. The commenter also recommended that the EPA define building ventilation including laboratory hoods as *de minimis* or insignificant. The commenter stated that general building ventilation practices should not be included as emissions units. The commenter also suggested defining these sources so their output is not part of the PTE

calculations. The commenter stated that they support the previous submissions which suggest all laboratory operations (e.g., R&D, Quality, Technical Services, etc.) deserve the same exemption.

Comment: A commenter (II-D-07) suggested that the EPA accept a one time mass balance to permanently exempt the source from any title V or CAAA obligation. This includes having to prove that the source needs to be excluded (e.g., synthetic minor). The commenter stated that if the source's actual emissions are well below 10 tpy for a single HAP, the facility should be required to re-certify their *de minimis* status only if there is a major change in the facility's operations. The commenter felt that this exemption would relieve the difficulty of doing any significant activity under limiting conditions.

Comment: A commenter (II-D-11) suggested the development of a preliminary screening methodology for facilities to use to determine if they meet the major source emission thresholds. The commenter felt that a screening tool would give facilities a good understanding of their potential to be considered major sources of HAP. The commenter stated that the screen could involve an inventory of HAP along with an evaluation of the likelihood of exceeding emission thresholds. If the results from the cursory review indicate a potential for major source classification, the facility can then quantify emissions according to established procedures.

According to the commenter, a formal screening tool would provide R&D facilities and regulators with information on emissions and documentation that a major source evaluation has occurred. The commenter mentioned three additional functions for this screening tool: (1) it could be easily updated as

operations or chemical use changes within the R&D operations; (2) it would minimize the regulatory burden on small businesses and exempt operations by providing quick applicability determinations; and (3) it will provide information on the commonalities in HAP use and handling in R&D environments.

Comment: A commenter (II-D-15) suggested that the EPA consider determining applicability by setting a minimum capacity in order for the facility to become subject to the source category requirements.

Comment: Nine commenters (II-D-28, II-D-44, II-D-49, II-D-56, II-D-57, II-D-66, II-D-79, II-D-98, and II-D-104) recommended that R&D facilities be granted a *de minimis* exemption from the statutory requirement to calculate PTE. One commenter (II-D-44) stated that they have no known reasonable method of making meaningful PTE estimates for HAP. One commenter (II-D-56) stated that R&D facilities, educational laboratories, and medical-health facilities should qualify for the *de minimis* exemption. One commenter (II-D-98) stated that laboratories should be exempted from the requirements to calculate PTE, whether or not the laboratory is associated with another facility. One commenter (II-D-104) requested that the EPA provide a standard method to calculate PTE for non-exempt facilities.

Comment: Four commenters (II-D-35, II-D-43, II-D-52, and II-D-83) were concerned about the definition of the term *de minimis*. One commenter (II-D-35) stated that the definition of what constitutes *de minimis* will be essential to clarify how the rule affects R&D operations that are collocated with production operations. One commenter (II-D-52) stated that it would be extremely difficult to establish a precise meaning of the term

"*de minimis*," as it is used in the R&D definition. The commenter feels that this is because the definition of "R&D facility" must be sufficiently generic to cover all industries. The commenter referred to the § 112(g), Part 70, and HON definitions, which include *de minimis* exemptions. One commenter (II-D-83) suggested that the EPA elaborate on and provide guidance on the interpretation of the term *de minimis*, in regard to the manufacture of products for commercial sale. The commenter stated that they provide substances in small quantities to others for research or medical use, often for a fee.

Comment: A commenter (II-D-64) requested that if the regulatory threshold hinges upon PTE, the EPA create a *de minimis* exemption for facilities that can demonstrate actual emissions below the threshold.

Comment: A commenter (II-D-66) suggested that improved communication between the EPA and universities would assist the EPA in determining an appropriate *de minimis* exception to the listing requirements.

Comment: A commenter (II-D-86) felt that the EPA would be justified in determining that pharmaceutical R&D activities are *de minimis* and do not need to be regulated. The commenter suggested that pharmaceutical R&D operations and facilities should be explicitly excluded.

Comment: A commenter (II-D-102) requested that R&D facilities be exempted from the regulations. The commenter stated that the EPA has the power to exclude *de minimis* activities from regulation. The commenter referred to the

Aerospace MACT, where the EPA chose not to regulate specific operations because HAP emissions were so small, additional control would be difficult, and the EPA had little data on the subject.

5.2 Exemptions

Comment: A commenter (II-D-08) recommended that the EPA exempt combustion research units from the proposed source category for R&D facilities. The commenter stated that this exemption should include new, existing, modified, or reconstructed devices that are used exclusively for combustion R&D, as well as the period of time that non-research devices are used in research efforts. The commenter stated that applying technology-based performance standards to combustion research boilers conflict with the purpose of conducting combustion research. In support of the recommended exemption, the commenter referred to the new source performance standards (NSPS) for new, modified, and reconstructed small industrial-commercial-institutional steam generating units (40 CFR part 60, subpart Dc), which excludes such research units. The commenter also referred to subpart Dc, which excluded from regulation those steam generating units, which otherwise meet the applicability requirements, during periods of combustion research. Any temporary change to an existing steam generating unit for the purpose of conducting combustion research is not considered a modification under § 60.14. According to the commenter, the definition of "combustion research" in 40 CFR 60.14c is appropriate and workable. The commenter suggested using the same definition of combustion research for any future MACT for R&D facilities.

The commenter stated that the reasons for excluding combustion research from the NSPS also warrant excluding these units from the R&D MACT. According to the commenter, combustion research provides the basis for development of MACT for regulating combustion emissions. The commenter also stated that the limited nature of operations (i.e., less than 5 percent of the time) is further reason to exempt these units.

Comment: Two commenters (II-D-16 and II-D-32) referred to § 112(d)(1) which gives the EPA the authority to "distinguish among classes, types, and sizes within a category or subcategory in establishing such standards...." The commenters stated that previous MACT rulemakings indicate that the EPA relies on § 112(d)(1) to establish applicability cut-offs. According to the commenters, under these previous MACT, R&D facilities with certain characteristics would be either exempted from the standards or subject to only minimal requirements. The commenters recommended the Agency follow a similar approach in any R&D MACT.

Comment: Two commenters (II-D-17 and II-D-24) requested exemptions for specific SIC codes. One commenter (II-D-17) recommended that all facilities with the primary SIC 8221 should be exempted from the regulation. One commenter (II-D-24) requested that R&D facilities that fall under SIC 2252 be excluded from consideration for this rule.

Comment: A commenter (II-D-27) suggested that R&D facilities not be listed separately under § 112(c) but to continue to be exempted under each NESHAP. According to the commenter, under § 112(c)(7), the EPA is not required to establish a separate source category for research or laboratory

facilities. Instead, the commenter stated that the EPA must determine if such an approach is necessary to ensure equitable treatment for R&D facilities. The commenter felt that specifically exempting R&D operations from individual MACT standard may "strike the right balance" between the goals of § 112 of the Act and the specific goal of § 112(c)(7) to ensure just and fair treatment of R&D facilities.

The commenter also referred to the § 112(g) rulemaking. The commenter stated that § 112(g) states that MACT requirements must be met for new constructed and reconstructed major sources, but not modifications of existing sources. The commenter felt that controlling R&D facilities under a MACT standard may be as problematic as regulating modifications to existing sources under § 112(g) of the Act.

The commenter felt that exempting R&D operations from each NESHAP appeared to be within the EPA's regulatory discretion. The commenter stated that the EPA routinely exercises this discretion to define categories and subcategories and the "affected sources" subject to every NESHAP. The commenter referred to the HON and the NESHAP for Magnetic Tape Manufacturing Operations, in which the EPA used its regulatory discretion to establish exemptions from specific source NESHAP, when the benefits of regulation do not overcome the burdens of regulation.

Comment: Two commenters (II-D-28 and II-D-79) felt that emissions from academic activities should be exempt from title III rules, because academic sources are a much smaller scale and more sporadic than industrial emission sources (including industrial R&D facilities).

Comment: Two commenters (II-D-38 and II-D-67) recommended that the EPA add a standard R&D exemption to the 40 CFR part 63 general provisions. According to the commenters, adding an exemption to the general provisions will ensure R&D is exempt from all existing and future industry-specific part 63 rules. One commenter (II-D-38) stated that, to date, the EPA has included R&D exemptions in individual NESHAP on a case-by-case basis. The commenter noted that although most of the proposed NESHAPs include some form of R&D exemption, some existing NESHAPs do not contain exemptions (e.g., shipbuilding and repair NESHAP, dry cleaning facility NESHAP, and halogenated solvent cleaning NESHAP).

Comment: A commenter (II-D-38) felt that there are slight inconsistencies among R&D exemptions. The commenter provided an examples of some NESHAP that state that R&D activities are exempt regardless of whether they are collocated with production facilities. The examples include: petroleum refinery NESHAP, organic hazardous air pollutants from equipment leaks, the preamble of the final printing and publishing industry NESHAP. The commenter also cited examples of NESHAP that are silent on the location issue. These examples include the ethylene oxide NESHAP, and the epoxy resins production NESHAP.

Comment: Two commenters (II-D-52 and II-D-60) stated that the EPA would need to exempt from all other MACT standards, a source that is already covered by a MACT for a particular R&D category or subcategory.

Comment: Two commenters (II-D-57 and II-D-79) recommended that the EPA consider exempting from the R&D source category, the

laboratory hood systems referenced in the Massachusetts Operating Permit program regulations (310 CMR 7.00: Appendix C(5)(I)18).

Comment: A commenter (II-D-60) stated that the Agency should focus its efforts on drawing brighter lines in underlying MACT standards to ensure that any R&D exemptions are sufficiently narrow to minimize abuse.

Comment: A commenter (II-D-80) requested that the R&D source category specifically exempt academic R&D activities.

5.3 The Rule Should Take the Form of a Work Practice or Performance-based Standard

Comment: Eighteen commenters (II-D-16, II-D-27, II-D-28, II-D-32, II-D-38, II-D-41, II-D-44, II-D-49, II-D-53, II-D-54, II-D-57, II-D-64, II-D-65, II-D-66, II-D-76, II-D-79, II-D-96, and II-D-98) recommended that, to regulate R&D facilities, the EPA rely on a performance-based standard rather than numerical emission standards or add-on control emissions standards. Five commenters (II-D-38, II-D-44, II-D-53, II-D-66, and II-D-76) felt that a performance-based standard would be a practical and effective method of reducing laboratory air emissions. Three commenters (II-D-44, II-D-49, and II-D-66) stated that performance-based standards have proven to be used successfully to regulate laboratory activities. Four commenters (II-D-28, II-D-53, II-D-57, and II-D-79) recommended that waste minimization and pollution prevention best management practices be part of the standard. Two commenters (II-D-28 and II-D-79) recommended that the performance-based standard be applicable to both area and major sources.

Seven commenters (II-D-16, II-D-27, II-D-32, II-D-49, II-D-64, II-D-66, and II-D-76) referred to § 112(h) of the Act and one commenter (II-D-64) referred to § 112(d)(5). Under the appropriate circumstances, these regulations authorize the EPA to develop work practice, operational, and alternative standards. The commenters felt that, due to the variability of operations at R&D facilities, developing emission standards for R&D facilities would not be feasible. Therefore, the commenters recommended developing performance-based MACT standards for R&D facilities under § 112(h).

Four commenters (II-D-16, II-D-32, II-D-64, and II-D-76) felt that performance-based standards would preserve operational flexibility for R&D facilities. Two commenters (II-D-16 and II-D-32) felt that operational flexibility could be maintained without sacrificing environmental protection. Two commenters (II-D-64 and II-D-76) felt that performance-based standards would reduce emissions from laboratories and still provide universities the flexibility to fulfill their educational objectives.

Three commenters (II-D-28, II-D-38, and II-D-79) stated that precedents had been set regarding performance-based standards for regulations. Two commenters (II-D-28 and II-D-79) referred to a case where pollution prevention was set as a control technology. The commenters pointed to the July 23, 1996 Federal Register (Vol. 61, Number 142, pages 38248-38344), where the EPA stated it believes regulations allow pollution prevention as RACT/(lowest achievable emission rate (LAER)). Another commenter (II-D-38) referred to the use of OSHA standards in EPA's Risk Management Program (RMP) regulations. In the RMP, the EPA incorporates OSHA's process safety management program requirements (40 CFR part 68).

A commenter (II-D-49) stated that considering the burden of permits, a performance-based standard would be effective for the

EPA and facilities. The commenter felt that such a standard would be protective of public health and the environment.

Two commenters (II-D-28 and II-D-79) requested that R&D be treated consistently among titles I, III, IV, and V of the CAA. The commenters also referred to a letter submitted to the EPA by the American Chemical Society (ACS) (April 9, 1991) in which the ACS indicated that they would support standards for an approach that relies on emission control work practices, following the OSHA 'Laboratory Standard.' The commenters also referred to a letter submitted to the EPA by the National Research Council (NRC) (July 7, 1997) in which the NRC refers to its publication Prudent Practices in the Laboratory: Handling and Disposal of Chemicals. The commenters concurred with the ACS and NRC recommendations for performance-based standards. The commenters stated that laboratories are already required by OSHA regulations to implement a chemical hygiene program. The commenters felt that, therefore, the performance-based system would be easy to implement. The commenters also felt that this system would be readily accepted by industry and academic institutions and would be the most cost effective method of protecting human health and the environment.

A commenter (II-D-96) referred to the EPA's statement in the ANPR that subjecting R&D facilities to a standard designed for commercial production process would be inequitable and inappropriate. The commenter stated that the most equitable standard would be a performance-based standard. The commenter indicated that such a standard would require the input of all stakeholders. The commenter felt that an approach that would require permits would restrict research capabilities and adversely affect R&D operations.

A commenter (II-D-27) requested that all lab and bench-scale R&D operations be eligible for exemptions from any broad work

practice of operational standard. The commenter indicated that such exemptions would be consistent with exemptions provided in other NESHAP. The commenter also felt that such exemptions would be justified given the low levels of emissions from these operations.

Two commenters (II-D-53 and II-D-54) recommended that any performance standards take into account the professional expertise within the laboratory. One commenter (II-D-54) stated that R&D facilities are closely supervised by technically trained personnel. The commenter also indicated that these facilities are operated according to long established "good laboratory practices." The commenter felt that good laboratory practices should be the core of regulations for R&D facilities.

Three commenters (II-D-57, II-D-76, and II-D-79) suggested that any performance standards be based on an operator training and awareness program. Two commenters (II-D-57 and II-D-79) recommended that the training and awareness program include chemical purchasing, use, handling, and disposal procedures.

5.4 Base Regulation on Actual, not Potential, Emissions

Comment: Nine commenters (II-D-07, II-D-20, II-D-22, II-D-46, II-D-52, II-D-60, II-D-66, II-D-75, and II-D-79) recommended that the regulation be based on actual emissions rather than potential emissions. One commenter (II-D-07) felt that R&D facilities should be exempted from PTE calculations. The commenter indicated that it would be futile to attempt to predict the infinite range of operations that could occur under a laboratory hood/exhaust system. One commenter (II-D-46) stated that calculating PTE for R&D facilities was impractical.

Two commenters (II-D-22 and II-D-79) were concerned about the EPA's proposed method of using PTE for determining major

source status for R&D laboratories. The commenters felt that too many small sources would be incorrectly categorized as major sources.

A commenter (II-D-52) stated that emissions based on year-round operation bear no relationship to normal operations of R&D facilities. The commenter also stated that these emission estimates are not related to the "PTE" of these facilities. The commenter based their conclusion on a review of actual emissions data from several of their plants.

A commenter (II-D-60) stated that estimating emissions based on year-round operation would be unreasonable. The commenter also stated that methodology would have no relationship between the facility's PTE and normal operation.

A commenter (II-D-66) suggested the EPA reconsider the using PTE to designate source categories. The commenter stated that PTE calculations are unacceptably impractical and burdensome.

A commenter (II-D-75) based their recommendation to use actual rather than PTE estimates on the Agency's mandate to "assure equitable treatment of such facilities," and the regulatory requirement that PTE be based on a facility's physical and operational design.

Comment: A commenter (II-D-87) suggested that the *de minimis* exemptions be based on actual stack monitoring or a possession threshold below which there would be no expectation of exceeding 10,000 lb/yr of emissions. The commenter recommended that the compliance method be determined by the generator.

5.5 Discussion on Definition of R&D, Including Statutory Definition

The ANPR refers to the definition of research or laboratory facilities included in § 112(c)(7) which reads:

"...any stationary source whose primary purpose is to conduct research and development into new processes and products, where such source is operated under the close supervision of technically trained personnel and is not engaged in the manufacture of products for commercial sale in commerce, except in a *de minimis* manner."

Several comments were received concerning this definition.

Comment: A commenter (II-D-07) felt that the definition of R&D should include the following: "...activity that is under the control of a few qualified persons with no or only *de minimis* commercial applications..." The commenter felt that by including this statement within the definition, operations that could be larger or commercial in nature would be eliminated.

Comment: Six commenters (II-D-16, II-D-32, II-D-38, II-D-52, II-D-69, and II-D-85) stated that R&D operations and laboratory facilities are not well defined in EPA's rules. The commenters felt that the EPA was not consistent in the definitions for R&D in various regulations promulgated under the CAA. The commenters pointed out that the definition of "research or laboratory facility" under § 112(c)(7), and the definition and usage of "research or laboratory activities" under § 112(g), and under the draft final Part 70 Revisions Package differ.

Two of the commenters (II-D-16 and II-D-32) stated that "R&D Facilities" should be defined to be consistent with the definition in § 112(c)(7) of the CAA. The commenters felt that this approach will serve to avoid conflict with the statute. The commenters also felt that inconsistency with other § 112 rulemaking will be avoided. The commenters pointed to the *Comment Response Document* for the Draft Final § 112(g) rule where the EPA explained that this approach was followed "in the interest of consistency with previous exclusions for research and development activities under other CAA programs and its

anticipated use in the title V program..." The commenters felt that to further promote these objectives, the EPA should adopt the same definition in any §112 R&D rulemaking process it elects to pursue.

A commenter (II-D-38) stated that if the EPA lists R&D, the EPA should add a standard exemption to the 40 CFR Part 63 general provisions to ensure consistency in the R&D definition for all Part 60 rules. The commenter recommended that the EPA replace OSHA's definition of "laboratory use" with the § 112(c) definition of "research and laboratory facility." The commenter stated that most R&D simulates some aspect of production, although on a small scale. The commenter felt that the § 112(c) definition stating that a research or laboratory facility "is not engaged in the manufacture of products for commercial sale in commerce, except in a *de minimis* manner," is much better. The commenter provided examples illustrating that the language in R&D definitions are inconsistent from NESHAP to NESHAP. The commenter mentioned that some NESHAPs exempt "research and development facilities", defined as "laboratory operations (40 CFR Part 63, §63.522); another exempts "research and laboratory equipment" (40 CFR Part 63, §63.820); and another exempts "research and development facilities" as "stationary sources" the primary purpose of which is to conduct research and development (40 CFR Part 63, §63.801).

A commenter (II-D-52) felt that the EPA would have difficulty developing a generic definition of the term "R&D facilities." The commenter also felt that a definition of the term "R&D facilities" would need to be developed. The commenter pointed out that several existing MACT standards include source category-specific definitions of "R&D facilities" (e.g., the HON, 40 CFR part 63, subpart F, section 63.101). The commenter felt that it is important to reconcile the R&D exemptions in the

existing MACT standards with any generic definition of R&D. According to the commenter, reconciling the definitions would ensure that no "regulatory gaps" would be created.

A commenter (II-D-69) questioned how the definition for the R&D source category differs from "research or laboratory facility" or "research or laboratory activities." The commenter requested that a standardized term and definition be used in all Clean Air Regulations.

A commenter (II-D-85) felt that a clear category definition is necessary to resolve the differences between "research," "laboratory," and "development" facilities. The commenter stated that a clear and unambiguous definition is critical prior to regulation of these activities. According to the commenter, this distinction is necessary due to the broad range of research, teaching and laboratory activities present at academic institutions.

Comment: Three commenters (II-D-20, II-D-22, and II-D-79) proposed that pilot plants that are separate from laboratory operations (i.e., larger than bench scale) should be specifically excluded from the laboratory source category. The commenters indicated that laboratories do not make products. The commenters stated that laboratories use small quantities of a variety of chemicals. According to one commenter (II-D-20), the recordkeeping burdens associated with calculating emissions from these facilities far outweigh any public benefit from control of their emissions. The commenter also stated that many facilities also have "pilot operations" that are associated with R&D laboratory activities, but should be considered scale-up facilities for commercial production. The commenter felt that pilot plants represent a clear point at which material has left the laboratory and is proceeding towards commercial production.

Two commenters (II-D-22 and II-D-79) recommended that the source category should only include those that have been identified as major sources.

Comment: A commenter (II-D-20) stated that the EPA should develop clear and objective tests to determine which activities fall within the definition of "research and development." The commenter indicated that R&D laboratories associated with manufacturing sites usually include substantial quality control and technical service activities in the same facility with activities which might be considered to be true research and development. The commenter mentioned that most of their laboratory activities are actually minor modifications of existing formulations for new customer applications, rather than activities that might be considered to be true research and development of new products. The commenter also felt that quality assurance/quality control (QA/QC), technical service, and product application activities should not fall within the definition of "research and development" under the standard.

Comment: A commenter (II-D-26) felt that to prevent confusion and to meet Congress' clear directive, only facilities that are primarily engaged in R&D should be included in this source category. The commenter stated that they have many laboratories associated with manufacturing, product quality, industrial hygiene, materials inspection, environmental testing, etc. The commenter remarked that these activities should be clearly identified as non-R&D facilities if the source category is listed.

Comment: Four commenters (II-D-28, II-D-29, II-D-79, and II-D-104) referred to the R&D definition as it applies to academic

activities. Two commenters (II-D-28 and II-D-79) suggested the following definition be adopted for academic activities to be excluded from regulation under title III and title V:

"Academic Activities means; teaching, research, study and laboratory activities conducted at elementary and secondary schools, colleges, universities and professional schools, providing academic or technical instruction, furnishing academic courses and granting academic degrees, certificates or diplomas."

One commenter (II-D-29) stated that academic institutions are not engaged in any production nor are they engaged in research in the new processes or products related to production, as defined in the Act. The commenter also stated that the research is "basic" science. One commenter (II-D-104) stated that at educational institutions, laboratories support R&D and non-R&D activities. The commenter requested that the EPA consider that "research" and "laboratories" are unique concepts. The commenter also remarked that research, teaching, medical, and testing laboratories are indistinguishable at academic institutions. The commenter requested that the EPA exempt research and laboratory facilities located at academic institutions from the R&D source category.

Comment: A commenter (II-D-35) stated that the definition of "R&D" must be clear as to the extent to which it includes testing and evaluation.

Comment: Ten commenters (II-D-23, II-D-44, II-D-45, II-D-56, II-D-57, II-D-59, II-D-70, II-D-79, II-D-95, and II-D-99) stated that research occurs in teaching, medical, and testing laboratories, often simultaneously, and that facilities cannot segregate ventilation systems and stacks according to these classifications. According to the commenters, therefore, separating these activities into different emission categories would not be feasible.

Comment: Three commenters (II-D-44, II-D-56, and II-D-59) mentioned the expanded definition for "research and development activities" proposed in the draft Part 70 regulations. According to the commenters, in the draft part 70 regulations the definition of § 112(c)(7) was expanded to include theoretical research, and research and development on new and existing processes and products for theoretical (basic) research. Two commenters (II-D-44 and II-D-56) indicated that they supported this expanded definition. One commenter (II-D-44) recommended that a separate category for R&D, if necessary, should include all laboratories (research, teaching, testing and medical laboratories).

Comment: Six commenters (II-D-45, II-D-57, II-D-66, II-D-70, II-D-79, and II-D-99) felt that there does not appear to be a definition of "R&D facility." According to one commenter (II-D-45), terms such as R&D, facility, laboratory, etc. are used without being clearly defined. Four commenters (II-D-57, II-D-66, II-D-70, and II-D-79) urged the EPA to clarify which types of sources are to be included and excluded from the "research and development" source category. Three commenters (II-D-57, II-D-66, and II-D-79) also requested clarification on how PTE should be calculated, and how these sources will be regulated. One commenter (II-D-99) stated that before any listing or regulation is developed, R&D must be defined.

Comment: Two commenters (II-D-52 and II-D-60) suggested that since reconciling all of the definitions of R&D would be difficult, the EPA should consider refraining from listing and regulating R&D facilities under § 112 until MACT standards for source categories listed under § 112(c)(1) and the draft final Part 70 Regulations Package are finalized and implemented.

In support of this suggestion, one commenter (II-D-60) pointed out that the Agency has proposed to address problems with regulating R&D sources by granting States significant discretion with respect to defining and regulating R&D facilities. The commenter pointed to the May 14, 1997 draft final Part 70 Revisions Package, in which the EPA proposed to address defining *de minimis* and calculating PTE by remaining silent and allowing States the flexibility to develop and implement State-specific definitions and methods.

Comment: A commenter (II-D-83) pointed to the § 112(c)(7) definition of "research and laboratory facility" and suggested that the EPA elaborate on and provide guidance on the interpretation of the term *de minimis*.

Comment: Two commenters (II-D-93 and II-D-103) felt that § 112 draws a distinction between R&D facilities associated with commercial processes and the chemistry, biology, and other laboratories at colleges and universities.

Comment: Two commenters (II-D-32 and II-D-97) pointed out that § 112(c)(7) refers to research and *laboratory* facilities and not research and *development* facilities. One of the commenters (II-D-32) felt that the lawmakers did not use the word "development" for a reason. The commenter also felt that the agency's broad consideration of all types of research and analytical laboratories was intended, partly because they realized a variety of activities in the private and public sector have the potential to cause some emissions of HAP. The other commenter (II-D-97) suggested that the focus of the EPA proposal should be consistent with § 112(c)(7) of the CAA.

Comment: A commenter (II-D-98) stated that laboratories should be defined and regulated in a similar manner under all titles of the CAA. The commenter recommended that the regulations should be established on a national (rather than state) level to avoid confusion within a highly mobile population.

5.6 Use Existing Laboratory Safety Regulations/Practices (OSHA, National Research Council)

Comment: Ten commenters (II-D-28, II-D-38, II-D-41, II-D-44, II-D-57, II-D-66, II-D-70, II-D-79, II-D-93, and II-D-103) suggested that the EPA use the Chemical Hygiene Plan in OSHA's Laboratory Standard as a model for a performance-based standard. Two commenters (II-D-41 and II-D-66) felt that OSHA had successfully utilized a performance-based standard approach in regulating laboratories. One commenter (II-D-41) felt that by following OSHA's approach, the burden on the regulated community would be minimized. One commenter (II-D-70) felt that using OSHA's regulations as a model would be consistent with congressional intent of granting special treatment to R&D facilities in recognition of the special nature and social value of laboratory activities.

A commenter (II-D-38) felt that the OSHA regulations recognize the unique nature of R&D. According to the commenter, these regulations do not impede innovation or the need to preserve confidentiality of business information, and are protective of health. The commenter stated that traditional forms of control do not "fit" when applied to R&D sources. The commenter pointed out that R&D facilities are already subject to OSHA's Chemical Hygiene Plan regulations. Therefore, the

commenter felt that these work practice standards would represent MACT floor for R&D facilities.

Comment: Two commenters (II-D-22 and II-D-79) stated that the EPA should focus its efforts on ways to implement best management practices at those facilities that meet the major source criteria. The commenters indicated that there are existing standards that might be readily adopted. The commenters felt that adoption of existing laboratory practices should result in the same or better control of emissions than implementation of traditional control requirements.

Comment: A commenter (II-D-53) referred to its report *Prudent Practices in the Laboratory: Handling and Disposal of Chemicals (Prudent Practices)*. The report was partially funded by the EPA. The commenter stated that the report was a revision of two widely used, earlier volumes that dealt with laboratory safety, public protection, and waste management. The revised report assessed the needs of all those who manage, handle and dispose of chemicals in the laboratory workplace. According to the commenter, *Prudent Practices* identifies areas of laboratory activity that need improvement. The report makes recommendations to laboratory workers, chemical suppliers, and regulators at all levels. One recommendation in the report is that federal, State, and local lawmakers and regulators strive for conformity and consistency in the regulations that affect laboratories. The commenter suggested that the EPA use the recommendations in *Prudent Practices* to develop a performance-based standard.

Comment: A commenter (II-D-65) suggested that the standards developed for major sources in an R&D facility focus on the

implementation of generally available control technologies to address emissions.

6.0 COMMENTS ON POTENTIAL TO EMIT ISSUES

6.1 R&D Operations Are Variable, Making it Difficult or Impossible to Determine Potential to Emit (PTE)

Comment: Fifty-three commenters (II-D-12, II-D-13, II-D-15, II-D-16, II-D-20, II-D-26, II-D-30, II-D-31, II-D-32, II-D-33, II-D-34, II-D-37, II-D-38, II-D-40, II-D-41, II-D-43, II-D-44, II-D-45, II-D-46, II-D-48, II-D-49, II-D-51, II-D-52, II-D-55, II-D-56, II-D-57, II-D-58, II-D-60, II-D-61, II-D-65, II-D-66, II-D-67, II-D-69, II-D-70, II-D-73, II-D-74, II-D-75, II-D-76, II-D-77, II-D-79, II-D-82, II-D-83, II-D-86, II-D-88, II-D-91, II-D-92, II-D-93, II-D-96, II-D-97, II-D-99, II-D-100, II-D-103, and II-D-104) commented how the variable, unpredictable, and dynamic nature of R&D activities will make it difficult or impossible to determine PTE.

Two commenters (II-D-12 and II-D-83) cited the legal definition of PTE (40 CFR § 63.2) as "the maximum capacity of a stationary source to emit a pollutant under its physical design." Eight commenters (II-D-13, II-D-20, II-D-31, II-D-33, II-D-38, II-D-41, II-D-69, and II-D-77) stated that this industrial/manufacturing PTE methodology is not well suited to R&D. Specifically, one commenter (II-D-69) believed that if the currently used PTE were applied to his facilities, a five-fold fluctuation from the actual emissions at any given time would not be unexpected. Three commenters (II-D-40, II-D-61, and II-D-67) expressed concern that PTE would designate R&D operations as major sources, when actual emissions are not nearly the at the levels of the PTE. Specifically, one commenter (II-D-67) stated that R&D facilities are frequently built with much more capacity than is actually used, and equipment often stands idle for periods of time between experiments. This large capacity would

have a significant PTE, but there would not be simultaneous actual emissions from the entire capacity.

Several aspects of R&D activities that make the above stated PTE definition not applicable to R&D operations were identified by commenters. Many commenters were concerned about the calculation of PTE by applying emissions 24 hours per day, 365 days per year (8760 hours per year). Twenty-one commenters (II-D-15, II-D-20, II-D-32, II-D-37, II-D-38, II-D-40, II-D-44, II-D-46, II-D-48, II-D-51, II-D-52, II-D-60, II-D-65, II-D-69, II-D-73, II-D-74, II-D-75, II-D-77, II-D-79, II-D-82, and II-D-83) believed that emissions often occur much less regularly than 8,760 hours used in PTE. These commenters stated that, in fact, the R&D emissions are variable over time, often only eight hours per day, intermittent, or batch. One commenter (II-D-40) described a September 6, 1995 memorandum regarding PTE calculation for emergency generators. This memo allowed the assumption of 500 hours per year (hr/yr) operation, and the commenter felt a similar departure from 8,760 hr/yr is necessary for R&D estimates. Ten commenters (II-D-26, II-D-33, II-D-37, II-D-38, II-D-46, II-D-69, II-D-73, II-D-75, II-D-92, and II-D-96) cited variable or frequently modified experimental conditions and sources, such as fume hoods, work benches, analytical instruments, and pilot plants in the difficulties of calculating PTE. Eighteen commenters (II-D-26, II-D-33, II-D-34, II-D-37, II-D-38, II-D-40, II-D-44, II-D-46, II-D-57, II-D-69, II-D-73, II-D-76, II-D-79, II-D-82, II-D-92, II-D-96, II-D-99, and II-D-104) described the great variability in chemicals and raw materials, often in small quantities, used in experimentation as a source of problems in applying PTE. One commenter (II-D-69) stated that their facility's chemical inventory was approximately 14,000 different chemicals. One commenter (II-D-82) provided an example of a bio-organics laboratory that typically uses

chemicals in 100-milliliter (ml) quantities for only a few hours at a time. Nine commenters (II-D-26, II-D-40, II-D-51, II-D-57, II-D-66, II-D-70, II-D-73, II-D-79, and II-D-99) believed the application of PTE to R&D would be burdensome or costly because PTE is inconsistent for use with R&D facilities. One commenter (II-D-73) provided a cost estimate of more than \$1 million for emissions monitoring to determine PTE.

Commenters also provided several legal arguments to support their statements regarding the difficulty of applying PTE to R&D facilities. Seven commenters (II-D-12, II-D-66, II-D-74, II-D-79, II-D-83, II-D-93, and II-D-103) cited the EPA's federal register notice regarding the applicability of title I and title V to R&D facilities (60 FR 45558): "In light of the previously mentioned difficulty of performing emission calculations, and the data gathering done by the EPA to date, which indicates that even large R&D facilities tend to have very low emissions, the EPA considers it of little benefit to require R&D facilities to go through extensive efforts to calculate PTE." Similarly, commenter II-D-34 cited the same notice (Part 70 Operating Permit Rule revisions), which states: "emissions of R&D activities are unpredictable but low, emissions are difficult and costly to estimate, and few applicable requirements typically apply." Three commenters (II-D-52, II-D-60, and II-D-75) cited the case of *United States v. Louisiana-Pacific Corporation* which states "[H]ypothesizing the worst possible emissions from the worst possible operation is the wrong way to calculate potential to emit." The commenters believed that this precedent would be violated by applying PTE to R&D because the calculated PTE would bear no rational relationship to the facility's normal operations.

6.2 It Is Not Feasible to Determine PTE for R&D Based on Material Usage/balance Calculations

Comment: Seven commenters (II-D-28, II-D-37, II-D-44, II-D-51, II-D-64, II-D-76, and II-D-79) stated that it is not feasible to determine PTE for R&D facilities based on materials usage/balance calculations.

Five of the commenters (II-D-28, II-D-51, II-D-64, II-D-76, and II-D-79) cited the difficulty in maintaining a chemical inventory and records system for tracking all chemicals used at the facility. One commenter (II-D-28) stated that purchasing is generally decentralized. Thus, a large variety of chemicals, in small quantities, are being managed by different departments. The commenter provided the example that a typical organic chemistry lab has more than 3000 containers over 100 ml, and many more under that volume. It would be nearly impossible to track the chemicals, and even more difficult to estimate what quantities were used over time. Additionally, the generalization of which chemicals were reacted or present in mixed wastes would be equally difficult. One commenter (II-D-64) cited similar difficulties in tracking purchases, storage, use, and disposal. The commenter estimated that a tracking system for a facility with more than 1000 R&D laboratories would cost at least \$500,000. An example of a tracking system attempted by the commenter's colleague was cited. The university tried to develop a comprehensive chemical tracking system, but after several years and approximately \$1.5 million, they abandoned the project due to difficulties. One commenter (II-D-51) also attempted a mass balance emissions estimation. Records of purchase were tracked, but tracking was complicated by decentralized purchasing. It was assumed that all chemicals purchased were used, and none were lost to wastewater. Spent solvents were contained, and the

researchers were asked to record the identity and quantity. The commenter stated that this is more accurate than analytical determination of content, which is impractical due to the heterogeneous nature of the wastes. The rough estimates of this mass balance indicated an average of 0.2 lb VOC/day for each of the facility's 180 laboratory hoods. The labor effort expended was estimated at 3,400 hours.

Alternatively, two commenters (II-D-37 and II-D-44) cited the variety of processes and chemicals for the difficulties in applying mass balance calculations. One commenter (II-D-37) found inaccuracy in simply subtracting solvent waste from purchases to determine emissions, and difficulty in estimating the composition and concentration of the wastes.

6.3 PTE Calculation Methodology and Estimates, General or Specific to Particular Facilities

Comment: Ten commenters (II-D-09, II-D-41, II-D-46, II-D-57, II-D-64, II-D-69, II-D-70, II-D-76, II-D-79, and II-D-83) requested guidance for clear, consistent PTE calculation methodology for R&D operations. One commenter (II-D-46) requested that stakeholders be involved in this process, and consideration of good lab practices for emission prevention and employee protection and safety. Two commenters (II-D-57 and II-D-79) suggested developing PTE methodologies in the fashion that has been used for industrial processes in the EPA's AP-42 emissions factors document.

Comment: Thirty-six commenters (II-D-03, II-D-10, II-D-14, II-D-24, II-D-26, II-D-28, II-D-29, II-D-31, II-D-33, II-D-34, II-D-35, II-D-38, II-D-40, II-D-41, II-D-51, II-D-52, II-D-57, II-D-58, II-D-61, II-D-65, II-D-66, II-D-71, II-D-73, II-D-74,

II-D-75, II-D-76, II-D-79, II-D-82, II-D-83, II-D-84, II-D-85, II-D-86, II-D-87, II-D-93, II-D-102, and II-D-103) provided estimates of PTE calculations for R&D facilities and operations. The specifics of these comments are described below.

One commenter (II-D-03) provided estimates of emissions that would represent PTE for a specific laboratory. The calculation used 8,760 hours and the theoretical maximum limit of emissions (the concentration at which an alarm sounds and equipment is shut down). The estimate was for arsine and phosphine emissions from a pilot plant. The calculated emissions are 6 lb/yr.

One commenter (II-D-10) estimated lab hood PTE at 0.09 tpy general VOC. The PTE calculations were based on 8,760 hr/yr emissions and estimates of type and quantity of chemicals provided by experimenters. Actual emissions were estimated at 0.02 tpy. The commenter also provided a pilot plant example of PTE calculation for toluene emissions. Hourly use estimates were determined and applied for 8,760 hr/yr. The PTE was determined to be 137 tpy. However the actual emissions in 1996 were approximately 0.1 tpy because the plant was only operated a few hours per week and the materials varied.

One commenter (II-D-14) provided emissions estimates using a very conservative model. Experienced staff identified labs with the greatest PTE. Each lab was inspected, workers interviewed, and a PTE estimate generated. The commenter included an attachment of VOC/HAP emissions which were considered for each lab, the annual quantity of each used, and a PTE. The PTE calculated for 11 labs ranged from 1.29 to 0.0014 tpy. Results indicated that if 100% of the inputs were lost as air emissions, the major source threshold would not be met. The exception is the Lay Auto Laboratory, which tests internal combustion engines. However, the laboratory does not emit all, or most, of its fuels uncombusted. Thus, an emissions factor for over-the-road

vehicles was applied to the fuel inputs. Similarly, a 13% emissions factor was applied to standard laboratory practices. The standard laboratory practices emissions factor was determined by a paper out of Purdue University titled "Approaches for Quantifying Potential to Emit from Laboratory Fume Hoods," which was included with the commenter's letter.

One commenter (II-D-29) has monitored laboratory emissions for 10 years and has found that the emissions from their academic research activities are very low. They used combined computer modeling, actual emissions testing, and tracer gas studies. The PTE calculations were below 6 lb/hood/yr, which is approximately 6,000 lb/yr for the entire campus. The example calculation for a biomedical research building was attached. In the example, 15 samples from an emissions point attached to 20 hoods was tested. Samples were analyzed for three heavily used solvents. Using non-detects at the detection limit and applying emissions 8,760 hr/yr, estimated emissions were 11.7 lb/yr total. However, it is unlikely the hoods would be used more than 12 hr/day 5 days/week, thus reducing the estimate to 6 lb/yr. The commenter also provided emissions estimates for the new facility construction of a Microsystems Technology Laboratory (semiconductor research). Each researcher listed each piece of equipment and the materials used in it. The information was collected in order to estimate worst case emissions. Total emissions were 3.23 lb/day for 24 chemicals (not all 24 materials were HAP). At 5 days/week, 52 weeks/yr this would be 840 lb/yr total emissions for 32 exhaust fans. Another estimate was provided for total VOC emissions from three fume hoods in the Biology Department. The hoods were identified as high volume users. Records were kept over an eight week period for volume and duration of use for each chemical. Evaporation losses were estimated. It was then assumed that emissions would be 40 hr/week, 52 weeks/yr with 10% evaporation

losses. The average emissions were 6.65 lb VOC/100 cubic feet per minute (cfm) exhaust. If this were extrapolated to the 150 fume hoods in the building, the VOC emissions would be approximately 1,000 lb/yr.

One commenter (II-D-31) described how they have evaluated their laboratory emissions. They developed a survey to estimate potential emissions from research laboratories (teaching labs were exempted) based on chemical usage, waste information, laboratory square footage, and number of laboratories. The survey was completed by 55 randomly selected labs. The resulting data was used to develop a site-specific emissions factor. The emissions factor was then applied to over 700 labs to estimate potential emissions. The emissions factor was compared to those developed for R&D by two other universities. The complete procedures were provided with the comments.

One commenter (II-D-38) provided several facility specific examples. Emissions inventories of 22 pilot plants revealed 13 out of 1,000 pieces of equipment had VOC emissions in excess of the Minnesota threshold (1 tpy actual or 2.28 lb/hr potential emissions). The commenter has found there are several ways of calculating PTE for lab hoods, but none are very reflective of the actual emissions. They estimated PTE for a series of lab hoods using 50 parts per million (ppm) methyl ethyl ketone (MEK) (minimum odor concentration). The estimated hoods ran 1500 cfm at 60°F for 8,769 hr/yr. The estimation showed 2.7 lab hoods have emissions of 10 tpy. Similarly, 6.7 hoods have estimated emissions of 25 tpy, and 26.7 hoods have estimated emissions of 100 tpy. These results indicated only 3 hoods would be a major source. An R&D facility with 68 hoods would have a PTE of 250 tpy. Actual emissions rates are orders of magnitude lower. Actual VOC emissions of representative hoods were estimated at 0.3 tpy, 0.00118 tpy, 0.0011 tpy, 0.00008 tpy, and 0.00021 tpy.

7.0 INFORMATION PROVIDED IN COMMENTS ABOUT ACTUAL R&D EMISSIONS

Comment: Thirty-three commenters (II-D-03, II-D-24, II-D-26, II-D-28, II-D-33, II-D-34, II-D-35, II-D-40, II-D-41, II-D-46, II-D-51, II-D-52, II-D-57, II-D-58, II-D-60, II-D-61, II-D-64, II-D-66, II-D-71, II-D-73, II-D-74, II-D-75, II-D-76, II-D-79, II-D-82, II-D-83, II-D-84, II-D-85, II-D-86, II-D-87, II-D-93, II-D-102, and II-D-103) provided information about actual emissions from various types of R&D sources. One commenter (II-D-03) provided estimation of actual emissions from his academic institution. This is the 23rd largest university as far as enrollment, so there are likely to be many universities with less emissions. The methodology for this calculation was described. Three hundred thirty-seven lab hoods were identified, and a one month survey of use attached to each one. Two hundred twenty surveys (65%) were recovered, of which 133 had no written response. The 88 hoods that with completed surveys were used to calculate an average of 13 lb/yr emissions (max was 127 lb/yr). $13 \text{ lb/yr} * 337 \text{ hoods} = 4381 \text{ lb/yr total}$. There is great uncertainty in this number due to the nonresponse survey results and the variable use of some hoods during the year.

A commenter (II-D-24) provided actual emissions for a large scale facility. The actual emissions were 68 lb/yr ammonia and 50 lb/yr diethanolamine. Extrapolation of these numbers to an R&D facility with similar emissions characteristics would estimate emissions of 0.1 lb/yr ammonia and 0.07 lb/yr diethanolamine. Additionally, SIC 2252 uses dye products that are up to 4% chromium and copper (HAP). These metals are complexed in the dyes' chemical structure and are not lost as air emissions.

A commenter (II-D-26) provided information from a New Jersey Emission Statement Program survey. Emissions estimation from

7,681 lab hoods at 156 facilities showed average emissions of 1.7 lb/yr/hood.

A commenter (II-D-34) provided an example of actual emissions from an aerospace facility. Actual VOC emissions from R&D paint formulations were estimated at less than 40 lb/yr.

A commenter (II-D-46) described actual emissions for their R&D facility in South Charleston, West Virginia. The facility has approximately 500 laboratories and three pilot plants. The commenter estimates HAP emissions to be about 6 tpy.

A commenter (II-D-51) provided several examples of methods used to calculate actual emissions. First, 158 fume hoods (21% of the facility's hoods) were analyzed for an 8 hour working day over several weeks. EPA test methods were not used, due to cost. Emissions averaged 0.0122 lb VOC/hr/hood, or 0.1 lb/day. In the second example, another facility tried the mass balance approach to emissions estimation. The purchase records were totaled for VOC. It was assumed that all purchases were used, and that none were lost to wastewater. Spent solvents were recovered, and tagged with identity and quantity of the chemicals. The recovered amounts were subtracted from the purchased amount to estimate a 0.2 lb VOC/day/hood emissions rate for each of the site's 180 lab hoods. The third example cited another company that used a modified EPA Method TO-14 to detect concentrations as low as 50 parts per billion (ppb). The method was used to measure emissions from seven analytical R&D lab hoods manifolded into one duct. Using non-detects as at the detection limit, this survey showed emissions of 0.005 to 0.06 lb organics/day/hood. However, these were one time actual estimates which will likely never be repeated due to the dynamic emissions. The fourth example was of a member facility, which has over 300 hoods and total air emissions of less than 0.2 tpy. This facility would

have to increase its use of HAP more than two orders of magnitude to approach TLV/100 using SCREEN3.

Two commenters (II-D-52 and II-D-60) provided examples of actual emissions. Actual toluene/xylene emissions from a R&D facility were calculated to be 2 tpy. Similarly, actual MEK emissions from another facility were calculated to be 0.256 tpy. If PTE were applied to the facilities tested for toluene/xylene and MEK above, the sources would be determined major sources. However, the estimated actual emissions are much lower than the major source cutoffs.

A commenter (II-D-57) provided actual emissions estimates from their title V Operating Permit application. Actual VOC emissions were conservatively estimated at 6 tpy for the facility's 1,000 laboratories.

A commenter (II-D-58) estimated annual emissions of 4.6 tons VOC/HAP. This number was obtained by estimating the facility's entire chemical inventory was lost as emissions. That was conservative considering the facility has scrubbers and cold traps, not all chemicals used are actually lost, and the total includes VOC, not just HAP.

A commenter (II-D-61) estimated air toxics using data from chemical purchases and waste disposal quantities. They used a conservative methodology for compliance with the North Carolina State program. These calculations showed the HAP emissions from their 500+ hoods were close to the major source threshold.

A commenter (II-D-71) estimated their modern R&D facility operates with emissions below 5 tpy for all HAP.

A commenter (II-D-73) cited "numerous studies" that used a wide range of methodologies to estimate emissions. The commenter stated that the studies show emissions of R&D facilities are minimal regardless of methodology used. Data was provided from 15 sources. The estimated emissions range was from 300 to 16400

lb/yr. All estimated sources were below the major source cut off. Based on six conservative studies, the emissions ranged from 0.004 lb/day/lab to 0.07 lb/day/lab. That would indicate emissions from 2,900 collocated labs would be required to meet the major source threshold. A summary of four studies indicated that the average pharmaceutical emissions were 0.004 to 0.22 lb/day/hood. Except for one of the studies, the emissions evaluated were VOC, California air toxics, or specific chemicals.

A commenter (II-D-74) conservatively estimated actual campus emissions at 4.8 to 6.5 tpy. Conservative assumptions include estimation of emissions for 8 hr/day, 365 day/yr. The data these estimates are based on cost hundreds of thousands of dollars and approximately 10 years to collect.

A commenter (II-D-75) provided an example of a Fortune 50 company which has only one R&D center. Assuming all purchased chemicals were emitted to the air, annual emissions were estimated at 1,500 lb/yr.

A commenter (II-D-82) cited an emissions study by another company. The study showed emissions from pharmaceutical organic chemistry, analytical chemistry, and molecular biology labs were in the range of 0.004 to 0.18 lb/day/fume hood. Total emissions were about 76 to 5,068 lb/yr for the facilities. Each estimate was generated using annual data times an emission factor. The emission factors were developed by process simulation. All estimates are for emission of benzene, CCl₃H, dioxane, HCOH, and DCM.

A commenter (II-D-84), a State commenter, provided some information they possess regarding their experience in regulating R&D facilities for State permitting, in hopes that it will be helpful in rulemaking. The commenter has conducted evaluations of emissions from pilot plants, educational facilities, and hospitals. The State program, after review, determined that R&D

facility ventilation and exhaust systems would be exempt until the EPA completed rulemaking. The State-exempted R&D activities are limited to the production of noncommercial quantities. Under the State's former permitting system, major or area source pilot plants were permitted for the discharge of carcinogenic or radioactive contaminants. Emissions rates were evaluated for 852 hoods, and a summary of the data was provided. Results show 57.5 percent of the facilities emit less than 0.01 lb/hr, 27.5 percent emit 0.01 to 0.1 lb/hr, 10 percent emit 0.1 to 1.0 lb/hr, and 5 percent emit more than 1.0 lb/hr. There are limitations to the data, including: emissions rates are based on engineering judgement, no stack testing was conducted, and only carcinogens are covered (not all HAP are considered). The commenter provided detailed 1991 information from a large R&D facility in their State, which includes 3,500 emissions sources from 500 stacks. The facility estimates total emissions of a variety of chemicals at 26 lb/hr or 52,000 lb/yr. The State commented that the standards should be based on good laboratory ventilation practices, as addressed in the American National Standard for Laboratory Ventilation. The State also provided 1992-93 estimates of chemical use and emissions at a large R&D chemical development facility for several HAP and non-HAP. They also included a letter from an academic institution, which provides lab hood emissions estimates and methodology.

A commenter (II-D-85) stated that their Title V Operating Permit indicates they have 1,600 fume hoods serving 2000 research locations. HAP emissions conservatively estimated did not exceed major source thresholds, and could be as low as 25 percent of the major source threshold.

A commenter (II-D-86) described a 1994 emissions study, which showed average emissions at one facility of 0.098 lb VOC per hood/day.

A commenter (II-D-87) estimated that total campus emissions are less than 1000 lb/yr.

A commenter (II-D-102) provided emissions examples from several sources. A study by the Bay Area Air Quality Management District of California estimated emissions from a 370,000 square foot laboratory at about 50 lb VOC/day. Stack testing of a smaller pharmaceutical company measured emissions of 0.05 lb VOC per hood/day or 18 lb VOC/hood/yr. The commenter also quoted a Purdue study that estimates 20 lb VOC/hood/yr and a New Jersey working group that estimated 5 lb to 30 lb VOC/hood/yr. The commenter stated that HAP emissions would be even lower.

Fourteen commenters (II-D-26, II-D-28, II-D-33, II-D-35, II-D-40, II-D-41, II-D-64, II-D-66, II-D-74, II-D-76, II-D-79, II-D-83, II-D-93, and II-D-103) cited an emissions calculation for an R&D facility which was described by the EPA in the Part 70 Operating Permits Revisions of August 31, 1995 (60 FR 45556, 45557). The citation describes a study where a two million square foot facility with 3,000 researchers and 40 stacks serving 600 labs. The study showed an estimated annual VOC emissions rate of less than 12 tons per year (tpy), even if the facility operated 8,760 hr/yr.

8.0 INFORMATION PROVIDED IN COMMENTS ABOUT UNIVERSITY R&D

8.1 Do Not Regulate University R&D

Comment: Twenty-one commenters (II-D-14, II-D-17, II-D-18, II-D-19, II-D-29, II-D-49, II-D-57, II-D-64, II-D-66, II-D-76, II-D-77, II-D-79, II-D-80, II-D-89, II-D-92, II-D-93, II-D-94, II-D-99, II-D-101, II-D-103, and II-D-104) requested that academic R&D laboratories be exempted from the R&D source category under § 112. One commenter (II-D-92) stated that the language and legislative history of the CAA, regulatory precedents, operational differences between industrial and academic R&D facilities, and the lack of data on how these facilities impact health or the environment all support not regulating colleges and universities. Three commenters (II-D-17, II-D-19, and II-D-29) indicated that academic facilities have very low emissions, primarily due to the small amount of chemical usage. One commenter (II-D-19) stated that their academic R&D laboratories have controls in place to comply with conservative standards for all radioactive air emissions. Two commenters (II-D-29 and II-D-99) stated that the risk to human health and the environment from academic R&D laboratories is insignificant.

Seven commenters (II-D-14, II-D-18, II-D-64, II-D-77, II-D-79, II-D-89, and II-D-94) felt that the language in § 112(c)(7) allows the EPA sufficient discretion to decide not to list academic R&D laboratories. According to one commenter (II-D-64), there is no intent evidenced in the legislative history to include within the scope of regulation, facilities in an academic setting where the research activities are not involved in new processes or products. Four commenters (II-D-77, II-D-79, II-D-89, and II-D-94) stated that the primary purpose of academic research is teaching and training intended for the betterment of

society. The commenters remarked that new processes and products resulting from the research are secondary. One commenter (II-D-77) remarked that scale, public interest, and commercial application differentiate academic laboratories from manufacturing R&D. The commenter felt that academic research laboratories differ significantly from industrial operations. The commenter referred to the rulemaking record for the OSHA Laboratory Standard. As stated in the summary to the Occupational Exposures to Hazardous Chemicals in Laboratories, 29 CFR part 1910, published in the Federal Register, Vol. 55, No. 21, January 31, 1990, "laboratories typically differ from industrial operations in their use and handling of hazardous chemicals." Three commenters (II-D-79, II-D-89, and II-D-94) remarked that academic research stems from the educational, academic, intellectual, and teaching mission of the university. According to the commenters, manufacturing research focuses on products or processes related to the manufacturing of products, the purpose of which is to develop or enhance a product for proprietary gain.

Four commenters (II-D-77, II-D-79, II-D-89, and II-D-94) referred to the legislative history of § 112(c)(7). According to the commenters, Congress intended to regulate *commercial* R&D (i.e., associated with manufacturing operations). The commenters felt that there was nothing in the legislative history to suggest that Congress intended to regulate academic research under § 112(c)(7).

Two commenters (II-D-93 and II-D-103) stated that there is no factual basis that would justify including academic laboratories on the source category list. The commenters stated that there are dramatic differences between R&D activities that operate in support of manufacturing/commercial operations and laboratories and research facilities at academic institutions.

According to the commenters, laboratories at academic institutions typically do not support any other emission sources on campus, and they are not associated with any type of commercial process. The commenters further stated that there are rarely production-oriented R&D activities and pilot plants at academic institutions. The commenters indicated that the materials prepared and consumed are normally experimental, and are used in very small scale experiments. The commenters stated that these activities are involved in teaching and research applications, and involve education-oriented goals or original research.

A commenter (II-D-49) stated that university research, teaching, medical, and testing activities are inseparable. Therefore, according to the commenter, these activities cannot be regulated based on a category such as "research." The commenter recommended that the EPA engage in ongoing discussions and investigations with universities about the nature and extent of university laboratory emissions.

A commenter (II-D-76) felt that for academic institutions, no practical method exists to determine applicability to an R&D standard or to assess compliance with the standard. The commenter stated that it is not possible to know at any time which chemicals or quantities of chemicals are being emitted. According to the commenter, activities conducted in an academic setting continually change to meet the needs of the institution and its students.

Seven commenters (II-D-14, II-D-17, II-D-18, II-D-66, II-D-79, II-D-89, and II-D-94) stated that equitable treatment does not necessitate the regulation of academic research facilities. Two commenters (II-D-14 and II-D-18) stated that college and university R&D facilities would not meet the emissions thresholds. The commenters felt that it would not be equitable

treatment if these facilities were still required to complete an evaluation more as an exercise to evaluate a minor portion of laboratories that may have a limited VOC/HAP PTE above the threshold. One commenter (II-D-66) stated that university research or laboratory facilities do not involve sources of emissions such as pilot plants or trial manufacturing activities as are seen in industrial settings. Three commenters (II-D-79, II-D-89, and II-D-94) stated that it would be inequitable to subject colleges and universities to a new source category. The commenters stated that the EPA must determine whether it would be equitable to regulate colleges and universities. Furthermore, the commenters felt that colleges and universities could not be compared to manufacturing R&D operations and it would be inequitable to regulate academic research as if it were manufacturing. The commenters also stated that the only commonality between research activities located at academic institutions is that they occur on the same college campus. According to the commenters, this contrasts with manufacturing R&D which focuses on a particular product or process for proprietary gain.

Three commenters (II-D-79, II-D-89, and II-D-94) stated that applying MACT standards to academic research would be difficult, and with questionable benefit, since academic research activities taking place at any one time are so diverse.

A commenter (II-D-103) agreed with the EPA's finding, as stated in the ANPR, that R&D sources to be included in the source category should be limited to those associated with manufacturing sources already included in the listed source categories. The commenter also agreed with the EPA in that there is no factual basis for including academic laboratory facilities on the source category list.

Comment: Two commenters (II-D-28 and II-D-79) requested that academic activities be exempt from title III and title V regulations. The commenters suggested the following definition be adopted for academic activities to be excluded from regulation under title III and title V:

“Academic Activities means; teaching, research, study and laboratory activities conducted at elementary and secondary schools, colleges, universities and professional schools, providing academic or technical instruction, furnishing academic courses and granting academic degrees, certificates or diplomas.”

The commenters felt that with this definition, sources such as central steam and electric generation plants, waste management operations and degreaser would still have to comply with the MACT standards. The commenters also felt that with this definition, significant emissions sources at academic institutions would still be required to calculate PTE. The commenters stated that this approach is reasonable because it recognizes the difficulty of calculating and controlling emissions from academic activities, and allows an exemption that recognizes applicability of title III and title V requirements to significant emission sources. The commenters also stated that this definition satisfies the CAA requirement that R&D activities be treated in an “equitable” manner.

8.2 University R&D Operations Have *de minimis* Emissions

Comment: Fourteen commenters (II-D-03, II-D-14, II-D-17, II-D-28, II-D-29, II-D-49, II-D-64, II-D-66, II-D-77, II-D-79, II-D-85, II-D-89, II-D-92, and II-D-94) believed that there is sufficient evidence to conclude that emissions from university R&D operations are not major sources of HAP. Two commenters (II-

D-28 and II-D-79) stated that emissions from academic activities are on a much smaller scale than industrial R&D facilities.

A commenter (II-D-03) indicated that they have an annual lab hood emission rate of 4,381 lb/yr at their university. The commenter further estimated that using a conservative average of 13 lb/yr per lab hood for a national estimate, even large universities (e.g., those with 1,500 lab hoods) would not meet the major source criteria. The commenter felt that their data demonstrates that emissions from universities are always low and in many cases, nonexistent.

Two commenters (II-D-14 and II-D-94) provided emissions tables for eleven of their university's laboratories. The laboratories presented were the ones assumed to have the highest PTE, and HAP emissions ranged from 0.0014 tpy to 1.29 tpy. The commenters felt that the tables illustrated that even if 100 percent of the raw material used on an annual basis was converted to HAP emissions, the major source thresholds would not be approached. The commenters mentioned one exception from the Lay Auto Laboratory. The commenters felt, however, that even the most inefficient combustion engine would not produce a significant amount of HAP emissions.

Two commenters (II-D-17 and II-D-77) referred to the small quantities of emissions from academic R&D activities. One commenter (II-D-17) stated that air emissions from the university's laboratories are produced from small quantities (ranging from several milliliters, to five gallons) of a large variety of chemicals used in many experiments. One commenter (II-D-77) stated that many research projects used very small quantities of chemicals (as small as milligrams or micrograms). The commenter remarked that cost was a factor, and that investigators and administrators would not be likely to waste resources on excessive chemical inventories or inefficient

processes. According to the commenter, the universities also have a powerful vested interest in minimizing risks to the health and safety of students, staff, and the public. The commenter stated that chemical inventories, wastes and employee exposures are minimized. The commenter further stated that due to these practices, potential emissions are thereby minimized. The commenter felt that academic research laboratories have little potential to be significant emission sources.

A commenter (II-D-29) stated that low generation rates within the university's laboratory hoods and dilution result in extremely low concentrations of HAP in the exhaust streams. The commenter performed several studies to determine emissions from the university's laboratory operations. The results of these studies indicate that emissions from the commenter's academic research activities are low (potential emissions less than 6,000 lb/yr).

Two commenters (II-D-49 and II-D-66) indicated that even the largest universities do not approach the major source thresholds for HAP even using the most conservative estimates. One commenter (II-D-49) suggested that universities assist the EPA in determining a *de minimis* exception to the listing requirements.

A commenter (II-D-64) felt that actual emissions in an academic setting would be significantly below those reported for industrial facilities. According to the commenter, only an extremely small fraction of the chemicals handled in a laboratory have the opportunity to volatilize. The commenter indicated that calculations performed in their laboratories using the conservative dispersion model outlined in State regulations indicate that no HLV (as defined in the State regulations) is exceeded.

8.3 University PTE Is Difficult to Calculate

Comment: Fourteen commenters (II-D-03, II-D-17, II-D-28, II-D-31, II-D-49, II-D-64, II-D-66, II-D-70, II-D-76, II-D-77, II-D-79, II-D-89, II-D-92, and II-D-94) provided comments on the difficulty of calculating PTE from university R&D facilities. One commenter (II-D-03) stated that there is a wide degree of uncertainty regarding any calculation of emissions. According to the commenter, the use of hoods can vary widely throughout the year. The commenter provided the example that the use of laboratory hoods may be greater in the summer months because researchers have fewer teaching responsibilities. One commenter (II-D-31) stated that the use of PTE criterion overstates the true potential of these university laboratories to emit regulated air pollutants. One commenter (II-D-49) stated that PTE calculations are an unacceptable and impractical burden. One commenter (II-D-64) requested that the EPA clarify the proposed method for calculating PTE from academic laboratories. Four commenters (II-D-77, II-D-79, II-D-89, and II-D-94) stated that PTE calculations could not be performed due to the variability inherent in academic research. The commenters remarked that since PTE calculations are based on 24-hour operation, PTE estimates would be meaningless. The commenters stated that university research is a function of the design and nature of the research and it would be misleading to assume a 24-hour worst case scenario.

A commenter (II-D-17) stated that a single laboratory or laboratory units may have several different users conducting research using different chemicals in the same area of chemicals. The chemicals and chemical usage may change several times during the course of laboratory work. According to the commenter, this precludes accurate estimation of emissions. The commenter reiterated that these emissions would be very small.

Two commenters (II-D-28 and II-D-79) stated that in order to calculate emissions using a mass balance, the university would need a detailed inventory of incoming chemicals. According to the commenters, college and university laboratories use a variety of chemicals in small quantities, in different locations, and under the control of several different university personnel. The commenters stated that standard mass balance calculations cannot be done reliably because of thousands of small containers, and the difficulty of estimating the quantity used, in storage, in reaction products, and in waste mixtures from each container. The commenters also stated that academic activities are not typical unit-based operations, making calculation of emissions extremely difficult.

A commenter (II-D-66) stated that the EPA should not rely on emission estimations or calculations because of the shortcomings of these methods when applied to university research or laboratory facilities. The commenter felt that calculation of PTE requires highly speculative assumptions, and has little relationship to actual activities or potential emissions.

Two commenters (II-D-70 and II-D-76) mentioned that estimating emissions from university R&D activities are difficult because emissions from the research, teaching, medical, and testing laboratories are physically inseparable.

A commenter (II-D-76) stated that the dynamic nature of chemical usage precludes the effective use of emissions tests to quantify R&D emissions at colleges and universities. According to the commenter, consistent, identifiable "processes" do not exist at a college or university. The commenter stated that any emission test would provide only a snap-shot of chemical usage and emissions and would not be a reliable indicator of PTE.

A commenter (II-D-92) stated that the lack of predictability of chemicals used and quantity of emissions from one lab,

multiplied over 2,000 laboratories, highlights the difficulty of just gathering the information to calculate emissions for R&D facilities at universities.

9.0 INFORMATION PROVIDED IN COMMENTS ABOUT CONTROL COSTS AND OPTIONS

Comment: Thirty commenters (II-D-03, II-D-10, II-D-12, II-D-14, II-D-17, II-D-27, II-D-28, II-D-29, II-D-31, II-D-32, II-D-34, II-D-37, II-D-38, II-D-44, II-D-48, II-D-51, II-D-58, II-D-64, II-D-73, II-D-74, II-D-79, II-D-82, II-D-83, II-D-84, II-D-86, II-D-91, II-D-95, II-D-97, II-D-98, and II-D-99) provided statements on control options or costs. One commenter (II-D-37) believed that the EPA should collect and evaluate control information before listing R&D in order to avoid listing a source category that cannot be practically regulated. Another commenter (II-D-34) cited the draft preamble of the Part 70 Operating Permit Rule revisions. In this draft the EPA states it "is not aware of any existing substantive control requirements...that apply to R&D."

Four commenters (II-D-32, II-D-37, II-D-44, and II-D-98) had differing viewpoints on pollution prevention as a control option. One commenter (II-D-37) stated that an R&D MACT would inhibit pollution prevention. Another commenter (II-D-32) believed that pollution prevention through requiring the use of non-HAP materials would limit the flexibility of R&D experimentation. Conversely, one commenter (II-D-98) believed that pollution prevention would be the best control option. One commenter (II-D-44) believed pollution prevention is currently a trend in laboratory procedure. Five commenters (II-D-27, II-D-28, II-D-37, II-D-38, and II-D-79) were concerned with the secondary pollution that would be generated by control technologies. Potential secondary pollution includes greenhouse gasses, criteria pollutant emissions, water discharges, and solid wastes. Generally, the commenters want the HAP reductions to outweigh the secondary pollution effects.

Nine commenters (II-D-28, II-D-37, II-D-38, II-D-73, II-D-79, II-D-82, II-D-86, II-D-91, and II-D-99) expressed concern that the low levels of HAP emissions combined with large air volumes and small scale equipment would make control expensive or difficult. Two commenters (II-D-28 and II-D-79) believed that this is especially true for the brief or intermittent emissions from university R&D activities. One commenter (II-D-82) expressed concern that the low pollutant concentrations would preclude some control technologies, such as incineration. Similarly, five commenters (II-D-27, II-D-28, II-D-38, II-D-79, and II-D-82) stated that the full-scale or industrial controls are not applicable to related R&D activities. One commenter (II-D-27) was concerned that a second control would be necessary if the full-scale control were implemented for R&D processes because the full-scale control is suited to a process that does not change. One commenter (II-D-27) also provided text from the NESHAP for Magnetic Tape Manufacturing Operations (59 FR 64586). The text states that the EPA has determined that the use of production controls is not technically feasible for R&D. The commenter found that these technical problems would increase the cost of MACT controls for R&D facilities. Two commenters (II-D-28 and II-D-79) suggested that university R&D facilities are not well suited for industrial controls.

Fourteen commenters (II-D-10, II-D-14, II-D-27, II-D-28, II-D-29, II-D-38, II-D-48, II-D-51, II-D-64, II-D-73, II-D-74, II-D-79, II-D-91, and II-D-99) expressed concern for the cost of determining emissions and designing, purchasing, installing, operating, or maintaining appropriate control technologies. Generally, the commenters found that the HAP reductions may not outweigh the costs. For example, one commenter (II-D-28) estimated that it would take two years and \$1.3 million to approximate potential emissions. Three commenters (II-D-28, II-

D-29, and II-D-79) also desired the consideration of indirect costs, such as the disruption of research.

Ten commenters (II-D-17, II-D-27, II-D-28, II-D-32, II-D-38, II-D-73, II-D-79, II-D-82, II-D-97, and II-D-99) provided comments on how the design of a specific control for R&D facilities would be very difficult because the processes or HAP are continuously changing. One commenter (II-D-73) was concerned that R&D facilities would have to over-install or constantly retrofit controls to control the changing emissions. Over-installation would be very expensive, while retrofitting would require installation of a new MACT for each change in the R&D. One commenter (II-D-82) stated that their facility has up to 10,000 different reagents, generally in quantities of 100 ml or less. One commenter (II-D-97) stated that the calculation of control technology "floors" would be difficult given the variable nature of R&D.

One commenter (II-D-95) provided a portion of the text of Senator Harkin's statement to the Congressional Committee on Environment and Public Works regarding control options for R&D facilities:

"[Permitting and controlling these emissions] may be a virtually impossible task since it would require that the operator anticipate what chemicals may be emitted over the course of the permit period and in what amounts...It is simply not feasible to change the controls as research progresses."

Similarly, five commenters (II-D-12, II-D-74, II-D-79, II-D-83, and II-D-97) provided portions of the text of Senator Harkin's discussion of control options on the floor to the United States Senate during the discussion of the 1990 Clean Air Act Amendments (136 Cong. Rec. S3748-01 April 3, 1990).

"R&D facilities typically have a large number of process vents, and low and very changeable emissions. It would not be unusual for such facility to have over 300 vents, all of which would have to be controlled and permitted, as the bill

is now written. This may be a virtually impossible task, since it would require that the operator anticipate what chemicals may be emitted over the course of the permit period and in what amounts.

Implementing the controls may be equally difficult. For example, a chemist may use a gallon of hydrochloric acid 1 day to cause a reaction in a process and the next day use a half gallon of volatile organic chemical to purify the product of the reaction. The mandated control technology for the hydrochloric acid could be a scrubber while the control for the VOC might be a condenser or a carbon vent-sorb. It is simply not feasible to change the controls as the research progresses. These unique characteristics must be taken into account if the EPA sets any standards for R&D facilities."

Comment: Sixteen commenters (II-D-03, II-D-10, II-D-14, II-D-28, II-D-29, II-D-31, II-D-37, II-D-38, II-D-44, II-D-48, II-D-51, II-D-58, II-D-64, II-D-74, II-D-84, and II-D-86) provided specific information on control options and costs that have been previously considered or implemented.

A commenter (II-D-03) provided information on a pilot plant that has a continuous emissions monitoring system (CEMS). The system monitors emissions which include arsine and phosphine. The CEMS is necessary for health and safety reasons. The system sounds an alarm when the emissions concentration reaches a set limit [50 parts per billion, by volume (ppbv) of arsine and phosphine or 100 ppbv both]. When the alarm sounds all systems are shut down. The alarm may only sound twice per year. It can be assumed that the concentration at which the alarm sounds is the maximum emissions. This assumption indicates the pilot plant emissions are 6 lb/yr.

A commenter (II-D-10) provided information on their experience with incinerators as a control. Incinerators usually cost about \$2 million. Toluene (as a HAP) emissions from a pilot plant were estimated at 0.1 tons/yr. That would mean a cost of \$20 million per ton HAP control. Control is only necessary a few

hours per week. The incinerator must be operated at a minimum temperature. It will be energy intensive to maintain the minimum temperature for a few hours a week. Similarly scrubbers have minimum operating conditions. It may be difficult for R&D operations to meet the minimum operating conditions.

A commenter (II-D-14) described the costs incurred when their power plant was identified as a major source. The effort required 140 employees and two external consultants. A report of more than 500 pages was filed with the State agency. The cost of these permit development/application activities was approximately \$150,000.

A commenter (II-D-28) estimated that it would require seven full-time positions to collect, enter, and verify emissions for compliance with an R&D NESHAP. The same commenter (II-D-28) provided bid information it obtained in anticipation of the NESHAP for treatment, storage, and disposal facilities. Bids for thermal oxidizers and carbon adsorption filters were obtained. The bid for the thermal oxidizer was for a simple slot hood. The unit and installation were bid at \$278,000. Annual operating costs were estimated at \$65,280. The commenter's facility has approximately 1,200 fume hoods potentially covered by the R&D NESHAP. This would require a total cost of \$333,600,000 installation and \$78,336,000 annual operating costs. Additionally, the oxidizers are sources of several criteria pollutants. The bid for carbon adsorption was for a conventional fume hood. The carbon adsorption was estimated to be 85 percent efficient. Efficiency is dependent on the chemicals being controlled. There are a number of costs associated with each carbon adsorption unit. The activated carbon unit was bid at \$950. Necessary modifications of the ventilation system were estimated at \$4,350. Disposal of the activated carbon as hazardous waste would cost about \$1,625. Sensors for detecting

total hydrocarbon breakthrough for each filter were bid from \$2,000 to \$10,000. Data loggers for the sensor were priced at \$1,200 to \$10,000. Installation of the sensor and data logger system was bid at \$2,000 to \$10,000. Annual utility costs were estimated to raise \$760 per year. The total installation would cost \$12,600,000 to \$42,360,000. Annual operation costs would be approximately \$3,212,000.

The commenter also provided an example of R&D emissions estimates. The commenter cited a recent American Industrial Hygiene Conference session where a recent study of R&D buildings was discussed. The study considered 300 researchers, 38 processes, and 1,200 chemicals. The median duration of the R&D processes was 1 hour (8.3-hour mean). Median emissions were 0.2 lb/hr. The median duration of pilot plant processes was 6 hours (62-hour mean). Median emissions were 3.7 lb/hr. The commenter used these survey results as evidence that emissions do not warrant the estimated costs of control.

A commenter (II-D-29) stated that installation of an air cleaning device (filter or scrubber) per fume hood was estimated at approximately \$8,000. This price includes a new fan to address increased resistance. Some hoods may need more costly devices, depending on the type of chemical(s) used. For the facility's 1,000 hoods, that corresponds to about \$8 million in costs. There would be additional costs due to the interruption of research due to construction and long term operation/maintenance.

A commenter (II-D-37) provided control specific information on control emissions and industry processes. The commenter was concerned that the large volume of air with low VOC [HAP] generated by R&D facilities is not well suited to add-on control. The example provided was for a 15 million British thermal units (MMBtu) catalytic oxidizer burning natural gas. The oxidizer

requires 42,000 standard cubic feet per minute (scfm) flow to operate appropriately. Each standard pharmaceutical R&D hood is about 3,000 scfm. This corresponds to 14 hoods required to supply the oxidizer. Emissions from the fuel used by the oxidizer are 8.9 tpy NO_x and 2.2 tpy CO [criteria pollutants]. The increased criteria pollutant emissions must be weighed against the HAP reduction. The commenter (II-D-37) also provided pharmaceutical R&D survey results. The Pharmaceutical Research and Manufacturers of America (PhRMA) annual survey, 1997, is quoted. Sixty percent of R&D expenditures are for development. Development is undertaken in order to reduce raw materials costs, and reduce waste treatment/disposal costs. These pollution prevention activities should be encouraged by the agency, not restricted.

A commenter (II-D-38) provided examples pertinent to the applicability and cost of controls. An example was made of carbon canisters as a control option. These are not viable control options for hoods because explosions can occur if ketones are used in the hood. It would be difficult to predict the use of ketones because of the variability in R&D processes. An example of a previously installed thermal oxidizer was provided for a R&D coater. VOC emissions were reduced from 3.8 lb/yr to 0.13 lb/yr. Given the cost of oxidizers, the commenter finds that the reductions are not cost effective. Additionally, the oxidizer emitted more pounds of pollutant than it controlled (0.4 lb PM-10, 0.02 lb SO_x, 3.4 lb NO_x, and 0.74 lb CO). Aside from cost, it is often technically difficult to fit control devices to the small pieces of equipment used in R&D.

A commenter (II-D-44) provided trends in accepted laboratory procedure that lead to control. There is improved effort to trap air emissions as a part of the lab [experimental] apparatus. Pollution prevention, through the use of less toxic substances,

is increasing. Personnel instruction is raising awareness about not using hoods as disposal devices.

A commenter (II-D-48) provided a specific example of the high cost of compliance. Higher costs will lead to negative effects on R&D. The example provided was a compliance chemical inventory system which cost \$400,000 in 1995. A MACT would mean much higher costs to R&D.

A commenter (II-D-51) provided an emissions testing example for a "major R&D facility". A building with 158 fume hoods, comprising 21 percent of the laboratory's fume hoods, was monitored for eight hour work days over several weeks. It was found that the average emissions per hood were 0.0122 lb VOC/hr, or 0.1 lb/day. [15.8 lb/day all hoods]. However, EPA test methods were not used for the analysis. Using EPA methods would have increased the cost from \$26,000 to as high as \$260,000.

A commenter (II-D-58) provided an example of controls at one of their facilities. If the entire chemical inventory were lost as VOC and HAP, it would be only 4.6 tons. These are conservative estimates because the facility has scrubbers and cold traps as control.

A commenter (II-D-64) stated that a filter and charcoal adsorption unit are the only emissions control available for fume hoods. Due to the typical configuration of the exhaust systems, a control would have to be placed on the stack of each hood at academic institutions. The control requires exhaust fans to move the air through the filter, in addition to the control unit itself. The installation costs for fan and control are estimated at \$10,000 to \$50,000 per unit. This would total \$10 to \$50 million to an institution with 1,000 hoods, plus \$500,000 to \$1,000,000 per year in operating and maintenance costs.

A commenters (II-D-74) provided input on how calculations and estimation of HAP, or conducting risk assessments for R&D

facilities are very expensive. The university has spent \$400,000 evaluating air emissions in compliance with the California Environmental Quality Act. The same commenter estimated the county of Santa Clara, CA Toxic Gas Ordinance (TGO) has added approximately \$2 million to the cost of a research facility where toxic gases are used above exempt quantities. TGO requires the use of engineering and administrative controls for each research experiment.

A State commenter (II-D-84) provided information and schematics on the pollution control equipment that is in place at a chemical development facility in their State. The equipment is an array of condensers and scrubbers that reduce HAP and non-HAP emissions.

A commenter (II-D-86) completed a study showing the emission rate from a representative sample of lab hoods was 0.098 lbs VOC/day/hood. This is for a 12 square feet (ft²) hood that has a face velocity of 100 feet per minute (ft/min) for industrial hygiene purposes. This is a flow rate of 1200 cfm. A large facility with hundreds of hoods could exceed 1 million cfm outflow per day. The commenter believed that the high, variable large volume combined with the low concentrations pollutants would make it difficult to effectively reduce the pollutant emissions.

10.0 INFORMATION PROVIDED IN COMMENTS ABOUT R&D FACILITIES

Comment: Thirty-seven commenters (II-D-01, II-D-08, II-D-10, II-D-12, II-D-13, II-D-14, II-D-24, II-D-28, II-D-29, II-D-33, II-D-34, II-D-38, II-D-47, II-D-48, II-D-51, II-D-52, II-D-55, II-D-57, II-D-61, II-D-62, II-D-64, II-D-65, II-D-66, II-D-67, II-D-69, II-D-71, II-D-73, II-D-74, II-D-77, II-D-83, II-D-88, II-D-92, II-D-94, II-D-95, II-D-99, II-D-101, and II-D-104) provided comments describing their research and development facilities.

A commenter (II-D-01) stated that their facilities use only small amounts of HAP. The commenter stated that material balance thresholds indicate that their facilities would only be an area source.

A commenter (II-D-08) stated that they are in the business of testing burners, boilers, processes, and special equipment arrangements for combustion devices. According to the commenter, devices as large as 100 thousand British thermal units per hour (MBtu/hr) are tested to determine boiler scale-up characteristics. The product is accurate data or information used to advance clean coal technologies. The commenter stated that this ultimately would lead to achieving a cleaner environment and attainment of air quality standards, and other environmental criteria. The commenter estimated that in one of their busiest years they operated one of their 50 MBtu/hr boilers only 161.5 hours of a possible 8,760 hrs (1.84 percent). The average firing was only 20.2 MBtu/hr.

A commenter (II-D-10) separated their R&D activities into two categories: laboratory experimentation and pilot plants. The commenter defined laboratory processes to include the study, development, analysis of new and existing flooring products, ceiling products, etc., and coatings for these products.

According to the commenter, laboratory procedures may include small-scale distillations, extractions, pH measurements, mixing, coating, etc. The commenter defined pilot plants to include similar equipment to that found in full-scale facilities, only on a smaller scale. The commenter stated that their pilot plants include coating operations, printing, board and felt making, etc. According to the commenter, pilot plants operate only a few hours per week. The commenter indicated that a wide range of materials are used, some containing HAP. The commenter also indicated that the pilot plant would need to have the ability to emit many other VOC or HAP to do comparative studies to find substitutes for HAP or possibly using other HAP-containing materials that may be emitted at a lower level.

A commenter (II-D-12) indicated that they conduct research in the areas of energy conservation, materials development, magnetic fusion energy, nuclear safety, robotics and programming, biomedical and environmental sciences, medical radioisotope development and basic chemistry and physics. This commenter stated that a computerized teaching system is maintained for all hazardous material purchases. Based on queries of this system, the commenter indicated that they purchase less than 15 tpy of total HAP and no more than 3 tpy of any individual HAP.

A commenter (II-D-13) stated that they have four research and development facilities in three States. According to the commenter, pollution control equipment is often linked to other processes within a commercial operation. The commenter indicated that the operation of control devices used in commercial operations may not be possible in a laboratory or pilot plant scale.

Two commenters (II-D-14 and II-D-94) stated that their power plant has been identified as a major source under the Clean Air Act. The commenters performed a survey to identify additional

air emissions sources. The commenters included an attachment describing the process used to identify these sources. According to the commenters, employees, an outside technical consultant, and an outside legal consultant were involved in preparing a report that identified the sources. The commenters indicated that this report was filed with the State authority.

A commenter (II-D-24) indicated that a typical research facility would process 0.14 percent of a manufacturing operation (12,000 units per month). According to the commenter, the chemical substances utilized are dependent on purchaser demands. The commenter indicated that regulated HAP emissions may include ammonia, diethanolamine, and glycol ethers. The commenter also indicated that the glycol ethers and ammonia are discharged via waste water.

Two commenters (II-D-28) stated that they operate a new Integrated Waste Management Facility (IWMF). According to the commenter, the IWMF is a nationally-recognized, state-of-the-art hazardous waste treatment, storage, disposal facility and chemical recycling and redistribution center. The facility symbolizes the commenter's commitment to pollution prevention and protection of the environment. The commenter also has four major teaching and research campuses and over 50 smaller experiment stations or research centers. The commenter stated that there are approximately 2,500 laboratories and 1,600 fume hoods in the system. According to the commenter, experiments performed in these hoods include inorganic and organic chemistry, lipid research, plant and soil analysis, tissue culturing and analysis, DNA research, etc. The commenter stated that the number of different experiments performed in a month may average approximately 2,000 and these experiments also differ from month to month.

A commenter (II-D-29) stated that they have approximately 1,000 laboratory chemical hoods. According to the commenter, each hood has an exhaust flow ranging from 250 to 1,000 cfm. The commenter also stated that there are an additional 600 other local exhaust systems for storage cabinets, ovens, and specialized equipment. The commenter indicated that these systems have exhaust flows that range from 25 to 500 cfm. The commenter indicated that there are currently no air cleaning devices for these exhaust hoods (with a few exceptions). The commenter stated that the major differences between research laboratories and industrial operations are: (1) laboratories use very small amounts of the substances; (2) laboratories use a wide variety of chemicals; (3) work is performed by or under the supervision of highly trained personnel; and (4) actual chemical handling and manipulation is conducted intermittently throughout the day for short periods of time.

Two commenters (II-D-33 and II-D-48) stated that their R&D facilities range from micro reactors, to bench-top operations, to pilot plants. The commenters indicated that micro reactors and most bench-scale units fit inside a lab or fume hood. According to the commenters, micro reactors have flow rates that range from 50 to 100 milliliters per hour. The commenters stated that pilot plants are scaled down to the smallest size that can produce viable results. According to the commenters, the scale is often 1 to 1,000,000. The commenters stated that process pilot plants have process flow rates in the range of 1 barrel/hour (bbl/hr) of oil to several bbl/hr (a full scale plant would have a flow rate of thousands of bbl/hr).

A commenter (II-D-48) stated that their largest pilot plant has a throughput of 1 to 2 barrels per day (bbl/day) as compared to 15,000 barrels per day for a similar commercial plant. The commenter stated that the largest process line is 9/16 inches in

diameter. The commenter indicated that typically 2/3 of the pilot plants operate 75 to 85 percent of the time and one-third operate less than 50 percent of the time. The commenter stated that the pilot plants are designed to gather detailed and precise information, such as material and energy balances. The commenter stated that the pilot plants are constructed to prevent losses of reactants and products. The commenter further stated that pilot plants use instruments to continuously monitor flow rates, pressure, temperature, etc. According to the commenter, these pilot plants are closely monitored because R&D experiments are expensive to run. The commenter noted that losses of even a few grams of material during a run could invalidate the data.

A commenter (II-D-34) stated that their R&D facilities typically have a large number of process vents and low, very changeable emissions. The commenter indicated that it is not unusual for an R&D facility to have over 300 vents. According to the commenter, depending on the research, the type of chemicals used changes from day to day. The commenter noted that it would not be feasible to change the controls as the research progresses. The commenter described each successive R&D activity as being highly dependent on the outcomes of the previous steps. The commenter further stated that this makes predicting specific steps/activities difficult. The commenter also noted that within the aerospace industry, they are already moving toward the use of low HAP and VOC coatings and solvents.

A commenter (II-D-38) stated that they own several R&D facilities in support of pharmaceuticals, medical, dental, adhesives, commercial graphics, tape, abrasives, imaging, specialty chemicals, etc. According to the commenter, the R&D operations fall under 20 or more different two-digit SIC codes. The commenter was concerned that if all collocated sources must be considered as one source regardless of SIC Code, the

commenter's R&D facilities would be considered a major source under § 112. The commenter noted, however, that if MEK is delisted, it is likely that their R&D activities would no longer be a major source of HAP. The commenter stated that their research is conducted to develop new processes and products. The commenter indicated that research units include bench-top, smaller than bench-scale, and small scale-up laboratory experiments. The commenter stated that researchers deal with small batches, hand mixing, and experimental materials. The commenter provided a list of over 140 different units used in R&D. The commenter noted that these units are considered insignificant under the State of Minnesota air regulations.

In 1996, the commenter generated nearly 30 percent of sales from products introduced within the previous four years. The commenter also invested almost 7 cents of every sales dollar in R&D and laboratory efforts. According to the commenter, a significant portion of their R&D efforts are tied to research in environmentally improved products and pollution prevention. The commenter mentioned that over the past 20 years, the pollution prevention program eliminated over 1.3 billion pounds of waste. The commenter also pointed out that new environmentally improved products developed in the R&D facilities include water based contact and other adhesives, replacements for ozone-depleting cleaning solvents, and chlorofluorocarbon (CFC)-free metered dose inhalers.

The commenter also indicated that they have developed and implemented a Chemical Hygiene Plan as required by OSHA. The plan is a part of the commenter's manual determining safe practices in the laboratory. According to the commenter, the guide establishes procedures, control measures, protective equipment and work practices that are capable of protecting employees from health hazards presented by hazardous chemicals

used at the commenter's facilities. The commenter believed that the practices and procedures established in the guide significantly reduce HAP emissions.

The commenter stated that they have developed a "Hazardous Air Pollutants Bulletin." The bulletin has been distributed within the commenter's facility and will soon be available electronically. The first sentence of the bulletin states that researchers should "avoid the use of hazardous air pollutants where possible."

A commenter (II-D-47) was concerned because they own and operate a Research and Development facility that may be affected by the proposed rule.

A commenter (II-D-51) was concerned that a breakdown of all chemicals found in reagents would not always be available from either the material safety data sheet (MSDS) or the manufacturer. The commenter indicated that less than one-fifth of the various reagents at one of their facilities are single chemicals. The commenter also noted that there are more than 100,000 different reagents used at that facility. According to the commenter, R&D operations at pilot plants may run 10 to 15 product candidates per year. The commenter stated that each candidate is varied countless times during the year and each candidate may take 5 to 10 process steps. The commenter stated that the raw materials differ from process step to process step. The commenter further explained that operations consist of 8 to 12 batch process steps per week. The commenter also noted that the total number of batches can be between 400 and 600 batches per year.

A commenter (II-D-52) was concerned that under the multiple source category approach, one facility might be subject to one MACT standard for R&D activities associated with the aircraft industry and the same facility might also be subject to the MACT

standard for R&D activities associated with the steam turbine industry.

A commenter (II-D-55) stated that their member companies utilize batch processes. The commenter stated that many member companies are custom chemical manufacturers who produce specialty chemicals by contracting with larger companies. The commenter stated that batch processing provides an efficient method to make small quantities of chemicals to meet specific needs and demands for specialized products. The commenter stated that batch processors provide products often made nowhere else in the world and keep imports down by responding quickly to customer demands.

The commenter noted that batch processes are distinct from continuous operations. The commenter defined a continuous operation as having a constant raw material feed to and continual product withdrawal from each unit operation. The commenter defined a batch process as having an intermittent introduction of frequently changing raw material into the process, varying process conditions imposed on the process within the same vessel, and an intermittent release of air emissions. The commenter indicated that batch process vessels are usually idle while waiting for raw materials, waiting for quality control checks, and undergoing cleaning, etc. The commenter also noted that the emissions from a batch process are substantially different from a continuous process.

A commenter (II-D-57) stated that they were a large research and educational institution. The commenter's institution has approximately 900 laboratory hoods, located in 1,500 laboratories. The commenter indicated that a significant number of these units are involved in R&D activities. The commenter also stated that these laboratories are used in teaching, medical and testing research.

A commenter (II-D-61) stated that they are a research-based pharmaceutical company that discovers, develops, manufactures, and markets innovative medicines. The commenter indicated that one of their largest sites serves as the main R&D facility. According to the commenter, this site is currently regulated under the North Carolina Air Toxics program.

A commenter (II-D-62) indicated that at their facility, the majority of R&D work consists of bench scale laboratory work. The commenter stated that it was not a major HAP source, but could be classified as an area source if it were determined to present a threat of adverse effects to human health or the environment.

A commenter (II-D-64) stated that they are an academic institution. According to the commenter, R&D activities in an academic setting are typically limited to the "laboratory bench" scale. The commenter stated that small volumes of many different chemicals are handled by researchers. The commenter indicated that chemicals reside in closed containers or systems except for when they are being used. The commenter also noted that only a small fraction of the chemicals handled in a laboratory have the opportunity to volatilize. The commenter described the exhaust systems as being older than 10 to 15 years. and that each fume hood is ducted to the building roof.

A commenter (II-D-65) stated that their R&D facility has emissions composed primarily of VOC and NO_x. According to the commenter, most processes on site operate for a short duration on fluctuating schedules.

A commenter (II-D-66) indicated that university research or laboratory facilities cannot be separated into R&D, teaching, analytical, or medical laboratories as has been suggested. The commenter stated that these activities usually occur in the same laboratory, often simultaneously.

A commenter (II-D-67) stated that they operate two large R&D facilities. The commenter indicated that one of the facilities is stand-alone and one is collocated with a polymer manufacturing facility. The commenter also has several operational support laboratories.

A commenter (II-D-69) indicated that R&D operations in the chemical industry involve the use of small quantities of chemicals. The commenter stated that quantities are kept small because cost of equipment and chemicals is proportional to size. The commenter stated that experimentation on a small scale minimizes cost and safety risks without jeopardizing the results. According to the commenter, replicate runs are performed to prove scientific theory. The commenter noted that pilot plant or mini-plant scale is the next step to successful experiments prior to normal or commercial scale.

A commenter (II-D-71) stated that their R&D operations are a combination of small bench scale and pilot plant activities. According to the commenter, a small fraction of bench scale work usually progresses to the pilot plant scale. The commenter also noted that some bench scale work is parallel to the pilot scale work. According to the commenter, R&D operations exist to invent new materials and design commercial scale processes. The commenter stated, however, that these operations are designed to use as little resources as possible, and to generate as much useful data as possible. The commenter further noted that it is common for a pilot plant in the R&D operations to operate for as little as 160 hours in four months and then be discontinued.

A commenter (II-D-73) provided a table summarizing emissions data from several R&D laboratories. In the table, the commenter presented types of labs which include academic, basic science, medical research, DOE research, pharmaceutical, organic chemistry, analytical chemistry, and molecular biology. The

commenter gathered information on emissions data from interviews with various personnel, purchase record review, gas studies, emission factors, statistical analyses, stack sampling, and mass balances. The commenter provided emissions estimates for the following pollutants: California Air Toxics, VOC, benzene, chloroform, CCl₃H, dioxane, HCOH, and DCM.

A commenters (II-D-74) stated that they operate R&D programs that are part of a high-temperature gas dynamics laboratory that conducts research on combustion by-products for the development of improved combustion controls. According to the commenter, this process is not operating due to the difficulty and expense of retrofitting existing buildings to meet the State air pollution codes.

A commenter (II-D-77) stated that approximately 1,500 individual research grants in 96 academic areas were awarded in 1995. According to the commenter, approximately 60 of these academic areas would be subject to the proposed rules. The commenter stated that these 60 areas include about 1,000 research laboratories, each having one to 12 students and staff working on unique projects.

Two commenters (II-D-77 and II-D-94) provided information about the sources of academic research project funding and how it contrasts manufacturing R&D. One commenter (II-D-77) stated that 70 percent of their sponsored research was funded by federal dollars. One commenter (II-D-94) stated that 64 percent of their sponsored research was funded by federal dollars. According to the commenter, this is not atypical of a large academic institution. The commenter remarked that this federal funding separates R&D operations at academic institutions from manufacturing R&D. The commenter further remarked that manufacturing R&D is typically sponsored by the private entity that would see economic gains from the results of the research.

Two commenters (II-D-83 and II-D-95) provided an excerpt from the Congressional Record in which R&D facilities were discussed. In the excerpt, it was indicated that R&D facilities have a large number of process vents, and low and changeable emissions. According to the speaker, it would not be unusual for such a facility to have more than 300 vents that would have to be controlled and permitted. The speaker felt that permitting and controlling these emissions would be virtually impossible since it would require the operator to predict what chemicals may be used or emitted during the permit period. The speaker also felt it was not feasible to change the control technologies as the research progresses.

A commenter (II-D-88) provided an illustration of a metal finishing R&D procedure. According to the commenter, a classic illustration of the scale of R&D activities in the surface finishing industry is that of "running a hull cell." The commenter described the experiment as using a trapezoidal beaker and a half-pint of solution. The commenter further stated that this experiment was designed to evaluate the electrodeposition process. The commenter stated that temperature, current density, additives, and variations of concentrations and chemistry are observed during the experiment to determine their effects on metal surfaces. The commenter felt that the level of risk to public health or the environment due to this type of experiment is negligible.

A commenter (II-D-92) stated that they operate over 2,000 separate laboratories. The commenter indicated that the work in each of these laboratories is managed by an individual who is responsible for the experimental design, selection of appropriate chemical reagents, and conducting the experiments, etc. According to the commenter, the activities in these laboratories are not conducted in support of any commercial process. The

commenter stated that the laboratories are designed to support teaching and research goals.

A commenter (II-D-99) stated that they are a medium sized biomedical research and educational institution with approximately 210 hoods located in 300 laboratories. The commenter indicated that a significant number of the laboratories are involved in clinical and basic research or laboratory activities.

Two commenters (II-D-101 and II-D-104) stated that they are a large research and educational institution with approximately 800 laboratory fume hoods located in 1,750 laboratories.

11.0 OTHER COMMENTS

11.1 State/Federal Judicial and Legislative Decisions

Comment: Seventeen commenters (II-D-10, II-D-20, II-D-22, II-D-23, II-D-30, II-D-46, II-D-57, II-D-59, II-D-61, II-D-62, II-D-64, II-D-65, II-D-67, II-D-69, II-D-74, II-D-79, and II-D-95) provided information on State regulations. Two commenters (II-D-10 and II-D-30) stated that R&D facilities are covered by current State permitting requirements. One commenter (II-D-67) stated that States have traditionally exempted R&D facilities from permit requirements. One commenter (II-D-20) stated that emissions from R&D operations (including QA/QC operations) are covered in their facility permits, usually as "insignificant sources."

Two commenters (II-D-10 and II-D-65) referred to the rules in Pennsylvania. One commenter (II-D-10) stated that, in the past, the Pennsylvania Department of Environmental Protection (PADEP) has considered pilot plants exempt from individual permitting and plan approval because of their low actual emissions. One commenter (II-D-65) referred to the PADEP exemptions which states that "approval is not required for the construction, modification, reactivation, or installation of the following ... Laboratory equipment used exclusively for chemical or physical analysis."

Two commenters (II-D-22 and II-D-79) referred to the State of California Toxic Air Contaminants Act and the Air Toxics Hot Spots Act. According to the commenters, no California air district has deemed a University of California campus or UC-operated National Laboratory a significant risk. The commenters stated that under the Air Toxics Hot Spots and district rules, the UC campus and National Laboratories have never been required

to do a risk reduction audit and plan. The commenters also stated that risk assessments completed for the Environmental Impact Reports (required by the State of California) for campus long range development plans have shown a low risk from laboratory air emissions. The commenters recommended the EPA develop a method for estimating emissions to allow for a quick and economical method of determining whether facilities would be major or area sources. The commenters further suggested that the EPA use information from existing reporting requirements to screen out facilities that are not major sources and for determining the appropriate level of regulation.

Three commenters (II-D-23, II-D-59, and II-D-95) stated that State Implementation Plans (SIPs) have long recognized the differences between R&D activities and manufacturing facilities. The commenters further stated that the EPA has reviewed and approved these differences. The commenters referred to the following SIPs that have exemptions for R&D facilities: (1) Pennsylvania - exempting from permit requirements, facility equipment used exclusively for chemical or physical analysis; (2) Illinois - exempting from permit requirements, facility equipment used exclusively for chemical or physical analysis; and (3) New Jersey - exempting from permits, processes utilizing less than 50 lb/hr of material. The commenters stated that these exemptions result from the unique operational and emissions characteristics.

A commenter (II-D-46) stated that in West Virginia, very small changes in R&D emissions trigger State minor source review requirements. Under West Virginia Office of Air Quality Regulation 13, any physical or operational change in emissions resulting in an increase of 2 lb/hr or 5 tpy requires a permit. Regulation 13 is a part of the SIP and is federally enforceable. The commenter felt that current West Virginia air permitting rules are adequate to address R&D issues on a localized basis.

Two commenters (II-D-57 and II-D-79) stated that the Massachusetts Department of Environmental Protection (MDEP) has a federally approved Operating Permit program. The commenters recommended that the EPA exempt the laboratory hood systems referenced in the MDEP Operating Permit program regulations.

A commenter (II-D-61) stated that the North Carolina Division of Air Quality has recently proposed exempting laboratory activities associated with chemical and physical analysis from the air toxics program.

A commenter (II-D-62) stated that the State of Illinois rules have classified bench-scale laboratory work categorically as an insignificant emission source.

A commenter (II-D-64) referred to the State of Connecticut air rules that regulate 850 HAP. According to the rules, stack emissions from all sources must be below the maximum acceptable stack concentration (MASC) for each HAP. The MASC is based on the height and location of the stack and the hazard limiting values (HLV) of the chemical. The HLVs are the highest acceptable concentration in the ambient air at the facility's property line and are set at 1/100 or 1/1000 of the occupational exposure limits.

A commenter (II-D-69) stated that Michigan and Kentucky have regulations that exempt R&D facilities from criteria pollutant and air toxic regulations.

Two commenters (II-D-74 and II-D-79) referred to the Toxic Gas Ordinance (TGO) implemented by the County of Santa Clara, CA. The commenters presented the ordinance as an example of a program that illustrates the adverse impact of a well intentioned program when applied to research and laboratory operations. The TGO was intended to regulate the use of toxic gases throughout the county and to serve as a model for the State of California. The TGO mandates the use of engineering and administrative controls

through a permit process for each research experiment. Research laboratories were covered by this regulation. The commenters have spent over \$6 million retrofitting three research buildings. Other toxic gas users have curtailed their use of some materials to meet the exemptions, thereby affecting their research. The TGO has also added approximately \$2 million to the cost of each new research building where toxic gases are used in above exempt quantities.

Comment: A commenter (II-D-08) supported the exemptions in the NSPS for new, modified, and reconstructed small industrial-commercial-institutional steam generating units (40 CFR part 60, subpart Dc). According to the commenter, combustion research units are exempt from the NSPS. Also exempt from regulation under the NSPS are those steam generating units that otherwise meet the applicability requirements of the subpart during periods of combustion research, noting that any temporary change to an existing steam generating unit for the purpose of conducting combustion research is not considered a modification. According to the EPA, research units are exempt because these units provide valuable data on the combustion process and methods of air pollution control.

Comment: Two commenters (II-D-26 and II-D-102) referred to Executive Order (EO) 12866 and the Small Business Regulatory Flexibility Act (SBRFA). As stated in EO 12866(a), "in deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating." The commenters stated that the EPA must consider the requirements of EO 12866 and SBRFA before proceeding to list R&D facilities as a NESHAP source category.

Comment: Fifteen commenters (II-D-17, II-D-28, II-D-29, II-D-31, II-D-33, II-D-34, II-D-48, II-D-49, II-D-53, II-D-58, II-D-66, II-D-59, II-D-79, II-D-93, and II-D-103) referred to federal programs, such as the OSHA Laboratory Standard, SARA Inventory and Reporting, and RCRA - Hazardous Waste and Waste Minimization, Mass TURA - Massachusetts Toxic Use Reduction Act. According to one commenter (II-D-29), all of these regulations, as they pertain to research laboratories, require a high level of control on the use of chemicals including training on handling and disposal. The regulations also require implementation of a program of waste minimization and reduction of the use of toxic chemicals. The commenter also referred to a consensus standard such as ANSI Z9.5 - Laboratory Ventilation. This standard provides guidelines for laboratory ventilation exhaust stack design to minimize risk to occupants of the laboratory building and surrounding buildings.

Two commenters (II-D-33 and II-D-48) stated that SARA 313 has both laboratory operations and product testing exemptions. The manufacture, process, or use of chemicals in a laboratory setting under the supervision of a qualified individual is exempt from the 313 reporting requirements. Also covered are support activities.

Seven commenters (II-D-17, II-D-31, II-D-49, II-D-53, II-D-58, II-D-66, and II-D-69) referred to OSHA's Laboratory Standard, to which most laboratories are subject. The Laboratory Standard requires facilities to prepare and maintain a written Chemical Hygiene Plan which governs appropriate handling of chemicals to control airborne releases and protect employees from exposure. One commenter (II-D-17) indicated that academic research facilities are laboratories as defined by OSHA. One commenter (II-D-31) stated that these best management practices reduce potential emissions.

Five commenters (II-D-28, II-D-48, II-D-79, II-D-93, and II-D-103) referred to the RCRA's impact on laboratories. Four commenters (II-D-28, II-D-79, II-D-93, and II-D-103) stated that RCRA requires all regulations applying to industry be required of educational labs. According to the commenters, the EPA is currently working with various agencies to accommodate the special needs of laboratories under RCRA regulations. One commenter (II-D-48) cited federal treatability study exemptions under RCRA. According to the commenter, these exemptions are a recognition that RCRA permitting is not appropriate for research-type treatability studies, and would act as a deterrent in finding cost-effective solutions to waste treatment and disposal problems.

Four commenters (II-D-33, II-D-34, II-D-48, and II-D-49) referred to a Toxic Substances Control Act (TSCA) exemption, excluding R&D activities from the need to submit a premanufacture notification. This exemption is applicable if manufacturing or processing small quantities solely for research and development. This exemption applies as long as employees are notified of any potential health risk and the chemical substance is used by or under the supervision of a technically qualified individual. Similarly, manufacturers or importers of chemicals used for research or scientific experimentation are exempt from the requirement to submit preliminary assessment information.

Comment: Nineteen commenters (II-D-12, II-D-16, II-D-26, II-D-28, II-D-32, II-D-33, II-D-34, II-D-35, II-D-41, II-D-64, II-D-76, II-D-79, II-D-83, II-D-91, II-D-93, II-D-101, II-D-102, II-D-103, and II-D-104) referred to the preamble to the August 31, 1995, proposed rule dealing with the applicability of title V to R&D facilities. The commenters indicated that the language in preamble supports not listing R&D as a source

category. The commenters quoted the preamble in which the EPA states that "in light of the previously mentioned difficulty of performing emission calculations and the data gathered by the EPA to date, which indicates that even large R&D facilities tend to have very low emissions, the EPA considers it of little benefit to require R&D facilities to go through extensive efforts in calculating PTE," and that there is a "small likelihood that any R&D operation will be major." The EPA further stated that "emissions of R&D activities are unpredictable but low, emissions are difficult and costly to estimate, and few applicable requirements typically apply" and that it "is not aware of any existing substantive control requirements...that apply to R&D activities." The EPA also stated that "...R&D may present a case suitable for the *de minimis* exception from the statutory requirement to calculate PTE, because emissions are so low as to yield a gain of trivial or no value compared to the difficulty associated with their measurements." In addition, the preamble states that § 112(c)(7) "clearly evidences a concern that R&D operations not be grouped with other types of operations in a way that overlooks the particular challenges associated with their regulation." The EPA also recognizes that the operations at R&D facilities "entail the use of small quantities of chemicals manipulated and released in a highly variable manner." The Agency also stated that "R&D operations should not generally be considered support facilities, since the 'support' provided is directed towards development of new processes or products and not to current production." In the proposed rule, the Agency further states: "Today's notice proposes to establish a narrow exception for R&D facilities. Because the major source definitions used under title V must be consistent with other Act programs, the EPA plans to follow this revision to part 70 with conforming

revisions to the major source definition in the § 112 general provisions and other § 112 rules."

Eleven commenters (II-D-12, II-D-34, II-D-38, II-D-56, II-D-57, II-D-69, II-D-79, II-D-80, II-D-83, II-D-85, and II-D-104) referred to the White Paper for Streamlined Development of Part 70 Permit Applications. In this document, the EPA discusses R&D and other laboratory activities and their relationship to title V. The commenters endorsed the Agency's position in this policy memorandum. According to the EPA, there is no need for an extensive inventory of chemicals and activities or a detailed description of emissions from the R&D or laboratory activity. The EPA also stated that SIP requirements usually consist of work practice requirements and permit applications need to contain statements acknowledging the applicability of, and certifying compliance with, these requirements. There is no need to inventory chemicals and activities or to provide a detailed description of emissions from the R&D or laboratory activity, and there is no need to monitor emissions as a part 70 permit responsibility. The EPA lists "bench-scale laboratory equipment used for physical or chemical analysis" as an activity that may be treated as "trivial."

Five commenters (II-D-32, II-D-51, II-D-52, II-D-55, and II-D-60) endorsed the May 14, 1997 Draft Final Part 70 Revisions Package. In this package, the EPA proposed to address key issues, such as defining *de minimis* and calculating PTE, by remaining silent and allowing states the flexibility to develop and implement State-specific definitions and methods. This proposal also would aggregate emissions from R&D facilities with those of a collocated source for purposes of determining major source status and applicability under § 112, but would not aggregate them for purposes of part 70 applicability.

A commenter (II-D-44) referred to the June 3, 1997 draft part 70. The commenter endorsed the draft part 70, that proposes a new definition for "research and development activities" that would include "theoretical research" and "research and development into new or improved processes and products."

A commenter (II-D-65) endorsed The Operating Permit Program, Final Rule, published on July 21, 1992. In the definition of major source, the EPA states that "...in many cases, States will have the flexibility to treat an R&D facility as separate from the manufacturing facility with which it is located. Under such an approach, the facility would be treated as though it were a separate source, and would be required to have a title V permit only if the R&D facility itself would be major source." Also under this rule, all non-major sources are exempt (except for affected sources and solid waste incineration) from the requirement to obtain a permit, until the EPA completes the rulemaking on applying the permitting program to non-major sources.

Comment: A commenter (II-D-102) stated that before issuing proposed or final rules, the EPA must comply with the following regulatory requirements: (1) Regulatory Flexibility Act - requires the EPA to prepare a regulatory flexibility analysis for proposed and final rules, unless the Agency certifies that the rule will have no significant economic impact on a substantial number of small entities; (2) SBRFA - requires the EPA assure small entities the opportunity to participate in the development of rules that affect them; (3) Executive Order 12866 - requires the EPA to subject any "significant" rule to OMB for its review and to prepare and publish a Regulatory Impact Analysis that assess the costs and benefits of the proposal, including potential alternatives; (4) UMRA - requires the EPA to assess the

effects of regulations on government entities and on the private sector; and (5) Paperwork Reduction Act - requires the EPA to evaluate and minimize the burden that its reporting and recordkeeping requirements will impose on regulated entities.

Comment: Four commenters (II-D-57, II-D-79, II-D-101, and II-D-104) felt that the EPA should play a strong leadership role in the development of regulations. The commenters referred to the President's and Vice President's March 16, 1995 report, "Reinventing Environmental Regulation." According to the commenters, while recognizing that the initiative contained in the report places an emphasis on a shift in responsibilities to State and local agencies, it should be noted that air pollution is often not limited to geographic or political boundaries and is therefore difficult to regulate as such to meet air quality objectives. The commenters remarked that air pollution is highly mobile and poses a greater number of trans-boundary concerns. The commenters also felt that individual State priorities may not address inter-state or regional air pollution concerns. In this context, the commenters specifically requested that the EPA clarify which sources would be included in the R&D source category, how PTE would be calculated, and how these sources would be regulated.

11.2 Extension of the Comment Period

Comment: Nine commenters (II-D-02, II-D-05, II-D-06, II-D-14, II-D-17, II-D-18, II-D-107, II-D-109, and II-D-110) requested an extension of the comment period. One commenter (II-D-36) was not prepared to provide formal comments, but requested that they be notified of any proposed regulations and to be included in any rule development discussions or stakeholder meetings.

Two commenters (II-D-02 and II-D-05) requested that an additional thirty days be allowed for comment. One commenter (II-D-02) felt that large corporations would not have enough time to identify the people to participate in the commenting, and to get the comments written, through a review process and to the EPA. The commenter stated that the allowed thirty days included a Federal holiday. The commenter also stated that they have other EPA activities that demand their attention. The commenter felt that they could not devote their full attention on this R&D issue. The commenter was not aware of any obstacles to extending the comment deadline. One commenter (II-D-05) stated that they would like to provide comments on several issues raised in the notice. The commenter felt that an extension would result in a more focused and useful comment on the notice.

Seven commenters (II-D-06, II-D-14, II-D-17, II-D-18, II-D-107, II-D-109, and II-D-110) requested a 60-day extension of the comment period. One commenter (II-D-06) referred to their large number of facilities that would be potentially impacted by the R&D regulations. The commenter stated that the current deadline would not allow enough time for development of information and materials relevant to issues in the ANPR. Two commenters (II-D-14 and II-D-18) stated that 30 days was not sufficient to allow the opportunity to gather member consensus and comment to the EPA. Four commenters (II-D-17, II-D-107, II-D-109, and II-D-110) requested more time to gather information and review the implications of regulations in the R&D area before providing comments.

11.3 Unique Comments

Comment: One commenter (II-D-28) referred to EPA's comments in the Draft Final Rule 70 Operating Permits, May 14, 1997 (Vol.

62, Number 91, FR, pp. 25877-25879). According to the commenter, these comments could be interpreted to mean that not all academic activities are considered R&D activities. The commenter felt that all academic activities should be granted R&D activity status because their variable nature is similar to industrial R&D activities. The commenter remarked that educational laboratories should be given the same proposed exemptions as industrial R&D laboratories. The commenter stated that activities in educational laboratories are even more variable and difficult to track than industrial R&D labs. The commenter further stated that teaching and research activities rotate and change on a very frequent basis.

Comment: One commenter (II-D-84) stated that the regulation of R&D facilities should be broadened to require the emission controls for extremely bioactive compounds and chemicals with unknown toxic potential.