ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2004-0305; FRL-9263-2]

RIN 2060-AQ43

National Emission Standards for Hazardous Air Pollutants: Primary Lead Smelting

AGENCY: Environmental Protection

Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing amendments to the national emission standards for hazardous air pollutants (NESHAP) for Primary Lead Smelting to address the results of the residual risk and technology reviews conducted as required under sections 112(d)(6) and (f)(2) of the Clean Air Act (CAA). These proposed amendments include revisions to the emission limits for lead, the addition of a lead concentration in air standard, and the modification and addition of testing and monitoring and related notification, recordkeeping, and reporting requirements. We are also proposing to revise provisions addressing periods of startup, shutdown, and malfunction to ensure that they are consistent with a recent court decision. Finally, we are proposing revisions to the rule's applicability provision to make it consistent with the definition of the source category and proposing other minor technical changes to the standard. We are also responding to a petition for rulemaking filed on the standard with regard to lead as a surrogate and regulation of volatile organic compounds (VOC) and acid gases.

DATES: Comments must be received on or before April 4, 2011. Under the Paperwork Reduction Act, comments on the information collection provisions are best assured of having full effect if the Office of Management and Budget (OMB) receives a copy of your comments on or before March 21, 2011.

Public Hearing. If anyone contacts EPA requesting to speak at a public hearing by February 28, 2011, a public hearing will be held on March 4, 2011.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-HQ-OAR-2004-0305, by one of the following methods:

- http://www.regulations.gov: Follow the on-line instructions for submitting comments.
- E-mail: a-and-r-docket@epa.gov, Attention Docket ID Number EPA-HQ-OAR-2004-0305.

- Fax: (202) 566–9744, Attention Docket ID Number EPA-HQ-OAR-2004-0305.
- Mail: U.S. Postal Service, send comments to: EPA Docket Center, EPA West (Air Docket), Attention Docket ID Number EPA-HQ-OAR-2004-0305, U.S. Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of two copies. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.
- Hand Delivery: U.S. Environmental Protection Agency, EPA West (Air Docket), Room 3334, 1301 Constitution Ave., NW., Washington, DC 20004, Attention Docket ID Number EPA-HQ-OAR-2004-0305. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions. Direct your comments to Docket ID Number EPA-HQ-OAR-2004-0305. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at http:// www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http:// www.regulations.gov or e-mail. The http://www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through http:// www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information

about EPA's public docket, visit the EPA Docket Center homepage at http://www.epa.gov/epahome/dockets.htm.

Docket. The EPA has established a docket for this rulemaking under Docket ID Number EPA-HQ-OAR-2004-0305. All documents in the docket are listed in the http://www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy. Publicly available docket materials are available either electronically in http:// www.regulations.gov or in hard copy at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the EPA Docket Center is $(202)\ 566-1742.$

Public Hearing. If a public hearing is held, it will begin at 10 a.m. on March 4, 2011 and will be held at EPA's campus in Research Triangle Park, North Carolina, or at an alternate facility nearby. Persons interested in presenting oral testimony or inquiring as to whether a public hearing is to be held should contact Ms. Virginia Hunt, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Metals and Minerals Group (D243-02), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-0832.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Ms. Sharon Nizich, Sector Policies and Programs Division (D243-02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone (919) 541–2825; fax number: (919) 541– 5450; and e-mail address: nizich.sharon@epa.gov. For specific information regarding the risk modeling methodology, contact Ms. Elaine Manning, Health and Environmental Impacts Division (C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-5499; fax number: (919) 541-0840; and e-mail address: manning.elaine@epa.gov. For information about the applicability of

the NESHAP to a particular entity,

contact the appropriate person listed in Table 1 to this preamble.

SUPPLEMENTARY INFORMATION:

TABLE 1—LIST OF EPA CONTACTS FOR THE NESHAP ADDRESSED IN THIS PROPOSED ACTION

NESHAP for:	OECA contact ¹	OAQPS contact ²
Primary Lead Smelting	Maria Malave, (202) 564-7027, malave.maria@epa.gov	Sharon Nizich, (919) 541–2825, nizich.sharon@epa.gov.

¹ EPA's Office of Enforcement and Compliance Assurance.

I. Preamble Acronyms and Abbreviations

Several acronyms and terms used to describe industrial processes, data inventories, and risk modeling are included in this preamble. While this may not be an exhaustive list, to ease the reading of this preamble and for reference purposes, the following terms and acronyms are defined here:

ADAF Age-dependent Adjustment Factors AERMOD Air dispersion model used by the HEM–3 model

AEGL Acute Exposure Guideline Levels ANPRM Advance Notice of Proposed Rulemaking

BACT Best Available Control Technology CAA Clean Air Act

CBI Confidential Business Information CEEL Community Emergency Exposure Levels

CEMS Continuous Emissions Monitoring System

CERMS Continuous Emission Rate Monitoring System

CFR Code of Federal Regulations EJ Environmental Justice

EPA Environmental Protection Agency ERPG Emergency Response Planning Guidelines

HAP Hazardous Air Pollutants HI Hazard Index

HEM-3 Human Exposure Model version 3 HON Hazardous Organic National Emissions Standards for Hazardous Air

Emissions Standards for Hazardous Air Pollutants

HQ Hazard Quotient

IRIS Integrated Risk Information System
Km Kilometer

LAER Lowest Achievable Emission Rate LOAEL Lowest Observed Adverse Effect Level

MACT Maximum Achievable Control Technology

MACT Code Code within the NEI used to identify processes included in a source category

MIR Maximum Individual Risk NAAQS National Ambient Air Quality Standard

NAC/AEGL Committee National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances

NAICS North American Industry Classification System

NAS National Academy of Sciences NATA National Air Toxics Assessment NESHAP National Emissions Standards for

Hazardous Air Pollutants NEI National Emissions Inventory NOAEL No Observed Adverse Effects Level NRC National Research Council NTTAA National Technology Transfer and Advancement Act

OAQPS EPA's Office of Air Quality Planning and Standards

OECA EPA's Office of Enforcement and Compliance Assurance

OMB Office of Management and Budget
PB-HAP Hazardous air pollutants known to
be persistent and bio-accumulative in the
environment

POM Polycyclic Organic Matter RACT Reasonably Available Control Technology

RBLC RACT/BACT/LAER Clearinghouse

RFA Regulatory Flexibility Act

RfC Reference Concentration

RfD Reference Dose

RTR Residual Risk and Technology Review

SAB Science Advisory Board

SBA Small Business Administration

SCC Source Classification Codes

SF3 2000 Census of Population and Housing Summary File 3

SIP State Implementation Plan

SOP Standard Operating Procedures

SSM Startup, Shutdown, and Malfunction TOSHI Target Organ-Specific Hazard Index TPY Tons Per Year

TRIM Total Risk Integrated Modeling System

TTN Technology Transfer Network UF Uncertainty Factor

UMRA Unfunded Mandates Reform Act URE Unit Risk Estimate

VOC Volatile Organic Compounds

VOHAP Volatile Organic Hazardous Air Pollutants

WWW Worldwide Web

Organization of this Document. The following outline is provided to aid in the location of information in this preamble.

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II. General Information

A. Does this action apply to me?

The regulated industrial source category that is the subject of this proposal is listed in Table 2 to this preamble. Table 2 is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this proposed action for the source categories listed. This standard, and any changes considered in this rulemaking, would be directly

²EPA's Office of Air Quality Planning and Standards.

applicable to sources as a Federal program. Thus, Federal, State, local, and tribal government entities are not affected by this proposed action. As defined in the source category listing report published by EPA in 1992, the Primary Lead Smelting source category is defined as any facility engaged in producing lead metal from ore concentrates; including, but not limited

to, the following smelting processes: sintering, reduction, preliminary treatment, and refining operations. As discussed in section III. (C)(3), to be consistent with the 1992 listing, EPA is proposing to change the applicability of the Primary Lead Smelting NESHAP to apply to any facility that produces lead metal from lead ore concentrates. Although the source category name in

the 1992 listing will remain Primary Lead Smelting (as in 1992 listing) we are proposing to change the title of the rule to refer to Primary Lead Processing. For clarification purposes, all references to lead emissions in this preamble means "lead compounds" (which is a HAP) and all reference to lead production means elemental lead (which is not a HAP) as provided under CAA 112(b)(7)).

TABLE 2—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS PROPOSED ACTION

Source category	NESHAP	NAICS code 1	MACT code ²
Primary Lead Smelting	Primary Lead Processing	331419	0204

¹ North American Industry Classification System.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this proposal will also be available on the World Wide Web (WWW) through the Technology Transfer Network (TTN). Following signature by the EPA Administrator, a copy of this proposed action will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules at the following address: http://www.epa.gov/ttn/atw/rrisk/rtrpg.html. The TTN provides information and technology exchange in various areas of air pollution control.

Additional information is available on the residual risk and technology review (RTR) Web page at http://www.epa.gov/ttn/atw/rrisk/rtrpg.html. This information includes source category descriptions and detailed emissions and other data that were used as inputs to the risk assessments.

C. What should I consider as I prepare my comments for EPA?

Submitting CBI. Do not submit information containing CBI to EPA through http://www.regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for

inclusion in the public docket. If you submit a CD ROM or disk that does not contain CBI, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. Send or deliver information identified as CBI only to the following address: Roberto Morales, OAQPS Document Control Officer (C404–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID Number EPA-HQ-OAR-2004-0305.

III. Background

A. What is the statutory authority for this action?

Section 112 of the Clean Air Act (CAA) establishes a two-stage regulatory process to address emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, after EPA has identified categories of sources emitting one or more of the HAP listed in section 112(b) of the CAA, section 112(d) of the CAA calls for us to promulgate NESHAP for those sources. "Major sources" are those that emit or have the potential to emit 10 tons per year (TPY) or more of a single HAP or 25 TPY or more of any combination of HAP. For major sources, these technology-based standards must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts) and are

commonly referred to as maximum achievable control technology (MACT) standards.

MACT standards must require the maximum degree of emission reduction through the application of measures, processes, methods, systems, or techniques, including, but not limited to, measures which (A) Reduce the volume of or eliminate pollutants through process changes, substitution of materials or other modifications; (B) enclose systems or processes to eliminate emissions; (C) capture or treat pollutants when released from a process, stack, storage, or fugitive emissions point; (D) are design, equipment, work practice, or operational standards (including requirements for operator training or certification); or (E) are a combination of the above. CAA section 112(d)(2)(A)(E). The MACT standards may take the form of design, equipment, work practice, or operational standards where EPA first determines either that, (A) a pollutant cannot be emitted through a conveyance designed and constructed to emit or capture the pollutants, or that any requirement for, or use of, such a conveyance would be inconsistent with law; or (B) the application of measurement methodology to a particular class of sources is not practicable due to technological and economic limitations. CAA sections 112(h)(1)-(2).

The MACT "floor" is the minimum control level allowed for MACT standards promulgated under CAA section 112(d)(3) and may not be based on cost considerations. For new sources, the MACT floor cannot be less stringent than the emission control that is achieved in practice by the best-

² Maximum Achievable Control Technology.

controlled similar source. The MACT floors for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emissions limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the bestperforming 5 sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor. We may establish standards more stringent than the floor based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements.

The EPA is then required to review these technology-based standards and to revise them "as necessary (taking into account developments in practices, processes, and control technologies)" no less frequently than every 8 years, under CAA section 112(d)(6). In conducting this review, EPA is not obliged to completely recalculate the prior MACT determination. NRDC v. EPA, 529 F.3d 1077, 1084 (D.C. Cir., 2008).

The second stage in standard-setting focuses on reducing any remaining "residual" risk according to CAA section 112(f). This provision requires, first, that EPA prepare a Report to Congress discussing (among other things) methods of calculating the risks posed (or potentially posed) by sources after implementation of the MACT standards, the public health significance of those risks, and the recommendations regarding legislation of such remaining risk. EPA prepared and submitted this report (Residual Risk Report to Congress, EPA-453/R-99-001) in March 1999. Congress did not act in response to the report, thereby triggering EPA's obligation under CAA section 112(f)(2) to analyze and address residual risk.

Section 112(f)(2) of the CAA requires us to determine for source categories subject to certain MACT standards, whether the emissions standards provide an ample margin of safety to protect public health. If the MACT standards that apply to a source category emitting a HAP that is "classified as a known, probable, or possible human carcinogen do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one-in-one million," EPA must promulgate residual risk standards for the source category (or subcategory) as necessary to provide an ample margin of safety to protect public health. CAA section 112(f)(2)(A). In

doing so, EPA may adopt standards equal to existing MACT standards if EPA determines that the existing standards are sufficiently protective. As stated in NRDC v. EPA, 529 F.3d 1077, 1083 (D.C. Dir. 2008), "If EPA determines that the existing technologybased standards provide an 'ample margin of safety, then the Agency is free to readopt those standards during the residual risk rulemaking." Section 112(f)(2) of the Clean Air Act further states that EPA must also adopt more stringent standards, if necessary, to "prevent taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect."2

When Section 112(f)(2) of the CAA was enacted in 1990, it expressly preserved our use of the two-step process for developing standards to address any residual risk and our interpretation of "ample margin of safety" developed in the National Emission Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/ Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants (Benzene NESHAP) (54 FR 38044, September 14, 1989). The first step in this process is the determination of acceptable risk. The second step provides for an ample margin of safety to protect public health, which is the level at which the standards are set (unless a more stringent standard is required to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental

The terms "individual most exposed," "acceptable level," and "ample margin of safety" are not specifically defined in the ČAA. However, CAA section 112(f)(2)(B) preserves the interpretation set out in the Benzene NESHAP, and the Court in NRDC v. EPA, concluded that EPA's interpretation of subsection 112(f)(2) is a reasonable one. See NRDC v. EPA, 529 F.3d at 1083 (D.C. Cir. 2008), which says "[S]ubsection 112(f)(2)(B) expressly incorporates EPA's interpretation of the Clean Air Act from the Benzene standard, complete with a citation to the *Federal* Register." See also, A Legislative History of the Clean Air Act Amendments of 1990, volume 1, p. 877 (Senate debate

on Conference Report). We notified Congress in the *Residual Risk Report to Congress* that we intended to use the Benzene NESHAP approach in making CAA section 112(f) residual risk determinations (EPA–453/R–99–001, p. ES–11).

In the Benzene NESHAP, we stated as an overall objective:

* * * in protecting public health with an ample margin of safety, we strive to provide maximum feasible protection against risks to health from hazardous air pollutants by (1) protecting the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1-in-1 million; and (2) limiting to no higher than approximately 1-in-10 thousand [i.e., 100-in-1 million] the estimated risk that a person living near a facility would have if he or she were exposed to the maximum pollutant concentrations for 70 years.

The Agency also stated that, "The EPA also considers incidence (the number of persons estimated to suffer cancer or other serious health effects as a result of exposure to a pollutant) to be an important measure of the health risk to the exposed population. Incidence measures the extent of health risks to the exposed population as a whole, by providing an estimate of the occurrence of cancer or other serious health effects in the exposed population." The Agency went on to conclude that "estimated incidence would be weighed along with other health risk information in judging acceptability." As explained more fully in our Residual Risk Report to Congress, EPA does not define "rigid line[s] of acceptability," but considers rather broad objectives to be weighed with a series of other health measures and factors (EPA-453/R-99-001, p. ES-11). The determination of what represents an "acceptable" risk is based on a judgment of "what risks are acceptable in the world in which we live" (Residual Risk Report to Congress, p. 178, quoting the Vinvl Chloride decision at 824 F.2d 1165) recognizing that our world is not risk-free.

In the Benzene NESHAP, we stated that "EPA will generally presume that if the risk to [the maximum exposed] individual is no higher than approximately 1-in-10 thousand, that risk level is considered acceptable." 54 FR 38045. We discussed the maximum individual lifetime cancer risk as being "the estimated risk that a person living near a plant would have if he or she were exposed to the maximum pollutant concentrations for 70 years." Id. We explained that this measure of risk "is an estimate of the upper bound of risk based on conservative assumptions, such as continuous exposure for 24 hours per day for 70 years." Id. We

^{2&}quot;Adverse environmental effect" is defined in CAA section 112(a)(7) as any significant and widespread adverse effect, which may be reasonably anticipated to wildlife, aquatic life, or natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental qualities over broad areas.

acknowledge that maximum individual lifetime cancer risk "does not necessarily reflect the true risk, but displays a conservative risk level which is an upper-bound that is unlikely to be exceeded." *Id.*

Understanding that there are both benefits and limitations to using maximum individual lifetime cancer risk as a metric for determining acceptability, we acknowledged in the 1989 Benzene NESHAP that "consideration of maximum individual risk * * * must take into account the strengths and weaknesses of this measure of risk." Id. Consequently, the presumptive risk level of 100-in-1 million (1-in-10 thousand) provides a benchmark for judging the acceptability of maximum individual lifetime cancer risk, but does not constitute a rigid line for making that determination.

The Agency also explained in the 1989 Benzene NESHAP the following: "In establishing a presumption for MIR [maximum individual cancer risk], rather than a rigid line for acceptability, the Agency intends to weigh it with a series of other health measures and factors. These include the overall incidence of cancer or other serious health effects within the exposed population, the numbers of persons exposed within each individual lifetime risk range and associated incidence within, typically, a 50-kilometer (km) exposure radius around facilities, the science policy assumptions and estimation uncertainties associated with the risk measures, weight of the scientific evidence for human health effects, other quantified or unquantified health effects, effects due to co-location of facilities, and co-emission of pollutants." Id.

In some cases, these health measures and factors taken together may provide a more realistic description of the magnitude of risk in the exposed population than that provided by maximum individual lifetime cancer risk alone. As explained in the Benzene NESHAP, "[e]ven though the risks judged "acceptable" by EPA in the first step of the Vinvl Chloride inquiry are already low, the second step of the inquiry, determining an "ample margin of safety," again includes consideration of all of the health factors, and whether to reduce the risks even further." In the ample margin of safety decision process, the Agency again considers all of the health risks and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including costs and economic impacts of controls, technological feasibility,

uncertainties, and any other relevant factors. Considering all of these factors, the Agency will establish the standard at a level that provides an ample margin of safety to protect the public health, as required by CAA section 112(f). 54 FR 38046.

B. How did we consider the risk results in making decisions for this proposal?

As discussed in section III.A of this preamble, we apply a two-step process for developing standards to address residual risk. In the first step, EPA determines if risks are acceptable. This determination "considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual lifetime [cancer] risk (MIR) ³ of approximately 1in-10 thousand [i.e., 100-in-1 million]." 54 FR 38045. In the second step of the process, EPA sets the standard at a level that provides an ample margin of safety "in consideration of all health information, including the number of persons at risk levels higher than approximately 1-in-1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision." Id.

In past residual risk actions, EPA has presented and considered a number of human health risk metrics associated with emissions from the category under review, including: the MIR; the numbers of persons in various risk ranges; cancer incidence; the maximum non-cancer hazard index (HI); and the maximum acute non-cancer hazard (72 FR 25138, May 3, 2007; 71 FR 42724, July 27, 2006). In our most recent proposals (75 FR 65068, October 21, 2010 and 75 FR 80220, December 21, 2010), EPA also presented and considered additional measures of health information, including: estimates of "facility-wide" risks (risks from all HAP emissions from the facility at which the source category is located); 4 demographic analyses (analyses of the distributions of HAPrelated risks across different social, demographic, and economic groups living near the facilities); and estimates of the risks associated with the maximum level of emissions which might be allowed by the current MACT standards (see, e.g., 75 FR 65068, October 21, 2010 and 75 FR 80220, December 21, 2010). EPA also discussed and considered risk estimation uncertainties. EPA is providing this same type of information in support of the proposed actions described in this **Federal Register** notice.

The Agency is considering all available health information to inform our determinations of risk acceptability and ample margin of safety under CAA section 112(f). Specifically, as explained in the Benzene NESHAP, "the first step judgment on acceptability cannot be reduced to any single factor" and thus "[t]he Administrator believes that the acceptability of risk under section 112 is best judged on the basis of a broad set of health risk measures and information." 54 FR at 38046. Similarly, with regard to making the ample margin of safety determination, as stated in the Benzene NESHAP "[I]n the ample margin decision, the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including cost and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors." Id.

The Agency acknowledges that flexibility is provided by the Benzene NESHAP regarding what factors EPA might consider in making determinations and how they might be weighed for each source category. In responding to comment on our policy under the Benzene NESHAP, EPA explained that: "The policy chosen by the Administrator permits consideration of multiple measures of health risk. Not only can the MIR figure be considered, but also incidence, the presence of noncancer health effects, and the uncertainties of the risk estimates. In this way, the effect on the most exposed individuals can be reviewed as well as the impact on the general public. These factors can then be weighed in each individual case. This approach complies with the Vinyl Chloride mandate that the Administrator ascertain an acceptable level of risk to the public by employing [her] expertise to assess available data. It also complies with the Congressional intent behind the CAA, which did not exclude the use of any particular measure of public health risk from the EPA's consideration with respect to CAA section 112 regulations, and, thereby, implicitly permits consideration of any and all measures of health risk which the Administrator, in [her] judgment, believes are appropriate to determining what will 'protect the public health." 54 FR at 38057.

For example, the level of the MIR is only one factor to be weighed in

³ Although defined as "maximum individual risk," MIR refers only to cancer risk. MIR, one metric for assessing cancer risk, is the estimated risk were an individual exposed to the maximum level of a pollutant for a lifetime.

⁴EPA previously provided estimates of total facility risk in a residual risk proposal for coke oven batteries (69 FR 48338, August 9, 2004).

determining acceptability of risks. It is explained in the Benzene NESHAP that "an MIR of approximately 1-in-10 thousand should ordinarily be the upper end of the range of acceptability. As risks increase above this benchmark, they become presumptively less acceptable under CAA section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability. Or, the Agency may find, in a particular case, that a risk that includes MIR less than the presumptively acceptable level is unacceptable in the light of other health risk factors." Id. at 38045. Similarly, with regard to the ample margin of safety analysis, EPA stated in the Benzene NESHAP that: "* * * EPA believes the relative weight of the many factors that can be considered in selecting an ample margin of safety can only be determined for each specific source category. This occurs mainly because technological and economic factors (along with the health-related factors) vary from source category to source category." Id. at 38061.

EPA wishes to point out that certain health information has not been considered to date in making residual risk determinations. In assessing risks to populations in the vicinity of the facilities in each category, we present estimates of risk associated with HAP emissions from the source category alone (source category risk estimates) and HAP emissions from the entire facility at which the covered source category is located (facility-wide risk estimates). We do not attempt to characterize the risks associated with all HAP emissions impacting the populations living near the sources in these categories. That is, at this time, we do not attempt to quantify those HAP risks that may be associated with mobile source emissions, natural source emissions, persistent environmental pollution, or atmospheric transformation in the vicinity of the sources in these categories.

The Agency understands the potential importance of considering an individual's total exposure to HAP in addition to considering exposure to HAP emissions from the source category and facility. This is particularly important when assessing non-cancer risks, where pollutant-specific exposure levels (e.g., Reference Concentration (RfC)) are based on the assumption that thresholds exist for adverse health effects. For example, the Agency recognizes that, although exposures attributable to emissions from a source category or facility alone may not indicate the potential for increased risk

of adverse non-cancer health effects in a population, the exposures resulting from emissions from the facility in combination with emissions from all of the other sources (e.g., other facilities) to which an individual is exposed may be sufficient to result in increased risk of adverse non-cancer health effects. In May 2010, the Science Advisory Board (SAB) advised us "* * * that RTR assessments will be most useful to decision makers and communities if results are presented in the broader context of aggregate and cumulative risks, including background concentrations and contributions from other sources in the area."5

While we are interested in placing source category and facility-wide HAP risks in the context of total HAP risks from all sources combined in the vicinity of each source, we are concerned about the uncertainties of doing so. At this point, we believe that such estimates of total HAP risks will have significantly greater associated uncertainties than for the source category or facility-wide estimates, and hence compounding the uncertainty in any such comparison. This is because we have not conducted a detailed technical review of HAP emissions data for source categories and facilities that have not previously undergone an RTR review or are not currently undergoing such review. We are requesting comment on whether and how best to estimate and evaluate total HAP exposure in our assessments, and, in particular, on whether and how it might be appropriate to use information from EPA's National Air Toxics Assessment (NATA) to support such estimates. We are also seeking comment on how best to consider various types and scales of risk estimates when making our acceptability and ample margin of safety determinations under CAA section 112(f). Additionally, we are seeking comments and recommendations for any other comparative measures that may be useful in the assessment of the distribution of HAP risks across potentially affected demographic groups.

- C. What other actions are we addressing in this proposal?
- 1. Startup, Shutdown and Malfunction

This proposed action would amend the provisions of the existing NESHAP that apply to periods of startup, shutdown, and malfunction (SSM). The proposed revisions of these provisions result from a Court decision that vacated portions of two provisions in EPA's "General Provisions" regulation under CAA section 112, governing the emissions of HAP during periods of SSM. The current Primary Lead Smelting MACT includes references to the vacated provisions in the General Provisions rule.

We are proposing to revise the Primary Lead Smelting MACT standard to require affected sources to comply with the emission limitations at all times and during periods of SSM. Specifically, we are proposing several revisions to subpart TTT including revising Table 1 to indicate that the requirements of the General Provisions pertaining to SSM do not apply and to revise language in § 63.1547 (g)(1) and (2) to remove the exemption for bag leak detection alarm time attributable to SSM from total allowed alarm time. For reasons discussed below, we are also proposing to promulgate an affirmative defense to civil penalties for exceedances of emission standards caused by malfunctions, as well as criteria for establishing the affirmative defense. These changes would go into effect upon the effective date of promulgation of the final rule.

The United States Court of Appeals for the District of Columbia Circuit vacated portions of two provisions in EPA's CAA Section 112 regulations governing the emissions of HAP during periods of SSM. Sierra Club v. EPA, 551 F.3d 1019 (D.C. Cir. 2008), cert. denied, 130 S. Ct. 1735 (U.S. 2010). Specifically, the Court vacated the SSM exemptions contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), that are part of a regulation commonly known as the "General Provisions Rule," that EPA had promulgated under section 112 of the CAA. When incorporated into CAA section 112(d) regulations for specific source categories, these two provisions exempt sources from the requirement to comply with the otherwise applicable CAA section 112(d) emission standard during periods of SSM.

We are proposing the elimination of the SSM exemption in this rule. Consistent with Sierra Club v. EPA, EPA is proposing standards in this rule that apply at all times. We are also proposing several revisions to Table 1 (the General Provisions Applicability table). For

⁵EPA's responses to this and all other key recommendations of the SAB's advisory on RTR risk assessment methodologies (which is available at: http://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/\$File/EPA-SAB-10-007-unsigned.pdf) are outlined in a memo to this rulemaking docket from David Guinnup entitled, EPA's Actions in Response to the Key Recommendations of the SAB Review of RTR Risk Assessment Methodologies.

example, we are proposing to eliminate the incorporation of the General Provisions' requirement that the source develop an SSM plan. We also are proposing to eliminate or revise certain recordkeeping and reporting that relate to the SSM exemption. EPA has attempted to ensure that we have not included in the proposed regulatory language any provisions that are inappropriate, unnecessary, or redundant in the absence of the SSM exemption. We are specifically seeking comment on whether there are any such provisions that we have inadvertently incorporated or overlooked.

In proposing standards in this rule, EPA has taken into account startup and shutdown periods and, for the reasons explained below, has not proposed different standards for those periods. Information on periods of startup and shutdown in the industry indicate that emissions during these periods do not increase. Furthermore, all processes are controlled by either control devices or work practices and these controls would not typically be affected by an SSM event. Also, compliance with the standard already requires averaging of emissions over a three month period, which accounts for the variability of emissions that may result during periods of startup and shutdown. Therefore, separate standards for periods of startup and shutdown are not

being proposed.

Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. However, by contrast, malfunction is defined as a "sudden, infrequent, and not reasonably preventable failure of air pollution control and monitoring equipment, process equipment, or a process to operate in a normal or useful manner * * * * (40 CFR 63.2). EPA has determined that malfunctions should not be viewed as a distinct operating mode and, therefore, any emissions that occur at such times do not need to be factored into development of CAA section 112(d) standards, which, once promulgated, apply at all times. In Mossville Environmental Action Now v. EPA, 370 F.3d 1232, 1242 (D.C. Cir. 2004), the court upheld as reasonable standards that had factored in variability of emissions under all operating conditions. However, nothing in section 112(d) or in case law requires that EPA anticipate and account for the innumerable types of potential malfunction events in setting emission standards. See, Weyerhaeuser v. Costle, 590 F.2d 1011, 1058 (D.C. Cir. 1978)("In the nature of things, no general limit, individual permit, or even any upset provision can anticipate all upset

situations. After a certain point, the transgression of regulatory limits caused by 'uncontrollable acts of third parties,' such as strikes, sabotage, operator intoxication or insanity, and a variety of other eventualities, must be a matter for the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation.").

Further, it is reasonable to interpret section 112(d) as not requiring EPA to account for malfunctions in setting emission standards. For example, we note that CAA section 112 uses the concept of "best performing" sources in defining MACT, the level of stringency that major source standards must meet. Applying the concept of "best performing" to a source that is malfunctioning presents significant difficulties. The goal of best performing sources is to operate in such a way as to avoid malfunctions of their units.

Moreover, even if malfunctions were considered a distinct operating mode, we believe it would be impracticable to take malfunctions into account in setting CAA section 112(d) standards for Primary Lead Smelting. As noted above, by definition, malfunctions are sudden and unexpected events and it would be difficult to set a standard that takes into account the myriad different types of malfunctions that can occur across all sources in the category. Moreover, malfunctions can vary in frequency, degree, and duration, further complicating standard setting.

In the unlikely event that a source fails to comply with the applicable CAA section 112(d) standards as a result of a malfunction event, EPA would determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during malfunction periods, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. EPA would also consider whether the source's failure to comply with the CAA section 112(d) standard was, in fact, "sudden, infrequent, not reasonably preventable" and was not instead "caused in part by poor maintenance or careless operation." 40 CFR 63.2 (definition of malfunction).

Finally, EPA recognizes that even equipment that is properly designed and maintained can sometimes fail and that such failure can sometimes cause or contribute to an exceedance of the relevant emission standard. (See, e.g., State Implementation Plans: Policy Regarding Excessive Emissions During Malfunctions, Startup, and Shutdown (Sept. 20, 1999); Policy on Excess Emissions During Startup, Shutdown,

Maintenance, and Malfunctions (Feb. 15, 1983).) EPA is therefore proposing to add to the final rule an affirmative defense to civil penalties for exceedances of emission limits that are caused by malfunctions. See 40 CFR 63.1542 (defining "affirmative defense" to mean, in the context of an enforcement proceeding, a response or defense put forward by a defendant, regarding which the defendant has the burden of proof, and the merits of which are independently and objectively evaluated in a judicial or administrative proceeding). We also are proposing other regulatory provisions to specify the elements that are necessary to establish this affirmative defense; the source must prove by a preponderance of the evidence that it has met all of the elements set forth in § 63.1551. (See 40 CFR 22.24.) The criteria ensure that the affirmative defense is available only where the event that causes an exceedance of the emission limit meets the narrow definition of malfunction in 40 CFR 63.2 (sudden, infrequent, not reasonably preventable and not caused by poor maintenance and/or careless operation). For example, to successfully assert the affirmative defense, the source must prove by a preponderance of the evidence that excess emissions "[w]ere caused by a sudden, short, infrequent, and unavoidable failure of air pollution control and monitoring equipment, process equipment, or a process to operate in a normal or usual manner * *" The criteria also are designed to ensure that steps are taken to correct the malfunction, to minimize emissions in accordance with §§ 63.1543(i) and 63.1544(e) and to prevent future malfunctions. For example, the source must prove by a preponderance of the evidence that "[r]epairs were made as expeditiously as possible when the applicable emission limitations were being exceeded * * * "" and that "[a]ll possible steps were taken to minimize the impact of the excess emissions on ambient air quality, the environment and human health * * *." In any judicial or administrative proceeding, the Administrator may challenge the assertion of the affirmative defense and, if the respondent has not met its burden of proving all of the requirements in the affirmative defense, appropriate penalties may be assessed in accordance with section 113 of the Clean Air Act (see also 40 CFR part 22.77).

Specifically, we are proposing the following changes to the rule.

• Added general duty requirements in \$§ 63.1543 and 63.1544 to replace General Provision requirements that reference vacated SSM provisions.

- Added replacement language that eliminates the reference to SSM exemptions applicable to performance tests in § 63.1546.
- Added paragraphs in § 63.1549(e) requiring the reporting of malfunctions as part of the affirmative defense provisions.
- Added paragraphs in § 63.1549(b) requiring the keeping of certain records during malfunctions as part of the affirmative defense provisions.
- Revised Table 1 to reflect changes in the applicability of the General Provisions to this subpart resulting from a court vacatur of certain SSM requirements in the General Provisions.
- 2. Lead as a Surrogate and Regulation of Volatile Organic Compounds (VOC) and Acid Gas Emissions

In a January 14, 2009, petition for rulemaking filed by the Natural Resources Defense Council and Sierra Club, the petitioners claim that for the Primary Lead Smelting MACT, EPA relied on lead as a surrogate for all HAP and they claim that it was inappropriate for EPA to do so in absence of a showing that lead is an appropriate surrogate for all other HAP (such as mercury, acid gases, and volatile organic compounds (VOC)). The petitioners asserted that EPA should set standards for other HAP absent a showing that lead is an appropriate surrogate for these HAP. They also assert that EPA's PM standard does not reflect the emission level achieved by the best performing sources and that EPA must re-open the rule to set floors for PM in accordance with CAA section 112(d)(3). A copy of the petition is included in the docket.

As part of this rulemaking, EPA is responding to the claims made by the petitioners regarding the Primary Lead

Smelting MACT.

As an initial matter, the petitioners are incorrect in their claim that EPA considers lead as a surrogate for all HAP. Rather, EPA used lead as a surrogate only for other metal HAP compounds in establishing the emissions limit in the current MACT standard for this source category (63 FR 19206 and 64 FR 30195). EPA determined in the 1999 rule that lead, a nonvolatile metal HAP, is an appropriate surrogate for other nonvolatile metal HAP including antimony, arsenic, chromium, nickel, manganese, and cadmium. In the proposed rule for the Primary Lead Smelting MACT (63 FR 19206), EPA discussed the use of lead as a surrogate for metal HAP emissions and explained that strong correlations exist between emissions of lead and other metal HAP and that the technologies identified for

the control of metal HAP are the same as those used to control lead emissions. Therefore, EPA expected that the standards requiring control of lead would achieve similar control of the other metal HAP emitted from primary lead smelters. No adverse comments were received regarding EPA's proposed rationale for relying on lead as a surrogate for other metal HAP emitted by these sources and EPA adopted that rationale in the final rule promulgating the Primary Lead Smelting MACT. The petitioners do not have any substantive basis as to why EPA's rationale is not supported. Nor do they claim that there is any new information that would support re-opening this issue. Thus they fail to present a basis for re-opening this

The petitioners also insist that EPA should have set standards for VOC and acid gases that are HAP because lead would not be a surrogate for these pollutants. EPA noted in the original proposal that due to small amounts of coke fed to the blast furnace, organic HAP (VOC) was emitted at a rate so low as to be infeasible to reduce. Again, no adverse comments were received on EPA's proposed conclusions, which were adopted in the final rule, and the petitioners do not now provide substantive support for their claim. Nor do they explain why any such claim could not have been raised during the initial rulemaking. Thus, they fail to present a basis for re-opening the rule on this issue.

Finally, petitioners claim that the "PM standard does not reflect the emission level achieved by the best performing sources." This claim is unclear as there is no PM standard in the Primary Lead Smelting MACT. The monitoring provisions provide that PM should be measured in relation to a predetermined PM level as one test for indicating baghouse performance. However, the PM levels are not enforceable emission limits, but merely an indication that the baghouse may not be operating properly. Again, these provisions were clearly explained in the proposed and final Primary Lead Smelting MACT rulemakings. Any claims concerning the appropriateness of these monitoring requirements should have been raised during the initial rulemaking process. Petitioners do not claim any new grounds for raising this issue now. Thus, the petition fails to provide a basis for re-opening the MACT.

3. Modification of the Applicability Provision

EPA is proposing to amend the applicability section to apply to any facility processing lead ore concentrate

to produce lead metal. Under the current applicability provisions, the affected sources include any sinter machine, blast furnace, dross furnace, process fugitive source, and fugitive dust source located at a primary lead smelter and excludes secondary lead smelters, lead refiners, or lead remelters. Combined with the current definition for "primary lead smelter," the current rule effectively only applies to facilities that produce lead metal from lead sulfide ore concentrates using pyrometallurgical techniques. While the only processes available for the production of lead from lead ore concentrate at the time the MACT rule was developed were pyrometallurgical techniques, that applicability language is narrower than the primary lead smelting source category description EPA identified in its source category listing issued pursuant to CAA section 112(c)(1), Documentation for Developing the Initial Source Category List (EPA-450/3-91-030, July 1992). In the source category listing, EPA defined the primary lead smelting source category as follows: "The Primary Lead Smelting source category includes any facility engaged in producing lead metal from ore concentrates. The category includes, but is not limited to, the following smelting processes: sintering reduction, preliminary treatment, and refining operations. The sintering process includes an updraft or downdraft sintering machine. The reduction process includes the blast furnace, electric smelting furnace with a converter or reverberatory furnace, and slag fuming furnace process units. The preliminary treatment process includes the drossing kettles and dross reverberatory furnace process units. The refining process includes the refinery process unit." The definition is clear that the primary intent was to cover sources that produce lead metal from ore concentrates, which would "include" the use of a pyrometallurgical process, but would not be limited to such. As noted previously, at the time we promulgated the MACT standard, the only method of producing lead metal from ore concentrates was through use of pyrometallurgical techniques and we adopted an applicability provision that focused on that process.

However, information provided by the sole operating primary lead smelting facility indicates that lead production is likely to continue at the current Doe Run facility, although using a process other than a pyrometallurgical technique. The new lead facility would continue to process lead ore concentrate

in order to produce lead metal. Based on the current applicability section and definitions, it could be interpreted that the future lead producing process, using techniques other than

pyrometallurgical, would not be subject to the NESHAP for primary lead smelters. Such a limited interpretation is not consistent with EPA's intent as evidenced by the broader definition in the source category list. Therefore, EPA is proposing to amend the applicability section to specify that the MACT applies to any lead processing facility that produces lead metal from lead ore concentrate. Consistent with the proposed revision to the applicability section, we are proposing to remove the definition of "primary lead smelter" and add a definition of "primary lead processor" which means any facility engaged in the production of lead metal from lead sulfide ore concentrates through the use of pyrometallurgical or other techniques. In addition, we are proposing to replace "primary lead smelter" with "primary lead processor" throughout 40 CFR subpart TTT. (§ 63.1541 through § 63.1545, § 63.1547 through § 63.1549). We are specifically asking for comment on this proposed change in the definition.

Because there is only one primary lead processing facility in the U.S., there will be no impact of this change on the number of existing facilities covered by the MACT.

We note, however, that although we are changing the applicability section to clarify that the MACT applies to all processes for producing lead metal from ore concentrates, we are not today proposing a specific MACT standard that would apply to the as-yet undemonstrated hydrometallurgical process which Doe Run has indicated that it plans to build at the current Doe Run facility. If and when that process begins operation, we will consider whether to revise the MACT standard to specifically address that process or any other new processes. However, the limits applicable to specific emission sources currently in operation as specified in the MACT and as revised under CAA sections 112(d)(6) and (f)(2) in this rulemaking would continue to apply to any emission source at the facility that continues in operation, such as the refinery. In addition, to the extent that we establish a final air lead concentration limit as proposed in § 63.1544, those limits would also continue to apply to the facility. We also are proposing that the plant-wide emission limit we are proposing today should continue to apply to any facility that meets the revised applicability definition, but we are specifically

soliciting comment on whether it should apply.

We are also taking this opportunity to clarify the reference to "lead refiners" in the second sentence of the applicability section, which provides that the MACT standard does not apply to "secondary lead smelters, lead refiners, or lead remelters." The intent of this provision was to make clear that secondary lead smelters would not be subject to the rule because secondary lead smelters were listed as a separate source category and addressed in a separate MACT standard. With regard to lead refiners and lead remelters, the intent was to provide that these activities, to the extent that they are not located at facilities that produce lead from lead ore concentrate, would not be subject to the Primary Lead Smelting MACT. However, it was not the intention of the rule to exempt kettle refining operations included as part of a primary lead processing facility. Therefore, EPA is proposing to add definitions for secondary lead smelters, lead refiners, and lead remelters in the definitions section of this NESHAP in order to further clarify the exemption in the applicability provisions with regard to these types of facilities. As this change only clarifies an existing provision in the rule, there will be no impact to the number of facilities covered by the rule.

4. Other Changes

The following lists additional minor changes we are proposing. This list includes rule changes that address editorial errors and plain language revisions.

- As part of EPA's effort to incorporate plain language into its regulations, replaced the word "shall" with "must." (§ 63.1543 through § 63.1550)
- Correction to the original rule ("thru" replaced with "through" in the definition of "tapping location"). (§ 63.1542)
- Minor wording change to definition of "fugitive dust source" to clarify meaning. (§ 63.1542)

IV. Analyses Performed and Background of the Source Category and MACT Standard

As discussed above, in this proposed rule we are proposing action to address the RTR requirements of CAA sections 112(d)(6) and (f)(2) for the Primary Lead Smelting MACT standard. In this section, we describe the analyses performed to support the proposed decisions for the RTR for this source category and we also include background information on the source category and the MACT standard.

A. How did we estimate risks posed by the source category?

The EPA conducted a risk assessment that provided estimates of the MIR posed by the HAP emissions from the one source in the source category, the distribution of cancer risks within the exposed populations, cancer incidence, HI for chronic exposures to HAP with the potential to cause non-cancer health effects, hazard quotients (HQ) for acute exposures to HAP with the potential to cause non-cancer health effects, and an evaluation of the potential for adverse environmental effects. The risk assessments consisted of seven primary steps, as discussed below.

The docket for this rulemaking contains the following document which provides more information on the risk assessment inputs and models: *Draft Residual Risk Assessment for the Primary Lead Smelting Source Category.*

1. Establishing the Nature and Magnitude of Actual Emissions and Identifying the Emissions Release Characteristics

For the Primary Lead Smelting source category, we compiled a preliminary dataset using readily available information, reviewed the data, and made changes where necessary. The preliminary dataset was based on data in the 2002 National Emissions Inventory (NEI) Final Inventory, Version 1 (made publicly available on February 26, 2006). The NEI is a database that contains information about sources that emit criteria air pollutants, their precursors, and HAP. The NEI database includes estimates of annual air pollutant emissions from point, nonpoint, and mobile sources in the 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands. The EPA collects this information and releases an updated version of the NEI database every 3 years.

On December 4, 2009, a CAA Section 114 Information Collection Request (ICR) was issued requesting information from the one facility in this source category. An updated dataset was created through incorporation of changes to the dataset from the ICR data review process and additional information gathered by EPA. The updated dataset contains information for the one facility in the source category and was used to conduct the risk assessment and other analyses that form the basis for the proposed risk and technology reviews. A copy of the dataset used and documentation of the risk assessment can be found in the docket.

2. Establishing the Relationship Between Actual Emissions and MACT– Allowable Emissions Levels

The available emissions data in the NEI and from other sources typically represent the estimates of mass of emissions actually emitted during the specified annual time period. These "actual" emission levels are often lower than the emission levels that a facility might be allowed to emit and still comply with the MACT standards. The emissions level allowed to be emitted by the MACT standards is referred to as the "MACT-allowable" emissions level. This represents the highest emissions level that could be emitted by the facility without violating the MACT standards.

We discussed the use of both MACTallowable and actual emissions in the final Coke Oven Batteries residual risk rule (70 FR 19998-19999, April 15, 2005) and in the proposed and final Hazardous Organic NESHAP (HON) residual risk rules (71 FR 34428, June 14, 2006, and 71 FR 76609, December 21, 2006, respectively). In those previous actions, we noted that assessing the risks at the MACTallowable level is inherently reasonable since these risks reflect the maximum level sources could emit and still comply with national emission standards. But we also explained that it is reasonable to consider actual emissions, where such data are available, in both steps of the risk analysis, in accordance with the Benzene NESHAP. (54 FR 38044, September 14, 1989.) It is reasonable to consider actual emissions because sources typically seek to perform better than required by emission standards to provide an operational cushion to accommodate the variability in manufacturing processes and control device performance.

As described above, the actual emissions data were compiled based on the NEI, information gathered from the facility and State, and information received in response to the ICR. To estimate emissions at the MACTallowable level, we developed a ratio of MACT-allowable to actual emissions for each source type (i.e., the individual stacks and the aggregate fugitive emissions) for the one facility in the source category. This ratio is based on the level of control required by the MACT standards compared to the level of reported actual emissions and available information on the level of control achieved by the emissions controls in use. For example, if there was information to suggest that an emission point type was being controlled by 98 percent while the

MACT standards required only 92 percent control, we would estimate that MACT-allowable emissions from that emission point type could be as much as 4 times higher (8 percent allowable emissions compared with 2 percent actually emitted), and the ratio of MACT-allowable to actual would be 4:1 for this emission point type. After developing these ratios for each emission point type at the one facility in this source category, we next applied these ratios to the maximum chronic risk estimates from the inhalation risk assessment to obtain maximum risk estimates based on MACT-allowable emissions. The estimate of MACTallowable emissions for the Primary Lead Smelting source category is described in section V of this preamble.

3. Conducting Dispersion Modeling, Determining Inhalation Exposures, and Estimating Individual and Population Inhalation Risks

Both long-term and short-term inhalation exposure concentrations and health risks from the source category addressed in this proposal were estimated using the Human Exposure Model (Community and Sector HEM-3 version 1.1.0). The HEM-3 performs three of the primary risk assessment activities listed above: (1) Conducting dispersion modeling to estimate the concentrations of HAP in ambient air, (2) estimating long-term and short-term inhalation exposures to individuals residing within 50 km of the modeled sources, and (3) estimating individual and population-level inhalation risks using the exposure estimates and quantitative dose-response information.

The dispersion model used by HEM-3 is AERMOD, which is one of EPA's preferred models for assessing pollutant concentrations from industrial facilities.⁶ To perform the dispersion modeling and to develop the preliminary risk estimates, HEM-3 draws on three data libraries. The first is a library of meteorological data, which is used for dispersion calculations. This library includes 1 year of hourly surface and upper air observations for 130 meteorological stations, selected to provide coverage of the United States and Puerto Rico. However, in this instance, site-specific meteorological data for the one facility in this source category were supplied by the state of Missouri and used for the modeling. The data provided by the state of Missouri were for eight quarters

(i.e., eight three-month periods) from April 1997 through June 1999. To obtain one year of meteorological data, we used the middle portion of these data, the year 1998, in our modeling. A second library of United States Census Bureau census block ⁷ internal point locations and populations provides the basis of human exposure calculations (Census, 2000). In addition, for each census block, the census library includes the elevation and controlling hill height, which are also used in dispersion calculations. A third library of pollutant unit risk factors and other health benchmarks is used to estimate health risks. These risk factors and health benchmarks are the latest values recommended by EPA for HAP and other toxic air pollutants. These values are available at http://www.epa.gov/ttn/ atw/toxsource/summarv.html and are discussed in more detail later in this section.

In developing the risk assessment for chronic exposures, we used the estimated annual average ambient air concentration of each of the HAP emitted by each source for which we have emissions data in the source category. The air concentrations at each nearby census block centroid were used as a surrogate for the chronic inhalation exposure concentration for all the people who reside in that census block. We calculated the MIR for the one facility as the cancer risk associated with a lifetime (70-year period) of exposure to the maximum concentration at the centroid of an inhabited census block. Individual cancer risks were calculated by multiplying the estimated lifetime exposure to the ambient concentration of each of the HAP (in micrograms per cubic meter) by its Unit Risk Estimate (URE), which is an upper bound estimate of an individual's probability of contracting cancer over a lifetime of exposure to a concentration of 1 microgram of the pollutant per cubic meter of air. In general, for residual risk assessments, we use URE values from EPA's Integrated Risk Information System (IRIS). For carcinogenic pollutants without EPA IRIS values, we look to other reputable sources of cancer dose-response values, often using California Environmental Protection Agency (CalEPA) URE values, where available. In cases where new, scientifically credible doseresponse values have been developed in a manner consistent with EPA guidelines and have undergone a peer review process similar to that used by

⁶ U.S. EPA. Revision to the Guideline on Air Quality Models: Adoption of a Preferred General Purpose (Flat and Complex Terrain) Dispersion Model and Other Revisions (70 FR 68218, November 9, 2005).

⁷ A census block is generally the smallest geographic area for which census statistics are tabulated

EPA, we may use such dose response values in place of, or in addition to, other values, if appropriate. In this review, IRIS values were available for both carcinogenic pollutants (cadmium and arsenic) emitted by the facility in this source category, and therefore IRIS values were used in the assessment.

Incremental individual lifetime cancer risks associated with emissions from the one source in the source category were estimated as the sum of the risks for each of the carcinogenic HAP (including those classified as carcinogenic to humans, likely to be carcinogenic to humans, and suggestive evidence of carcinogenic potential 8) emitted by the modeled source. Cancer incidence and the distribution of individual cancer risks for the population within 50 km of the source were also estimated for the source category as part of these assessments by summing individual risks. A distance of 50 km is consistent with both the analysis supporting the 1989 Benzene NESHAP (54 FR 38044) and the limitations of Gaussian dispersion models, including AERMOD.

To assess risk of non-cancer health effects from chronic exposures, we summed the HQ for each of the HAP that affects a common target organ system to obtain the HI for that target organ system (or target organ-specific HI, TOSHI). The HQ is the estimated exposure divided by the chronic reference value, which is either the EPA RfC, defined as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime," or, in cases where an RfC is not available, the Agency for Toxic Substances and Disease Registry (ATSDR) chronic Minimal Risk Level (MRL) or the CalEPA Chronic Reference Exposure Level (REL). The REL is defined as "the concentration level at or below which no adverse health effects are anticipated for a specified exposure duration.

Screening estimates of acute exposures and risks were also evaluated for each of the HAP at the point of highest off-site exposure for each facility (i.e., not just the census block centroids) assuming that a person was located at this spot at a time when both the peak (hourly) emission rate and hourly dispersion conditions occurred. In general, acute HQ values were calculated using best available, shortterm dose-response value. These acute dose-response values include REL, Acute Exposure Guideline Levels (AEGL), and Emergency Response Planning Guidelines (ERPG) for 1-hour exposure durations. Notably, for HAP emitted from this source category, REL values were the only such doseresponse values available. As discussed below, we used conservative assumptions for emission rates, meteorology, and exposure location for our acute analysis.

As described in the CalEPA's Air Toxics Hot Spots Program Risk Assessment Guidelines, Part I, The Determination of Acute Reference Exposure Levels for Airborne Toxicants, an acute REL value (http:// www.oehha.ca.gov/air/pdf/acuterel.pdf) is defined as "the concentration level at or below which no adverse health effects are anticipated for a specified exposure duration is termed the REL. REL values are based on the most sensitive, relevant, adverse health effect reported in the medical and toxicological literature. REL values are designed to protect the most sensitive individuals in the population by the inclusion of margins of safety. Since margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact.

To develop screening estimates of acute exposures, we first developed estimates of maximum hourly emission rates by multiplying the average actual annual hourly emission rates by a factor to cover routinely variable emissions. We chose the factor to use based on process knowledge and engineering judgment and with awareness of a Texas study of short-term emissions variability, which showed that most peak emission events, in a heavilyindustrialized 4-county area (Harris, Galveston, Chambers, and Brazoria Counties, Texas) were less than twice the annual average hourly emission rate. The highest peak emission event was 74 times the annual average hourly emission rate, and the 99th percentile ratio of peak hourly emission rate to the annual average hourly emission rate was 9.9 This analysis is provided in Appendix 4 of the *Draft Residual Risk Assessment for Primary Lead Smelting* which is available in the docket for this action. Considering this analysis, unless specific process knowledge or data are available to provide an alternate value, to account for more than 99 percent of the peak hourly emissions, we apply a conservative screening multiplication factor of 10 to the average annual hourly emission rate in these acute exposure screening assessments. For the Primary Lead Smelting source category, this factor of 10 was applied.

In cases where all acute HQ values from the screening step were less than or equal to 1, acute impacts were deemed negligible and no further analysis was performed. In the cases where an acute HQ from the screening step was greater than 1, additional sitespecific data were considered to develop a more refined estimate of the potential for acute impacts of concern. Ideally, we would prefer to have continuous measurements over time to see how the emissions vary by each hour over an entire year. Having a frequency distribution of hourly emission rates over a year would allow us to perform a probabilistic analysis to estimate potential threshold exceedances and their frequency of occurrence. Such an evaluation could include a more complete statistical treatment of the key parameters and elements adopted in this screening analysis. However, we recognize that having this level of data is rare, hence our use of the multiplier (i.e., factor of 10) approach in our screening analysis.

4. Conducting Multipathway Exposure and Risk Modeling

The potential for significant human health risks due to exposures via routes other than inhalation (i.e., multipathway exposures) and the potential for adverse environmental impacts were evaluated in a three-step process. In the first step, we determined whether any facilities emitted any HAP known to be persistent and bioaccumulative in the environment (PB-HAP). There are 14 PB-HAP compounds or compound classes identified for this screening in EPA's Air Toxics Risk Assessment Library (available at http://www.epa.gov/ttn/ fera/risk atra vol1.html). They are cadmium compounds, chlordane, chlorinated dibenzodioxins and furans, dichlorodiphenyldichloroethylene, heptachlor, hexachlorobenzene,

⁸These classifications also coincide with the terms "known carcinogen, probable carcinogen, and possible carcinogen," respectively, which are the terms advocated in the EPA's previous *Guidelines for Carcinogen Risk Assessment*, published in 1986 (51 FR 33992, September 24, 1986). Summing the risks of these individual compounds to obtain the cumulative cancer risks is an approach that was recommended by the EPA's SAB in their 2002 peer review of EPA's NATA entitled, *NATA—Evaluating the National-scale Air Toxics Assessment 1996 Data—an SAB Advisory*, available at: http://yosemite.epa.gov/sab/sabproduct.nsf/214C6E915BB 04E14852570CA007A682C/\$File/ecadv02001.pdf.

⁹ See http://www.tceq.state.tx.us/compliance/ field_ops/eer/index.html or docket to access the source of these data.

hexachlorocyclohexane, lead compounds, mercury compounds, methoxychlor, polychlorinated biphenyls, POM, toxaphene, and trifluralin. Emissions of two PB HAP were identified in the emissions inventory for the Primary Lead Smelting source category: Lead compounds and cadmium compounds.

Cadmium emissions were evaluated for potential non-inhalation risks and adverse environmental impacts using our recently developed screening scenario that was developed for use with the TRIM.FaTE model. This screening scenario uses environmental media outputs from the peer-reviewed TRIM.FaTE to estimate the maximum potential ingestion risks for any specified emission scenario by using a generic farming/fishing exposure scenario that simulates a subsistence environment. The screening scenario retains many of the ingestion and scenario inputs developed for EPA's Human Health Risk Assessment Protocols (HHRAP) for hazardous waste combustion facilities. In the development of the screening scenario a sensitivity analysis was conducted to ensure that its key design parameters were established such that environmental media concentrations were not underestimated, and to also minimize the occurrence of false positives for human health endpoints. See Appendix 3 of the risk assessment document for a complete discussion of the development and testing of the screening scenario, as well as for the values of facility-level de minimis emission rates developed for screening potentially significant multi-pathway impacts. For the purpose of developing de minimis emission rates for our cadmium multi-pathway screening, we derived emission levels for cadmium at which the maximum human health risk would be 1-in-1 million for lifetime cancer risk.

In evaluating the potential air-related multi-pathway risks from the emissions of lead compounds from the one facility in this source category, rather than developing a de minimis emission rate, we compared its maximum modeled 3month average atmospheric lead concentration at any off-site location with the current primary National Ambient Air Quality Standard (NAAQS) for lead (promulgated in 2008), which is set to a level of 0.15 micro-grams per cubic meter (µg/m³) based on a rolling 3-month period with a not-to-beexceeded form, and which will require attainment by 2016. 73 FR 66964. Notably, in making these comparisons, we estimated maximum rolling 3-month ambient lead concentrations taking into

account all of the elements of the NAAQS for lead. That is, our estimated 3-month lead concentrations are calculated in a manner that is consistent with the indicator, averaging time, and form of the NAAQS for lead, and those estimates are compared to the actual level of the lead NAAQS $(0.15 \, \mu g/m^3)$.

The NAAQS value, a public health policy judgment, incorporated the Agency's most recent health evaluation of air effects of lead exposure for the purposes of setting a national standard. In setting this value, the Administrator promulgated a standard that was requisite to protect public health with an adequate margin of safety. We consider values below the level of the primary NAAQS to protect against multi-pathway risks because, as mentioned above, the primary NAAOS is set as to protect public health with an adequate margin of safety. However, ambient air lead concentrations above the NAAQS are considered to pose the potential for increased risk to public health. We consider this NAAQS assessment to be a refined analysis given the numerous health studies, detailed risk and exposure analyses, and level of external peer and public review that went into the development of the primary NAAQS for lead, combined with the site-specific dispersion modeling analysis performed to develop the ambient concentration estimates due to emissions from the one Primary Lead Processing facility being addressed in this RTR. It should be noted, however, that this comparison does not account for possible population exposures to lead from sources other than the one being modeled; for example, via consumption of water from untreated local sources or ingestion of locally grown food. Nevertheless, the Administrator judged that such a standard, would protect, with an adequate margin of safety, the health of children and other at-risk populations against an array of adverse health effects, most notably including neurological effects, particularly neurobehavioral and neurocognitive effects, in children. 73 FR 67007. The Administrator, in setting the standard, also recognized that no evidence-or risk based bright line indicated a single appropriate level. Instead a collection of scientific evidence and other information was used to select the standard from a range of reasonable values. 73 FR 67006.

We further note that comparing ambient lead concentrations to the NAAQS for lead, considering the level, averaging time, form and indicator, also informs whether there is the potential for adverse environmental effects. This is because the secondary lead NAAQS, which has the same averaging time, form, and level as the primary standard, was set to protect the public welfare which includes among other things soils, water, crops, vegetation and wildlife. CAA section 302(h). Thus, ambient lead concentrations above the NAAQS for lead also indicate the potential for adverse environmental effects.

For additional information on the multi-pathway analysis approach, see the residual risk documentation as referenced in section IV.A of this preamble. The EPA solicits comment generally on the modeling approach used herein to assess air-related lead risks, and specifically on the use of the lead NAAQS in this analytical construct.

5. Assessing Risks Considering Emissions Control Options

In addition to assessing baseline inhalation risks and screening for potential multi-pathway risks, we also estimated risks considering the potential emission reductions that would be achieved by the particular control options under consideration. The expected emissions reductions were applied to the specific HAP and emissions points in the source category dataset to develop corresponding estimates of risk reductions.

6. Conducting Other Risk-Related Analyses, Including Facility-Wide Assessments and Demographic Analyses

a. Facility-Wide Risk

To put the source category risks in context, for our residual risk review, we also examine the risks from the entire "facility," where the facility includes all HAP-emitting operations within a contiguous area and under common control. In other words, we examine the HAP emissions not only from the source category of interest, but also emissions of HAP from all other emission sources at the facility. In this rulemaking, for the sole facility in the Primary Lead Smelting source category, there are no other significant HAP emission sources present. With the exception of organic HAP sources determined to present insignificant risk, all HAP sources have been included in the risk analysis. Therefore, the facility-wide risks are the same as the source category risk and no separate facility-wide analysis was necessary.

b. Demographic Analysis

To examine the potential for any environmental justice issues that might be associated with HAP emissions with this source category, we evaluated the distributions of HAP-related cancer and non-cancer risks across different social, demographic, and economic groups within the populations living near the one facility in this source category. The development of demographic analyses to inform the consideration of environmental justice issues in EPA rulemakings is evolving. EPA offers the demographic analyses in this rulemaking to inform the consideration of potential environmental justice issues, and invites public comment on the approaches used and the interpretations made from the results, with the hope that this will support the refinement and improve the utility of such analyses for future rulemakings.

For the demographic analyses, we focus on the populations within 50 km of any facility with emission sources subject to the MACT standard (identical to the risk assessment). Based on the emissions for the source category or the facility, we then identified the populations that are estimated to have exposures to HAP which result in: (1) Cancer risks of 1-in-1 million or greater, (2) non-cancer HI of 1 or greater, and/ or (3) ambient lead concentrations above the level of the NAAQS for lead. We compare the percentages of particular demographic groups within the focused populations to the total percentages of those demographic groups nationwide. The results, including other risk metrics, such as average risks for the exposed populations, are documented in a technical report in the docket for the source category covered in this proposal.10

The basis for the risk values used in the demographic analyses for the one facility subject to the Primary Lead Smelting MACT was the modeling results based on actual emissions levels obtained from the HEM-3 model described above. The risk values for each census block were linked to a database of information from the 2000 decennial census that includes data on race and ethnicity, age distributions, poverty status, household incomes, and education level. The Census Department Landview® database was the source of the data on race and ethnicity, and the data on age distributions, poverty status, household incomes, and education level were obtained from the 2000 Census of Population and Housing Summary File 3 (SF3) Long Form. While race and ethnicity census data are available at the census block level, the age and income census data are only available at the census block group level (which

includes an average of 26 blocks or an average of 1,350 people). Where census data are available at the block group level but not the block level, we assumed that all census blocks within the block group have the same distribution of ages and incomes as the block group.

We focused the analysis on those census blocks where source category risk results show either estimated lifetime inhalation cancer risks above 1in-1 million or chronic non-cancer indices above 1. In addition, in this case we also focused on those census blocks where estimated ambient lead concentrations were above the level of the lead NAAQS. For each of these cases, we determined the relative percentage of different racial and ethnic groups, different age groups, adults with and without a high school diploma, people living in households below the national median income, and for people living below the poverty line within those census blocks. The specific census population categories included:

- Total population;
- White;
- African American (or Black);
- Native Americans;
- Other races and multiracial;
- Hispanic or Latino;
- People living below the poverty line;
 - Children 18 years of age and under:
 - Adults 19 to 64 years of age;
 - Adults 65 years of age and over;
- Adults without a high school diploma.

It should be noted that these categories overlap in some instances, resulting in some populations being counted in more than one category (e.g., other races and multiracial and Hispanic). In addition, while not a specific census population category, we also examined risks to "Minorities," a classification which is defined for these purposes as all race population categories except white.

The methodology and the results of the demographic analyses for this source category are included in the technical report available in the docket for this action. (Risk and Technology Review—Analysis of Socio-Economic Factors for Populations Living Near Primary Lead Smelting Operations).

7. Considering Uncertainties in Risk Assessment

Uncertainty and the potential for bias are inherent in all risk assessments, including that performed for the source category addressed in this proposal. Although uncertainty exists, we believe the approach that we took, which used conservative tools and assumptions,

ensures that our decisions are health-protective. A brief discussion of the uncertainties in the emissions dataset, dispersion modeling, inhalation exposure estimates, and dose-response relationships follows below. A more thorough discussion of these uncertainties is included in the risk assessment documentation (*Draft Residual Risk Assessment for Primary Lead Smelting*) available in the docket for this action.

a. Uncertainties in the Emissions Dataset

Although the development of the RTR dataset involved quality assurance/ quality control processes, the accuracy of emissions values will vary depending on the source of the data, the degree to which data are incomplete or missing, the degree to which assumptions made to complete the datasets are accurate, whether and to what extent errors were made in estimating emissions values, and other factors. The emission estimates considered in this analysis are annual totals provided by the facility that do not reflect short-term fluctuations during the course of a year or variations from year to year. In contrast, the estimates of peak hourly emission rates for the acute effects screening assessment were based on multiplication factors applied to the average annual hourly emission rates (the default factor of 10 was used for Primary Lead Smelting), which is intended to account for emission fluctuations due to normal facility operations.

b. Uncertainties in Dispersion Modeling

While the analysis employed EPA's recommended regulatory dispersion model, AERMOD, we recognize that there is uncertainty in ambient concentration estimates associated with any model, including AERMOD. In circumstances where we had to choose between various model options, where possible, we selected model options (e.g., rural/urban, plume depletion, chemistry) that provided an overestimate of ambient concentrations of the HAP rather than an underestimate. However, because of practicality and data limitation reasons, some factors (*e.g.*, building downwash) have the potential in some situations to overestimate or underestimate ambient impacts. Despite these uncertainties, we believe that at off-site locations and census block centroids, the approach considered in the dispersion modeling analysis should generally yield overestimates of ambient HAP concentrations.

¹⁰ Risk and Technology Review—Analysis of Socio-Economic Factors for Populations Living Near Primary Lead Smelting Operations.

c. Uncertainties in Inhalation Exposure

The effects of human mobility on exposures were not included in the assessment. Specifically, short-term mobility and long-term mobility between census blocks in the modeling domain were not considered.¹¹ As a result, this simplification will likely bias the assessment toward overestimating the highest exposures. In addition, the assessment predicted the chronic exposures at the centroid of each populated census block as surrogates for the exposure concentrations for all people living in that block. Using the census block centroid to predict chronic exposures tends to over-predict exposures for people in the census block who live farther from the facility, and underpredict exposures for people in the census block who live closer to the facility. Thus, using the census block centroid to predict chronic exposures may lead to a potential understatement or overstatement of the true maximum impact for any one individual, but is an unbiased estimate of average risk and incidence.

The assessments evaluate the projected cancer inhalation risks associated with pollutant exposures over a 70-year period, which is the assumed lifetime of an individual. In reality, both the length of time that modeled emissions sources at facilities actually operate (i.e., more or less than 70 years), and the domestic growth or decline of the modeled industry (i.e., the increase or decrease in the number or size of United States facilities), will influence the future risks posed by a given source or source category. Depending on the characteristics of the industry, these factors will, in most cases, result in an overestimate both in individual risk levels and in the total estimated number of cancer cases. However, in rare cases, where a facility maintains or increases its emission levels beyond 70 years, residents live beyond 70 years at the same location, and the residents spend most of their days at that location, then the risks could potentially be underestimated. Annual cancer incidence estimates from exposures to emissions from these sources would not be affected by uncertainty in the length of time emissions sources operate. For the specific source in this source category we anticipate significant reduction in activities and emissions in the relatively

near future. If this happens, chronic risks based on the continuation of current emission levels will be over estimated.

The exposure estimates used in these analyses assume chronic exposures to ambient levels of pollutants. Because most people spend the majority of their time indoors, actual exposures may not be as high, depending on the characteristics of the pollutants modeled. For many of the HAP, indoor levels are roughly equivalent to ambient levels, but for very reactive pollutants or larger particles, these levels are typically lower. This factor has the potential to result in an overstatement of 25 to 30 percent of exposures.¹²

In addition to the uncertainties highlighted above, there are several factors specific to the acute exposure assessment that should be highlighted. The accuracy of an acute inhalation exposure assessment depends on the simultaneous occurrence of independent factors that may vary greatly, such as hourly emissions rates. meteorology, and human activity patterns. In this assessment, we assume that individuals remain for 1 hour at the point of maximum ambient concentration as determined by the cooccurrence of peak emissions and worstcase meteorological conditions. These assumptions would tend to overestimate actual exposures since it is unlikely that a person would be located at the point of maximum exposure during the time of worst-case impact.

d. Uncertainties in Dose-Response Relationships

There are uncertainties inherent in the development of the dose-response values used in our risk assessments for cancer effects from chronic exposures and non-cancer effects from both chronic and acute exposures. Some uncertainties may be considered quantitatively, and others generally are expressed in qualitative terms. We note as a preface to this discussion a point on dose-response uncertainty that is brought out in EPA's 2005 Cancer Guidelines; namely, that "the primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective." (EPA 2005 Cancer Guidelines, pages 1-7.) This is the approach followed here as summarized in the next several paragraphs. A

complete detailed discussion of uncertainties and variabilities in doseresponse relationships is given in the residual risk documentation which is available in the docket for this action.

Cancer URE values used in our risk assessments are those that have been developed to generally provide an upper bound estimate of risk. That is, they represent a "plausible upper limit to the true value of a quantity" (although this is usually not a true statistical confidence limit).¹³ In some circumstances, the true risk could be as low as zero; however, in other circumstances the risk could be greater.14 When developing an upper bound estimate of risk and to provide risk values that do not underestimate risk, health-protective default approaches are generally used. To err on the side of ensuring adequate healthprotection, EPA typically uses the upper bound estimates rather than lower bound or central tendency estimates in our risk assessments, an approach that may have limitations for other uses (e.g., priority-setting or expected benefits analysis).

Chronic non-cancer reference (RfC and RfD) values represent chronic exposure levels that are intended to be health-protective levels. Specifically, these values provide an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure (RfC) or a daily oral exposure (RfD) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. To derive values that are intended to be "without appreciable risk," the methodology relies upon an uncertainty factor (UF) approach (U.S. EPA, 1993, 1994) which includes consideration of both uncertainty and variability. When there are gaps in the available information, UF are applied to derive reference values that are intended to protect against appreciable risk of deleterious effects. The UF are commonly default values, 15 e.g., factors

¹¹ Short-term mobility is movement from one microenvironment to another over the course of hours or days. Long-term mobility is movement from one residence to another over the course of a lifetime.

¹² U.S. EPA. *National-Scale Air Toxics*Assessment for 1996. (EPA 453/R-01-003; January 2001; page 85.)

¹³ IRIS glossary (http://www.epa.gov/NCEA/iris/help_gloss.htm).

¹⁴ An exception to this is the URE for benzene, which is considered to cover a range of values, each end of which is considered to be equally plausible, and which is based on maximum likelihood estimates.

¹⁵ According to the NRC report, Science and Judgment in Risk Assessment (NRC, 1994) "[Default] options are generic approaches, based on general scientific knowledge and policy judgment, that are applied to various elements of the risk assessment process when the correct scientific model is unknown or uncertain." The 1983 NRC report, Risk Assessment in the Federal Government: Managing the Process, defined default option as "the option chosen on the basis of risk assessment policy that

of 10 or 3, used in the absence of compound-specific data; where data are available, UF may also be developed using compound-specific information. When data are limited, more assumptions are needed and more UF are used. Thus, there may be a greater tendency to overestimate risk in the sense that further study might support development of reference values that are higher (i.e., less potent) because fewer default assumptions are needed. However, for some pollutants, it is possible that risks may be underestimated.

While collectively termed "UF," these factors account for a number of different quantitative considerations when using observed animal (usually rodent) or human toxicity data in the development of the RfC. The UF are intended to account for: (1) Variation in susceptibility among the members of the human population (i.e., inter-individual variability); (2) uncertainty in extrapolating from experimental animal data to humans (i.e., interspecies differences); (3) uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure (i.e., extrapolating from sub-chronic to chronic exposure); (4) uncertainty in extrapolating the observed data to obtain an estimate of the exposure associated with no adverse effects; and (5) uncertainty when the database is incomplete or there are problems with the applicability of available studies. Many of the UF used to account for variability and uncertainty in the development of acute reference values are quite similar to those developed for chronic durations, but they more often use individual UF values that may be less than 10. UF are applied based on chemical-specific or health effectspecific information (e.g., simple irritation effects do not vary appreciably between human individuals, hence a value of 3 is typically used), or based on the purpose for the reference value (see the following paragraph). The UF applied in acute reference value derivation include: (1) Heterogeneity among humans; (2) uncertainty in extrapolating from animals to humans;

(3) uncertainty in lowest observed adverse effect (exposure) level to no observed adverse effect (exposure) level adjustments; and (4) uncertainty in accounting for an incomplete database on toxic effects of potential concern. Additional adjustments are often applied to account for uncertainty in extrapolation from observations at one exposure duration (e.g., 4 hours) to derive an acute reference value at another exposure duration (e.g., 1 hour).

As further discussed below, there is no RfD or other comparable chronic health benchmark value for lead compounds. Thus, to address multipathway human health and environmental risks associated with emissions of lead from this facility, ambient lead concentrations were compared to the NAAOS for lead. In developing the NAAQS for lead, EPA considered human health evidence reporting adverse health effects associated with lead exposure, as well as an EPA conducted multipathway risk assessment that applied models to estimate human exposures to air-related lead and the associated risk (73 FR 66979). EPA also explicitly considered the uncertainties associated with both the human health evidence and the exposure and risk analyses when developing the NAAQS for lead. For example, EPA considered uncertainties in the relationship between ambient air lead and blood lead levels (73 FR 66974), as well as uncertainties between blood lead levels and loss of IQ points in children (73 FR 66981).

In considering the evidence and risk analyses and their associated uncertainties, the EPA Administrator noted his view that there is no evidenceor risk-based bright line that indicates a single appropriate level. Instead, he noted, there is a collection of scientific evidence and judgments and other information, including information about the uncertainties inherent in many relevant factors, which needs to be considered together in making this public health policy judgment and in selecting a standard level from a range of reasonable values (73 FR 66998). In so doing, the Administrator decided that, a level for the primary lead standard of 0.15 µg/m³, in combination with the specified choice of indicator, averaging time, and form, is requisite to protect public health, including the health of sensitive groups, with an adequate margin of safety (73 FR 67006). A thorough discussion of the health evidence, risk and exposure analyses, and their associated uncertainties can be found in EPA's final rule revising the lead NAAQS (73 FR 66970-66981, November 12, 2008).

We also note the uncertainties associated with the health-based (i.e., primary) NAAOS are likely less than the uncertainties associated with doseresponse values developed for many of the other HAP, particularly those HAP for which no human health data exist. In 1988, EPA's IRIS program reviewed the health effects data regarding lead and its inorganic compounds and determined that it would be inappropriate to develop an RfD for these compounds, saying, "A great deal of information on the health effects of lead has been obtained through decades of medical observation and scientific research. This information has been assessed in the development of air and water quality criteria by the Agency's Office of Health and Environmental Assessment (OHEA) in support of regulatory decision-making by the Office of Air Quality Planning and Standards (OAQPS) and by the Office of Drinking Water (ODW). By comparison to most other environmental toxicants, the degree of uncertainty about the health effects of lead is quite low. It appears that some of these effects, particularly changes in the levels of certain blood enzymes and in aspects of children's neurobehavioral development, may occur at blood lead levels so low as to be essentially without a threshold. The Agency's RfD Work Group discussed inorganic lead (and lead compounds) at two meetings (07/08/1985 and 07/22/1985) and considered it inappropriate to develop an RfD for inorganic lead." EPA's IRIS assessment for Lead and compounds (inorganic) (CASRN 7439–92–1), http:// www.epa.gov/iris/subst/0277.htm.

We also note that because of the multi-pathway, multi-media impacts of lead, the risk assessment supporting the NAAQS considered direct inhalation exposures and indirect air-related multipathway exposures from industrial sources like primary and secondary lead smelting operations. It also considered background lead exposures from other sources (like contaminated drinking water and exposure to lead-based paints). In revising the NAAQS for lead, we note that the Administrator placed more weight on the evidence-based framework and less weight on the results from the risk assessment, although he did find the risk estimates to be roughly consistent with and generally supportive of the evidencebased framework applied in the NAAQS determination. 73 FR 67004. Thus, when revising the NAAQS for lead to protect public health with an adequate margin of safety, EPA considered both

appears to be the best choice in the absence of data to the contrary" (NRC, 1983a, p. 63). Therefore, default options are not rules that bind the Agency; rather, the Agency may depart from them in evaluating the risks posed by a specific substance when it believes this to be appropriate. In keeping with EPA's goal of protecting public health and the environment, default assumptions are used to ensure that risk to chemicals is not underestimated (although defaults are not intended to overtly overestimate risk). See EPA, 2004, An Examination of EPA Risk Assessment Principles and Practices, EPA/100/B-04/001 available at: http://www.epa.gov/osa/pdfs/ratf-final.pdf.

the health evidence and the risk assessment, albeit to different extents.

In addition to the uncertainties discussed above with respect to chronic, cancer, and the lead NAAQS reference values, there are also uncertainties associated with acute reference values. Not all acute reference values are developed for the same purpose, and care must be taken when interpreting the results of an acute assessment of human health effects relative to the reference value or values being exceeded. Where relevant to the estimated exposures, the lack of shortterm dose-response values at different levels of severity should be factored into the risk characterization as potential uncertainties.

Although every effort is made to identify peer-reviewed reference values for cancer and non-cancer effects for all pollutants emitted by the sources included in this assessment, some hazardous air pollutants continue to have no peer-reviewed reference values for cancer or chronic non-cancer or acute effects. Since exposures to these pollutants cannot be included in a quantitative risk estimate, an understatement of risk for these pollutants at environmental exposure levels is possible.

Additionally, chronic reference values for several of the compounds included in this assessment are currently under EPA IRIS review (e.g., cadmium and nickel), and revised assessments may determine that these pollutants are more or less potent than the current value. We may re-evaluate residual risks for the final rulemaking if, as a result of these reviews, a dose-response metric changes enough to indicate that the risk assessment supporting this notice may significantly understate human health risk.

e. Uncertainties in the Multipathway and Environmental Effects Assessment

We generally assume that when exposure levels are not anticipated to adversely affect human health, they also are not anticipated to adversely affect the environment. For each source category, we generally rely on the sitespecific levels of PB-HAP emissions to determine whether a full assessment of the multi-pathway and environmental effects is necessary. For PB-HAPS other than lead (i.e., cadmium), site-specific PB-HAP emission levels were far below levels which would trigger a refined assessment of multi-pathway impacts, thus we are confident that these types of impacts are insignificant for the one facility in this source category.

f. Uncertainties in the Facility-Wide Risk Assessment

We did not conduct a separate facility-wide risk assessment for this proposal because all of the HAP emission sources at the one facility subject to the MACT are covered by the MACT standard under review. Thus, the level of the facility-wide HAP emissions is the same as the level of emissions from the emissions sources subject to the MACT standard under review.

g. Uncertainties in the Demographic Analysis

Our analysis of the distribution of risks across various demographic groups is subject to the typical uncertainties associated with census data (e.g., errors in filling out and transcribing census forms), as well as the additional uncertainties associated with the extrapolation of census-block group data (e.g., income level and education level) down to the census block level.

B. How did we perform the technology review?

Our technology review is focused on the identification and evaluation of developments in practices, processes, and control technologies. If a review of available information identifies such developments, then we conduct an analysis of the technical feasibility of these developments, along with the impacts (costs, emission reductions, risk reductions, etc.). We then make a decision on whether it is necessary to amend the regulation to require any identified developments.

Based on specific knowledge of the primary lead smelting source category, we began by identifying known developments in practices, processes, and control technologies. For the purpose of this exercise, we considered any of the following to be a "development":

- Any add-on control technology or other equipment that was not identified and considered during MACT development;
- Any improvements in add-on control technology or other equipment (that was identified and considered during MACT development) that could result in significant additional emission reduction;
- Any work practice or operational procedure that was not identified and considered during MACT development;
- Any process change or pollution prevention alternative that could be broadly applied that was not identified and considered during MACT development.

In addition to looking back at practices, processes, or control technologies reviewed at the time we developed the MACT standards, we reviewed a variety of sources of data to aid in our evaluation of whether there were additional practices, processes, or controls to consider. One of these sources of data was subsequent air toxics rules. Since the promulgation of the MACT standard for the primary lead smelting source category addressed in this proposal, EPA has developed air toxics regulations for a number of additional source categories. We reviewed the regulatory requirements and/or technical analyses associated with these subsequent regulatory actions to identify any practices, processes, and control technologies considered in these efforts that could possibly be applied to emission sources in the primary lead smelting source category.

We also consulted EPA's RACT/ BACT/LAER Clearinghouse (RBLC). The terms "RACT," "BACT," and "LAER" are acronyms for different program requirements under the CAA provisions addressing the national ambient air quality standards. Control technologies, classified as RACT (Reasonably Available Control Technology), BACT (Best Available Control Technology), or LAER (Lowest Achievable Emission Rate) apply to stationary sources depending on whether the sources are existing or new, and on the size, age, and location of the facility. BACT and LAER (and sometimes RACT) are determined on a case-by-case basis, usually by state or local permitting agencies. EPA established the RBLC to provide a central database of air pollution technology information (including technologies required in source-specific permits) to promote the sharing of information among permitting agencies and to aid in identifying future possible control technology options that might apply broadly to numerous sources within a category or apply only on a source-bysource basis. The RBLC contains over 5,000 air pollution control permit determinations that can help identify appropriate technologies to mitigate many air pollutant emission streams. We searched this database to determine whether any practices, processes, or control technologies are included for the types of processes covered by the primary lead smelting MACT.

We also requested information from the facility regarding developments in practices, processes, or control technology. Finally, we reviewed other information sources, such as state or local permitting agency databases and industry-supported databases.

C. Overview of the Source Category and MACT Standards

1. Source Category and MACT Standard

The National Emission Standard for Primary Lead Smelting (or MACT rule) was promulgated on June 4, 1999 (64 FR 30194) and codified at 40 CFR part 63, subpart TTT. As promulgated in 1999, the MACT standard applies to affected sources of HAP at primary lead smelters. 16 The MACT defines "Primary lead smelters" as "any facility engaged in the production of lead metal from lead sulfide ore concentrates through the use of pyrometallurgical techniques." 40 CFR 63.1542. The MACT standard for the Primary Lead Smelting source category does not apply to secondary lead smelters, lead remelters, or lead refiners (§ 63.1541). Today there is one facility (The Doe Run Company in Herculaneum, Missouri) operating that is subject to the MACT standards (See Section V.A. below).

At the time of promulgation of the Primary Lead Smelting MACT rule, there were three operating lead smelters. Due to economic pressures (decreased market demand for lead) and regulatory pressures, two of the lead smelting facilities subject to the MACT standard have since been permanently closed, leaving one primary lead smelter currently operating in the United States. No new primary lead smelters have been built in the last 20 years, and no new primary lead processing facilities using pyrometallurgical techniques are anticipated in the foreseeable future. The one operating lead smelter is not collocated with other sources of HAP emissions.

Lead is used to make various construction and consumer products such as batteries, paint, glass, piping, and filler. Lead sulfide (PbS) ore concentrates are the main feed material to primary lead smelters. The primary lead smelting process consists of lead sulfide concentrate storage and handling, sintering of ore concentrates, sinter crushing and handling, smelting of sinter to lead metal, drossing (*i.e.*, removing the solid oxide deposits), refining and alloying of lead metal, and smelting of the drosses.

HAP are emitted from primary lead smelting as process emissions (stack), process fugitive emissions, and fugitive dust emissions. Process emissions are associated with the exhaust gases from sinter machines and blast and dross

furnaces. HAP expected in process emissions are metals (mostly lead compounds, but also some arsenic, cadmium, and other metals) and also may include small amounts of organic compounds that result from incomplete combustion of coke, which is charged along with sinter to the blast furnace. Process fugitive emissions occur at various points during the smelting process (such as during charging and tapping of furnaces) and the only HAP emitted are metal HAP. Fugitive dust emissions result from the entrainment of dust due to material handling, vehicle traffic, and wind erosion from storage piles and the only HAP emitted are metal HAP.

The MACT standard (40 CFR part 63, subpart TTT) applies to process emissions (stack) from sinter machines, blast furnaces, and dross furnaces; process fugitive emissions from sinter. blast furnace, drossing and refining processes, concentrate handling, and locations around such processes; and fugitive dust emission sources, such as roadways, storage piles and the plant yard. Process emissions of lead compounds from sinter machines, blast furnaces, and dross furnaces, and process fugitive emissions from the blast furnace and dross furnace charging, blast furnace and dross furnace tapping, and the sinter machine (charging, discharging, crushing, and sizing) are limited to 500 grams (g) of lead emissions per mega gram (Mg) of lead produced (500 g/Mg), which is equal to 1.0 pound (lb) of lead emissions per ton of lead produced (1 lb/ton). 40 CFR 63.1542(a). A plant-wide limit format was used for MACT because it was consistent with SIPs, the commingling of exhaust gases from processes to a single stack made it impossible to set limits for individual sources, it gave the facilities more flexibility in complying with the standard, and it promoted pollution prevention by giving each facility the ability to meet the emission limit through any combination of source reduction and control technology options. (63 FR 19208).

In addition to being subject to the plant-wide emission limit of the standard, process fugitive emissions must be captured by a hood and ventilated to a baghouse or equivalent control device and the hood design and ventilation rate must be consistent with American Conference of Governmental Industrial Hygienists recommended practices. 40 CFR 63.1543(b). In addition, the sinter machine area fugitives must be enclosed in a building that is ventilated to a baghouse at a rate that maintains a positive in-draft through any doorway opening. 40 CFR

63.1543(c). The MACT standard also requires the use of bag leak detection systems for continuous monitoring of baghouses. 40 CFR 63.1547(c)(9). For fugitive dust sources, as defined in 40 CFR 63.1544, the MACT standard requires that the owner or operator prepare and operate at all times according to a standard operating procedures (SOP) manual. The SOP manual must describe in detail the measures used to control fugitive dust emissions from plant roadways, material storage and handling areas, sinter machine areas, blast and dross furnace areas, and refining and casting operations areas. Existing work practice manual(s) that describe the measures in place to control fugitive dust sources required as part of a state implementation plan for lead satisfy this requirement.

2. MACT as it Applies to Doe Run Company Primary Lead Smelter, Herculaneum, Missouri

As stated above, the Doe Run Smelter in Herculaneum, Missouri, is the sole remaining lead processing facility in the United States subject to the MACT. The 1999 MACT rule established a plantwide lead emission limit of 1 lb of lead per ton of lead produced that applies to the aggregation of emissions from specific sources that discharge from air pollution control devices. Compliance with the plant-wide emission limit is demonstrated by annual stack testing. The rule lists nine sources as subject to the plant-wide limit including: (1) Sinter machine, (2) blast furnace, (3) dross furnace, (4) dross furnace charging location, (5) blast furnace and dross furnace tapping location, (6) sinter machine charging location, (7) sinter machine discharge end, (8) sinter crushing and sizing equipment, and (9) sinter machine area. At the Doe Run plant, lead emissions from these sources are controlled by baghouses that exhaust through two stacks. The sources in the sinter operation, the blast furnace, and the dross furnace are controlled by three baghouses all of which discharge through one emission point, which is designated as the main stack. The building that houses the blast furnace and dross kettles is vented to a separate baghouse (#7) which discharges through a separate stack, designated as the furnace area stack.

Under the 1999 MACT rule, all other sources of process fugitive and fugitive dust emissions are required to follow work practice standards detailed in the plant's standard operating procedures (SOP) manual.

The HAP emitted in the largest quantities from the Doe Run facility are

¹⁶ As provided above in section III(C)(3), we are proposing to change the standard to apply to Primary Lead Processors.

lead compounds, which account for over 99 percent of the total HAP emissions by mass. The remaining HAP emissions are arsenic, antimony, cadmium, cobalt, nickel and trace organic HAP. Negligible levels of organic HAP are also emitted from natural gas-fired space heating at the facility and the incomplete combustion of coke in the blast furnace. Further discussions of the emission profile for this facility is included in the Technical Support Document in the docket.

3. Missouri SIP and the Lead NAAQS as They Apply to Doe Run Company, Herculaneum, Missouri

In addition to the MACT standard, the Doe Run Company's primary lead smelter in Herculaneum, Missouri is subject to a SIP for the purpose of attaining and maintaining the lead NAAQS.¹⁷ The current SIP, which was approved in 2002, addresses the former lead ambient air concentration limit of 1.5 µg/m³ NAAQS. In addition, the 2007 SIP submittal from the State includes requirements addressing lead emissions from the Doe Run facility and can be found at http://www.dnr.mo.gov/env/apcp/docs/2009drh-leadsip.pdf.

In 2008, EPA revised the lead NAAQS from 1.5 $\mu g/m^3$ to 0.15 $\mu g/m^3$. In November 2010, EPA identified or "designated" several areas as not meeting the lead NAAQS. These "nonattainment" designations include portions of Jefferson County, Missouri surrounding the Doe Run facility. Missouri is required by the Act to take steps to further control pollution in this area, and to detail these steps in a revision to the SIP. The revised SIP is due to EPA within eighteen months after the effective date of the designation, or by June 2012, and attainment of the NAAQS should be achieved by 2016.

The SIP and the pending 2007 SIP submittal contain specific measures to be implemented by the Doe Run plant to reduce lead emissions. The State of Missouri revised the control requirements for the Doe Run facility in 2001 and 2007, requiring numerous emissions-reducing measures and improvements to add-on control devices, processes, and work practices. 18 These included

improvements to existing emission control technology, adding or upgrading enclosures, process changes and limitations, and work practices. These requirements are summarized below.

Point Source Requirements—As required under the SIP, lead emissions from the refining kettles and refining building emissions must be captured and vented to baghouses. Doe Run implemented these controls and vents the emissions to baghouses #8 and #9 and the exhaust from the baghouse #9 is combined with baghouse #7 exhaust and vented to a common stack. Although the MACT standard does not require Doe Run to do so, it has included emissions from refining Baghouses #8 and #9 in their demonstrations of compliance with the MACT plant-wide lead emission limit.

Under the 2007 SIP submittal, Doe Run was required to make improvements to existing baghouse controls including the installation of pleated filters and lowering the air-to-cloth ratio for baghouses, increased ventilation and improved ventilation hoods at the blast furnace, and using reverse flow technology for baghouse cleaning. The 2007 SIP submittal also required the installation of enclosures and/or partial enclosures for unloading ore concentrate, sinter storage, and the sides of the sinter machine (which will be evacuated to a baghouse).

Process Requirements—Process changes to reduce emissions required by the SIP included a process control system for the injection of air through the blast furnace tuveres located at the bottom of the blast furnace, limitations on individual process and overall plant throughputs, and limiting specific operations to only certain times of the day when the impact on ambient air concentrations is less. The SIP also stipulates that emissions from malfunctions will be reduced by alarms that sound when the baghouse fan malfunctions, an interlock system to restrict air flow into the blast furnace when the baghouse is not operating properly, and cameras for the dross and refinery kettles to detect kettle failure (i.e., when a plume of smoke is detected from the stack, the kettle burner can be immediately shut off and the problem corrected).

Fugitive Dust Requirements—Under both the current SIP and the 2007 SIP submittal, work practices are required to reduce fugitive dust emissions. Requirements include road watering and automatic sprinklers, using new regenerative sweepers to remove dust from paved surfaces to reduce emissions from traffic, maintaining a minimum water content percentage for ore concentrate and for baghouse dust that is loaded into railcars, and inspecting the siding that encloses buildings (followed by prompt repairs if needed).

Missouri requires Doe Run to report all metal HAP emissions annually based on a speciation analysis that was performed. ¹⁹ The state also requires an annual emissions inventory based on the stack tests for the point discharges and AP–42 or facility-specific emission factors for fugitive emissions.

As a result of the implementation of the emission control requirements in the currently approved 2002 SIP, and the additional requirements adopted by the state, as discussed above, the Doe Run facility has achieved a significant reduction of lead and metal HAP emissions since 2000 through a combination of reduced production levels and improved emissions controls. Based on emissions inventory data submitted to the Missouri Department of Natural Resources (DNR), total HAP emissions have been reduced from an estimated 140 tons in 2000 to 20 tons in 2008, and the majority of the 20 tons are lead compound emissions. The 2008 reported emissions reflect implementation of all emission controls stipulated in the 2002 SIP and the 2007 SIP revision.

4. Other Federal and State Actions Affecting Doe Run Company

More recently, the 2008 revision to the lead NAAQS has resulted in Doe Run Company deciding that it is not feasible for the facility to reduce emissions further to the level necessary to meet the newly revised NAAQS without closure of the current smelting operations. As a result of past and ongoing regulatory compliance issues at the facility, the facility has entered into a consent decree with U.S. EPA Region VII and the State of Missouri. Under the consent decree, the facility will, among other things, close the existing smelter operation and remediate the site to an agreed-upon level. The consent decree requires that all support operations for the smelter cease by December 31, 2013 and that the blast furnace cease operations by April 1, 2014. Remediation of the site is required to commence following approval of a plan to be submitted to EPA in January 2013. Under the consent decree, the existing refining, casting and alloying operations

¹⁷EPA most recently approved the Missouri SIP for Herculaneum in 2002 (67 FR 18497, April 16, 2002). Missouri Department of Natural Resources (MDNR) substantially revised the requirements for the smelter in 2007. EPA has proposed approval of this revision, but has not yet taken final action.

¹⁸ EPA most recently approved the Missouri SIP for Herculaneum in 2002 (67 FR 18497, April 16, 2002). MDNR substantially revised the requirements for the smelter in 2007. EPA has

proposed approval of this revision, but has not yet taken final action.

¹⁹ Doe Run Company submits annual emissions inventories to MDNR that report speciated metals using speciation factors for each metal/source derived in the late 1990s through emissions testing.

will be allowed to continue operation. Notice of the consent decree was published for public comment on October 15, 2010, (75 FR 63506). Once finalized, the consent decree is federally enforceable among the parties.

Prior to closure of the current smelter, the Doe Run Company may build and bring to full operation a new hydrometallurgical process that will produce lead from lead sulfide ore, potentially adjacent to the current smelter. The hydrometallurgical process uses chemical reactions involving fluboric acid which allows recovery of lead metal through leaching, electrowinning, and co-product treatment processes. Some of the lead from the new process is likely to undergo further processing at the existing refinery, primarily for remelting/casting purposes. Based on limited data from a demonstration project, Doe Run expects that lead emissions from the hydrometallurgical process will be minimal.

V. Analyses Results and Proposed **Decisions**

This section of the preamble provides a description of the dataset used in the RTR analysis, the results of our RTR for the source category, and our proposed decisions concerning changes to the Primary Lead Smelting MACT standard. As noted previously, all references to lead emissions in this proposal means "lead compounds," which is the regulated HAP under CAA section 112. All reference to lead production means the production of element lead.

A. What data were used in our risk analyses?

For the Primary Lead Smelting source category, we compiled a preliminary dataset using readily available information, reviewed the data, and made changes where necessary. The preliminary dataset was based on data in the 2002 National Emissions Inventory (NEI) Final Inventory, Version 1 (made publicly available on February

26, 2006), and the 2005 National Emissions Inventory (NEI), version 2.0 (made publicly available in October 2008). The 2005 NEI was updated to develop the 2005 National Air Toxics Assessment (NATA) Inventory. NATA inventory updates for the primary lead smelting category included SIP data provided by the state of MO to EPA. The 2005 NATA inventory was used with updated 2008 data received in an Information Collection Request (ICR) response from the Doe Run facility. The NEI is a database that contains information about sources that emit criteria air pollutants, their precursors, and HAP. The NEI database includes estimates of annual air pollutant emissions from point and volume sources, emission release characteristic data such as emission release height, temperature, velocity, and location latitude/longitude coordinates. We reviewed the NEI datasets, checked geographic coordinates, and made changes based on available information. We also reviewed the emissions and other data to identify data anomalies that could affect risk estimates.

The risk assessment was based on estimates of the actual emissions and allowable emissions. The estimates of actual emissions were for the year 2008 and were based on data from the ICR along with data from our NEI dataset. These estimates included both stack and fugitive emission sources. Fugitive dust sources include material handling (concentrate, sinter, fume and dross), plantwide resuspension (roadways, storage piles and plant vard) and other miscellaneous sources (vents and heat stacks). The material handling sources contribute approximately 84 percent of the total fugitive dust emissions, while plantwide resuspension and miscellaneous sources contribute approximately 11 and 5 percent, respectively. The estimates of allowable emissions were calculated using production data from the ICR response combined with the current emissions limits in the MACT standard.

Lead compounds account for about 99 percent of the HAP emissions from the source category, or about 20 tons in 2008. The facility also reported small emissions of five other metal HAP, and trace levels of 25 organic HAP.

The emissions data, calculations and risk assessment inputs for the Primary Lead Smelting source category are described further in the Technical Support Document for this action which is available in the docket for this proposed rulemaking.

We used the 2008 production information as the basis for calculating the MACT allowable ratio (allowable to actual) because the 2008 emissions are the most recent reported emissions that also reflect implementation of the requirements of the 2007 SIP revision. For more information on the ratio of actual to MACT-allowable emissions, see the Technical Support Document in the docket for this action describing the emission data information and estimation of MACT-allowable emission levels and associated risks and impacts.

B. What are the results of the risk assessments and analyses?

For the Primary Lead Smelting source category, we conducted an inhalation risk assessment for all HAP emitted. We also conducted a multi-pathway analysis for cadmium and lead. With respect to lead, we used the recentlypromulgated lead NAAQS to evaluate the potential for multi-pathway and environmental effects. Furthermore, we conducted a demographic analysis of population risks. Details of the risk assessments and additional analyses can be found in the residual risk documentation referenced in section IV.A of this preamble, which is available in the docket for this action.

1. Inhalation Risk Assessment Results

Table 3 provides an overall summary of the results of the inhalation risk assessment.

TABLE 3—PRIMARY LEAD SMELTING INHALATION RISK ASSESSMENT RESULTS

Maximum individual cancer risk (in 1 million) 1		Estimated population at risk	Estimated annual cancer incidence		nic non-cancer SHI ²	Maximum off-site refined acute
Actual emissions level	Allowable emissions level	≥ 1-in-1 million	(cases per year)	Actual emissions level	Allowable emissions level	non-cancer HQ ³
30	30	4,900	0.0008	1	1	0.6

¹ Estimated maximum individual excess lifetime cancer risk.

² Maximum TOSHI. The target organ with the highest TOSHI for the Primary Lead Smelting source category is the kidney.

³ The maximum acute HQ value shown uses the only available acute dose-response value for arsenic, which is the REL. See section IV.A of this preamble for explanation of acute dose-response values.

The results of the chronic inhalation cancer risk assessment indicate that, based on estimates of actual emissions from the base year 2008, the maximum individual lifetime cancer risk could be as high as 30-in-1 million with fugitive dust emissions of cadmium dominating the risk. The total estimated cancer incidence from this source category based on actual emission levels is 0.0008 excess cancer cases per year or one case in every 1,250 years. Approximately 200 people were estimated to have cancer risks above 10-in-1 million and approximately 4,900 people were estimated to have cancer risks above 1-in-1 million. When considering the maximum levels of emissions allowed under the current MACT standard, the MIR remains 30-in-1 million. The MIR remains the same since the fugitive dust emissions are governed by work practices, which under § 63.1544 are defined as the measures that will be "put into place to control fugitive dust emissions." Thus, the actual emissions, which reflect the measures that have been put in place, should be equivalent to the allowable

The maximum chronic noncancer TOSHI value is 1, with fugitive emissions of cadmium dominating those impacts. When considering MACT allowable emissions, the maximum chronic noncancer TOSHI value remains 1 since, for the reasons provided above, MACT-allowable fugitive emissions are equal to actual fugitive emissions.

Based on the acute REL value for arsenic, an off-site screening-level acute HQ value from this facility could be as high as 6. However, the emissions factor of 10 times the average hourly emissions rate is not appropriate in this instance, given that fugitive emissions are minimized during the meteorological conditions associated with the worst-case short-term impacts (*i.e.*, during low-wind, stable atmospheric conditions). Thus, we refined the

assessment and estimated a maximum off-site HQ value of 0.6.

The results of a multipathway screening analysis for cadmium emissions from this facility were well below the *de minimis* emission rate that would indicate a non-negligible risk of adverse health effects from multipathway exposures. We estimate the specific multipathway *de minimis* emission rate for cadmium to be 0.65 TPY and only 0.1 TPY is emitted from the one facility in this source category. Thus, there appears to be little, if any, multipathway risk associated with cadmium emissions from this facility.

In evaluating the potential multipathway risks from emissions of lead compounds, we compared modeled maximum 3-month rolling average atmospheric concentrations with the NAAQS for lead. Table 4 presents the results of our lead impact analysis broken down by emission point considering actual 2008 emissions as well as the maximum emissions of lead that the MACT standard would have allowed based on production rates for calendar year 2008. For purposes of our analysis, we determined separately the risk from each of the types or processes/ emissions sources regulated by the current MACT, with one exception. Under the MACT, emissions from the refining and casting area were considered fugitive emissions subject to work practice standards under § 63.1544. Since then, pursuant to requirements that the 2002 State SIP adopted for purposes of meeting the 1.50 µg/m³ lead NAAQS, Doe Run enclosed the refining and casting area and vents those emissions to the refinery stacks. We considered these stack emissions separate from the fugitive dust emissions. Thus, the four emission process/sources we evaluated for risk were: (1) The main stack, (2) the furnace area stack, (3) the refinery stack, and (4) fugitive emissions.

The analysis indicates that under both actual 2008 or MACT allowable

emission scenarios, emissions from the main stack do not result in lead levels above the NAAOS within the 50 km radius that was modeled. This is likely due to the height of the stack (500 feet), which would result in broader and further dispersal of lead emissions. However, results of the analysis did indicate that modeled ambient air lead concentrations resulting from this facility's fugitive dust emissions could exceed the NAAOS for lead by as much as 50-fold at the property boundary based on both actual and allowable emissions. Moreover, results indicate that modeled emissions from the furnace area stack could result in NAAQS exceedances under both actual 2008 and MACT-allowable emissions scenarios. In addition, the actual estimated emissions from the refining stacks, which were put into place based on requirements adopted by the State for purposes of the SIP, could result in NAAQS exceedances. We were unable to calculate a "MACT allowable" emission level for the refinery emissions, which under the MACT are included as fugitive emissions. This analysis also indicates that within 50 km of this facility, approximately 1,900 people could be exposed to ambient air lead concentrations exceeding the level of the NAAQS for

As mentioned above, to evaluate the potential for adverse environmental effects, we also compared maximum 3-month rolling average atmospheric concentrations with the current secondary NAAQS for lead, which is the same as the primary standard. Thus, the analyses presented in Table 4 also indicate the potential for adverse environmental effects from emissions of lead. Note that modeling performed for this analysis is based on different inputs than SIP modeling done for the one remaining primary lead facility, and thus results differ.

TABLE 4—SUMMARY OF MODELED LEAD CONCENTRATIONS RELATIVE TO THE NAAQS BASED ON ESTIMATED ACTUAL 2008 AND MACT ALLOWABLE EMISSIONS

Emission point	Actual 2008 emissions (TPY)	Maximum impact— actual emissions	Allowable emissions ¹ (TPY)	Maximum impact— allowable emissions
Main stack ²	2.74 1.81	0.05 times the NAAQS 3 times the NAAQS 2 times the NAAQS 50 times the NAAQS	NA 8.94	0.25 times the NAAQS. NA. 10 times the NAAQS. 50 times the NAAQS.

¹ Allowable emissions for the main stack and furnace area emission points are based on 1 lb of Pb/ton production (MACT limit); Refinery emissions are included as fugitive emissions under MACT but are now vented to a stack because of SIP requirements; therefore, we were unable to calculate a "MACT allowable" emission level.

² Main stack is the emission point for sinter machine, blast furnace and drossing operations.

³ Fugitive dust emissions are covered by work practices under current MACT and were calculated via emission factors assuming compliance with the MACT. The site of maximum ambient air lead concentration resulting from fugitive dust emissions occurs in close proximity to the southeast boundary of the facility (see Figure 3.1–1 of the risk assessment document). Note that this maximum result and its location are based on modeling 2008 emissions using 1998 site-specific meteorology, and that these may differ from inputs used for other types of modeling (e.g., SIP modeling.)

2. Facility-wide Risk Assessment Results

Our screening analysis determined that the organic HAP emissions from facility represented negligible risk and were determined to be insignificant with regard to this risk analysis. As a result, all significant HAP emissions from the one facility in this category are reflected in the risk analyses presented above; therefore, facility-wide risks are equivalent to those of the source category.

3. Model to Monitor Comparison

In addition to the results presented above, we also compared maximum AERMOD estimates of ambient air lead concentrations with those measured at 4 monitors in close proximity to the Herculaneum Primary Lead Smelting Facility for calendar year 2008. More specifically, we compared maximum 3-month rolling average lead concentrations (for calendar year 2008) calculated from data reported at the Main Street, Circle Street, South Cross, and Church Street monitors to the

maximum 3-month rolling average lead concentrations at model receptor locations in close proximity to these monitoring sites. These monitor locations were chosen because they represented the closest offsite monitors to the Herculaneum primary lead smelter. Thus, lead measurements at these monitoring sites would likely be dominated by emissions from this facility which is important given that AERMOD estimates of ambient air lead concentrations only considered lead emissions from this facility (i.e., only lead emissions from the Herculaneum primary lead smelter were used as inputs into AERMOD).

Results of this analysis are presented in Table 5 and indicate that with respect to the Main Street and Circle Street monitors, AERMOD underestimates 3-month maximum lead concentrations by approximately 2.8- and 4.2-fold, respectively. While these monitor to model comparisons are not in complete agreement on a point-by-point basis, we note that this would not be expected given the general uncertainties associated with using dispersion

modeling to estimate ambient pollutant concentrations and considering that the meteorological data used to develop the model estimates were from a different year than the actual monitoring and emissions data (i.e., meteorological data used in the AERMOD simulation was from 1998 while the emissions estimates and the monitoring data were from 2008). However, results do indicate that the maximum 3-month average lead concentration across the group of monitors nearest the facility is approximately equal to the maximum 3month average lead concentration estimated by AERMOD across the group of these monitoring sites (i.e., both the Main Street monitor and the South Cross AERMOD estimate indicate the maximum 3-month average lead concentration to be approximately 2.1 µg/m3). Taken together, these results indicate that AERMOD estimates of ambient air lead concentration provide a reasonable representation of the measured 3-month maximum lead concentrations present in the ambient air near this facility.

TABLE 5—COMPARISON OF AERMOD MODELED TO AMBIENT AIR LEAD CONCENTRATIONS REPORTED BY FOUR MONITORS SURROUNDING THE HERCULANEUM PRIMARY LEAD SMELTING FACILITY

Location	Maximum AEMOD modeled 3-month lead concentration (μg/m³)	Maximum monitored 3-month lead con- centration ²⁰ (μg/m³)	Model to monitor ratio ²¹
Main Street Circle Street South Cross Church Street	0.47	3.14	-4.6
	0.38	1.14	-3.0
	2.13	0.75	2.8
	1.99	0.47	4.2

4. Demographic Risk Analysis Results

Demographic analyses were performed to investigate the population

distribution of: (1) Cancer risks at or above 1-in-1 million and (2) risks from ambient air lead concentrations above the NAAQS for lead. Results are summarized in Table 5 and are based on modeling using estimated actual emissions levels for the population living within 50 km of this facility.

TABLE 6—PRIMARY LEAD SMELTING DEMOGRAPHIC RISK ANALYSIS RESULTS

	Nationwide	Population with cancer risk greater than 1 in a million	Population with ambient air lead concentrations exceeding the NAAQS
Total population	285,000,000	4,900	1,900
Race by percent			
White	75	96	96

²⁰ Maximum 3-month monitored concentrations were calculated for the year 2008 based on data submitted to EPA's Air Quality System (AQS).

²¹ Negative sign denotes an underestimation of AERMOD modeled ambient lead concentrations, relative to monitored concentrations. AERMOD

estimated concentrations were based on the 2008 emissions estimates described in section V.A.

TABLE 6DDIMABV	LEAD SMELTING	DEMOGRAPHIC RISK A	ANALVOIS DESILITS	Continued
I ABLE O-FRIMARY	LEAD SWELLING	DEMOGRAPHIC DISK /	ANALYSIS DESULIS-	-conunuea

	Nationwide	Population with cancer risk greater than 1 in a million	Population with ambient air lead concentrations exceeding the NAAQS
All Other Races	25	4	4
Race by percent			
White	75 12 0.9 12	96 4 0.2 1	96 3 0 0.8
Ethnicity by percent			
Hispanic	14 86	1 99	0.3 99.7
Income by percent			
Below poverty level	13 87	15 85	15 85

Results of the risk assessment indicate that there are approximately 4,900 people exposed to a cancer risk greater than 1-in-1 million, and 1,900 people in areas with ambient air lead concentrations above the NAAQS for lead. In both instances, the demographics analysis estimates that about 4 percent of these populations can be classified as a minority (listed as "all Other Races" in the table), which is well below the national percentage of 25. Similarly, in the cancer and lead demographic analyses, the percentage of "African American," "Hispanic," "Native American," and "Other and Multiracial" population groups are well below the corresponding national percentages. With respect to the percentage of those "Below the Poverty Level," in both demographic analyses there is a small (2 percent) increment above the corresponding national percentage. However, given that the total population affected is small (i.e., 4,900 individuals for cancer risk greater than 1-in-1 million and 1,900 individuals in areas with lead concentrations above the NAAQS), we do not think this indicates any significant potential for disparate impacts to the specific demographic groups analyzed.

Moreover, given the extent to which lead may impact children's health, we further note that our demographic analysis doesn't indicate the presence of a higher percentage of children than one would normally expect around this facility. That is, while the national percentage of children 18 years and younger is 27%, the percentage of children living near this facility who are estimated to be exposed to lead

concentrations above the NAAQS is only slightly higher at 28% (see Risk and Technology Review—Analysis of Socio-Economic Factors for Populations Living Near Primary Lead Smelting Facilities in the docket for this proposed rulemaking), a difference which is likely not significant.

C. What are our proposed decisions on risk acceptability and ample margin of safety?

1. Risk Acceptability

As noted in section III.B of this preamble, we weigh all health risk factors in our risk acceptability determination, including cancer risks to the individual most exposed, risk estimation uncertainty, and other health information. For the Primary Lead Smelting source category, the risk analysis indicates that the cancer risks to the individual most exposed could be as high as 30-in-1 million due to actual or MACT-allowable emissions. These risks are considerably less than 100-in-1 million, which is the upper bound of the presumptive range of acceptability. The incidence of cancer is very low-0.0008 excess cancer cases per year; or one case every 1,250 years. Similarly, the risks of chronic non-cancer health effects from HAP emissions other than lead were low, with a maximum HQ of 1. Moreover, while an initial screening analysis suggested that fugitive emissions of arsenic had the potential to create a risk of acute health effects, a refined analysis based on our knowledge of this emission source indicated that the risk was low (HQ = 0.6). In addition to these health analyses, a demographics analysis did

not indicate the potential for significantly disproportionate heath impacts (see above, section V(3)(c)). Thus, risks associated with the non-lead emissions from the Primary Lead Smelting source category for cancer, acute and chronic non-cancer health effects and environmental effects are considered acceptable.

However, since ambient air lead concentrations resulting from emissions from this facility were modeled to be in excess of the NAAQS for lead, the risks associated with lead emissions from this facility were judged to be significant. Our analysis estimated that modeled offsite ambient air lead concentrations (based on actual 2008 emissions) resulting from this facility could be as high as 50 times the NAAQS for lead based on fugitive dust emissions, and that approximately 1,900 individuals could be exposed to lead concentrations in excess of the NAAQS. Given that the NAAQS for lead was set to "provide increased protection for children and other at-risk populations against an array of adverse health effects, most notably including neurological effects in children, including neurocognitive and neurobehavioral effects (73 FR 67007)", we are proposing that risks associated with lead emissions from this source category are unacceptable.

As noted above, our risk analysis for lead was based on modeled 3-month rolling average lead concentrations in ambient air in comparison to the primary lead NAAQS. We believe that in order to provide an acceptable level of risk, lead concentrations in the ambient air must be reduced to the level of the lead NAAQS. Thus, we

considered specific emission limits for the three emission sources/points that were modeled to result in lead concentrations in excess of the NAAQS (see Table 4); refinery stack, furnace area stack, and fugitive dust emissions, with the majority of fugitive dust impacts from material handling sources. Based on our analysis, we conclude that in order to meet the NAAQS for lead at all model receptors, fugitive dust emissions would have to be reduced by approximately 98 percent to 0.064 TPY, refinery stack emissions and furnace area stack emissions would have to be reduced by approximately 80 percent to a total of 0.91 TPY (the maximum impacts of refinery and furnace emission points occur at the same location.) Further, because the maximum ambient air impacts of the refinery/furnace emissions, the fugitive dust emissions, and the main stack do not significantly overlap each other, we estimate that lead emissions from all emission points other than the main stack would have to be limited to a total of approximately 0.97 TPY in order to ensure 3-month rolling average ambient air lead concentrations do not exceed the lead NAAQS level of 0.15 µg/m³. As noted above, emissions from the main stack (i.e., emission point for sinter machine, blast furnace and drossing operations) did not result in ambient air lead concentrations in excess of the lead NAAQS at modeled locations within 50 km of the property boundary and thus we are not proposing any reductions at the main stack in order to ensure an acceptable level or risk.

Once we determined the emissions reductions necessary to achieve an acceptable level of risk, we investigated available emissions control options and their ability to reduce emissions and health risks for fugitive dust and for stack emissions from both the refining and furnace area stacks. Control options considered for reducing fugitive dust emissions and associated risks include improved or additional work practices, site remediation, application of additional capture/control measures, and lead production limitations. With the exception of site remediation, all of these control measures have been implemented to varying degrees at the Doe Run facility in response to the Missouri SIP, as revised in 2002 and the 2007 revisions submitted for approval to the SIP. As such, because the actual emissions for 2008 reflect the implementation of those control measures, requiring those controls under the MACT would be unlikely to yield the additional 98 percent reduction in fugitive emissions

necessary to meet the primary lead NAAQS level of 0.15 μg/m³. Thus, our evaluation of risks based on actual emissions already considered emissions with these controls largely in place. In order to ensure that site remediation efforts, or any other efforts the source may choose to undertake, will result in sufficient emission reductions to address the unacceptable level of risk, we are proposing to establish a lead concentration in air limit of $0.15 \mu g/m^3$ to be measured at locations approved by the Administrator. This lead concentration in air limit would be established as the enforceable requirement to address fugitive emissions under the MACT standard.²² Because we are proposing a concentration limit to address fugitive dust emissions, we no longer believe it is necessary for the affected facility to provide a plan to the Administrator describing work practices that will be used to reduce fugitive emissions. Therefore, we are proposing to remove the requirement to develop and submit a work practice standard operating procedure (SOP) manual as required in § 63.1544(a).

As an alternative to proposing compliance monitoring requirements for demonstration of compliance with the lead concentration in air limit, we considered retaining the current fugitive dust emissions requirement to develop and submit to the Administrator or delegated authority a work practices SOP. Using this alternative approach, we believe it would be necessary to modify the current general requirements for an SOP by specifying the minimum work practice requirements that the plan must include. For example, under this alternative approach, we would require that the SOP must include, at a minimum, detailed descriptions of all measures that would be used to control fugitive dust emissions from plant roadways; material storage, transfer and handling areas; sinter machine areas; furnace areas; refining and casting areas; and other areas the Administrator may identify. Further, EPA would require that the SOP contain detailed descriptions of work practices including road watering and automatic sprinklers, methods to remove dust from paved surfaces to reduce emissions from traffic, maintenance of minimum water content for ore concentrate and for baghouse dust that will be handled or transferred, and procedures for the

inspection of building siding or damages and openings. The SOP would be required to include procedures, including recordkeeping, to ensure that the work practices are being implemented at a frequency and in a manner that would ensure that fugitive dust emissions are being minimized. To determine whether the work practices described in the SOP are reducing emissions sufficient to comply with the lead concentration in air limit, the owner or operator would be required once a year to model the fugitive dust emissions using measurement data or emission factors according to an approved fugitive dust emissions modeling plan. At a minimum, EPA would require that this modeling plan include a detailed description of each fugitive dust emission source; a detailed description of the control practices or techniques used to limit fugitive dust emissions from each source; the emission factors, test data or other methods used to characterize and quantify lead emissions from each source; a description of the emissions modeling that will be used to estimate the concentrations of lead in air at or near the property boundary as contributed by each source as well as cumulatively contributed by all sources; a description of process or other conditions that would indicate the need to demonstrate compliance more often than annually; the calculations to be used to show compliance with the air lead concentration limit that consider the highest modeled air lead concentrations from the modeled fugitive dust sources and any contributions from background lead concentrations in air; and a description of the records that will be kept. We are seeking comments on the proposed requirements to monitor air lead concentrations versus the alternative approach described above, of requiring extensive work practices and a work practice SOP in conjunction with emissions modeling, to demonstrate compliance with the air lead concentration limit.

Measures available for reducing lead emissions from the refining and furnace area stacks include upgrading existing baghouses by replacing the existing fabric bags with high efficiency membrane bag filters. Another option would be to add extra in-line baghouses after existing baghouses. Such measures would reduce lead emissions and associated risk to within acceptable levels.

In summary, our analysis indicates that in order to ensure that lead emissions from this source do not pose an unacceptable risk, emissions from

²² Under the consent decree, of which we sought public comment last fall, fugitive dust sources will be addressed by site remediation; however, some fugitive dust emissions will remain during the remediation of the site, which will likely extend beyond April 2014.

this facility would need to be reduced to a level that would ensure that these emissions would not result in air lead levels greater than the 0.15 μg/m ³ for any 3-month period at all of the modeled locations. Further, we conclude that in order to achieve the 0.15 µg/m³ level (for any 3-month rolling average) at all modeled locations, fugitive dust emissions would need to be reduced by 98 percent and the emissions from the furnace area and refining operation stacks would need to be reduced by 80 percent. We have identified emission reduction and control options for achieving the required reductions, which include implementation of site remediation, work practices, and upgrade of existing baghouses with membrane bags and/or addition of an additional in-series baghouse.

We are proposing the following requirements to ensure that risk is reduced to an acceptable level.

- A stack lead emission cap of 0.91 TPY that would apply to the furnace area stack and the refining operation stacks.
- An air lead concentration limit of 0.15 μg/m³ based on 3-month rolling average (to be measured at locations approved by the Administrator) to ensure that fugitive dust emission levels will not exceed the NAAQS.

The proposed limits apply to both new and existing facilities. Any facility subject to the MACT would be required to meet these requirements for each emission unit it is operating that is subject to the limit. In order to address any fugitive dust emissions, the facility, regardless of whether it is operating all or just some of the emission sources covered by this action, would be required to meet the air lead concentration emission limit.

For both new and existing facilities, compliance with the air lead concentration limit would be demonstrated using lead compliance monitoring devices and would be based on a rolling 3-month average concentration. The proposed rule requires development of a monitoring plan for approval by the Administrator that includes the minimum sampling and analysis methods and compliance demonstration criteria provided in the rule. A provision is included in this proposed rule that allows for reduced monitoring if the facility demonstrates an air lead concentration for three consecutive years at less than 50 percent of the air lead concentration limit. The monitoring can be reduced to once every six months unless one of the 6month monitoring events exceeds 50 percent of the air lead concentration

limit, at which time monitoring will be required to resume based on the initial plan approved by the Administrator until another three years of consecutive monitoring below 50 percent of the air lead concentration limit is achieved. The compliance requirements discussed above were designed to allow for flexibility, prevention of redundant requirements, and also to provide consistency with current monitoring required at the site. We are soliciting comment on this approach. For existing facilities, compliance with the emission limit for the furnace area and refinery stacks would be demonstrated through stack testing conducted on a quarterly basis. All performance testing will be consistent with the existing MACT testing requirements, with the exception of frequency. As provided in § 63.153(e) of the current rule, the facility can reduce compliance testing frequency if the most recent three compliance tests demonstrated compliance. We are maintaining this provision, however, because this proposed rule increases the testing frequency to quarterly, the number of most recent tests necessary to comply with this provision will be increased from three to 12. New primary lead processing facilities would be required to demonstrate compliance using a lead continuous emission monitoring systems (CEMS). However, since the Agency has not finalized the performance specification for the use of these instruments, we are deferring the effective date of the requirement to install, correlate, maintain and operate lead CEMS until these actions can be completed. The lead CEMS installation deadline will be established through future rulemaking, along with other pertinent requirements. In the event operations commence at a new facility prior to promulgation of the performance specification, compliance would be demonstrated through quarterly stack testing until promulgation of the lead CEMS performance specification.

2. Ample Margin of Safety

Reducing lead emissions to meet the NAAQS would ensure that emissions of all HAP do not pose an unacceptable risk. Once we ensure that the risk is acceptable, we then look to determine whether further reductions are appropriate to ensure an ample margin of safety. In this part of our analysis, we again consider the health factors we considered to determine whether the risks are acceptable but we also consider the cost of controls.

With regard to lead emissions, we are proposing to require most of the emission sources at the facility to

implement all technically feasible controls in order to ensure that the ambient air meets the level of the lead NAAQS, which is the level that we have determined will ensure an acceptable level of risk. Because all feasible controls will need to be adopted in order to meet that proposed standard, there are no additional controls to consider for the three emission sources: Fugitive dust emissions, the furnace area stack, and the refinery stacks. We further note that the same controls we have proposed for the three emission points to reduce lead emissions are the same controls that would reduce risks from cadmium and all other metal HAP known to be emitted from this source category. Thus, we are proposing that the controls required to ensure that risk from lead emissions from those three emission points is acceptable also protect public health with an ample margin of safety with regard to emissions from all metal HAP from these three emission points. Notably, after these standards are in place, we estimate that the MIR cancer risk due to the non-lead HAP will be less than 1-in-1 million.

Our risk analysis indicates that the main stack emissions do not result in ambient air lead levels exceeding the NAAQS based on either actual or allowable emission levels. We determined, as discussed section V.D. below, that it is technologically feasible to reduce emissions from the main stack to a level well below the allowable level of the MACT, since those levels are currently being achieved, and thus we are proposing to require such controls under CAA section 112(d)(6). We evaluated whether there were additional controls to further reduce emissions from the main stack and determined that lead emissions from the main stack could be further reduced by replacing the standard cloth bags with membrane bags at a capital cost of approximately \$2 million and an annual cost of \$0.3 million. Assuming a 50 percent reduction from 2008 main stack emissions, the cost of reducing lead emissions would be about \$40,000 to \$229,000 per ton of lead. (See the Technical Support Document included in the docket for a complete discussion of this analysis.) Because the highest ambient air lead concentration resulting from the emissions from the main stack already is more than 20 times below the level that is considered acceptable, it was determined that although additional controls such as membrane bags could result in additional emission reductions, the additional controls are not warranted since they would not

appreciably reduce risk. We are proposing that the MACT standard, with the changes we are proposing under the section 112(d)(6) technology review as described in section V.D. below will provide an ample margin of safety with regard to emissions of lead and other HAP from the main stack.

D. What are the results and proposed decisions from the technology review?

We evaluated developments in practices, processes, and control technologies applicable to emission sources subject to the Primary Lead Smelting MACT. This included a search of the RBLC Clearinghouse, the California BACT Clearinghouse, the internet, and correspondence with state agencies and industry. We have determined that there have been advances in emission control measures since the Primary Lead Smelting MACT standard was originally promulgated in 1999.

The 1999 MACT limit was set using the lead emission limits from the lead SIPs for the three states in which primary lead smelting sources were operational at the time of the rulemaking. EPA took each of the three lead SIP limits, in lb/day, divided them by the corresponding lead production capacity, in tons/day, and calculated a lead emission rate in lb/ton. The results were as follows:

ASARCO—Missouri 1.0 lb/ton ASARCO—Montana 1.0 lb/ton Doe Run—Missouri 0.84 lb/ton

The values were ranked and the median value (1.0 lb/ton) was selected as representative of the MACT floor.

Since the MACT standard was promulgated, the industry has undergone significant changes. Two of the three facilities have shut down. The only remaining primary lead smelting facility is the Doe Run smelter at Herculaneum, Missouri, which is subject to control requirements under the Missouri SIP for lead. The existing SIP, as well as a 2007 SIP revision submitted by the State and proposed for approval by EPA require numerous emissions-reducing measures and improvements to add-on control devices, processes, and work practices. We considered these developments in practices, processes, and control technologies in our technology review.

Recent emissions tests (2000 through 2008) at the Doe Run facility support that these improvements have resulted in significantly lower emissions and demonstrate that actual lead emissions from the facility are much lower than are allowed under the current MACT rule. To assess the impacts of

developments in practices, processes and control technologies on lead emissions, emissions data from 2008 were compared with emissions data from 2000. Data from 2008 were selected because they reflect the many improvements that have been implemented at the facility since promulgation of the MACT rule. Emissions data from earlier years would not reflect all of the emission-reducing changes that have been implemented at the Doe Run facility given that some of the improvements were not implemented until 2007 and 2008. As described above, technological improvements to baghouses and processes that have been implemented at the facility since the MACT rule was promulgated have resulted in substantially lower emissions from these sources at this facility. These improvements include upgrade of cloth bags and ventilation improvements. In 2008, lead emissions from the main stack, which vents emissions from the sintering operation and the blast and dross furnace, were 13.31 TPY. In addition, emissions from the furnace area stack (i.e., the blast furnace and dross plant building which vent to baghouse 7) were 1.81 TPY, for a total of approximately 15.1 TPY. At the 2008 lead production rate of 149,500 tons, the lead emission rate for these sources at Doe Run was about 0.2 lb/ton, or 80 percent less than the current MACT limit of 1 lb/ton. Based on this demonstrated performance, EPA believes that under Section 112(d)(6), the MACT standard should be revised to reflect the reduction achieved in practice.

Because we believe that the 2008 emissions of 13.31 TPY from the main stack (or combined sintering/blast furnace/drossing operations) reflect the annual rate of emissions achievable as a result of the technological improvements that have been made since 1999, we are proposing an emission limit based on the actual 2008 annual emissions that vent to the main stack (i.e., sintering, blast furnace and drossing operations). In order to account for variability in the operation and emissions, recent stack tests were used to calculate the 95 percent upper predictive limit (UPL). The 95 percent UPL for the main stack is 15 TPY. Variability in the operations and emission for this source are discussed in more detail in Section E below.

Although we believe that there have been developments in processes, practices and control technologies with regard to the furnace area stack and with regard to refining and casting operations, as reflected by the more

stringent requirements that have been implemented in accordance with the approved SIP and the 2007 SIP revisions; we are not proposing additional requirements for these stacks as part of our technology review because we have already proposed that these stacks implement all feasible controls, regardless of cost, in order to ensure that the risks due to these emission points are acceptable. Thus, there are no additional developments in practices, processes and control technologies beyond those which are reflected in the emission limits we have proposed to meet CAA section 112(f)(2), above.

To be consistent with the existing MACT standard, EPA is proposing to retain the plant-wide pound per ton of production format that currently applies to the aggregate emissions from the main stack and the furnace area stack. Because there are also stacks for the refining and casting operations, we are proposing to include those emissions as part of the plant-wide emission limit. Thus we are proposing a plant-wide lead emission limit of 0.22 pounds of lead per ton of lead produced based on the proposed reductions due to the section 112 (f)(2) risk review for the furnace area and refining operations stacks (discussed above in Section C) and the reduction in emissions from the main stack (sinter/blast furnace/ drossing operations) based on this Section 112(d)(6) technology review This proposed plant-wide lead emission limit was determined by summing the 15 TPY for the main stack and the 0.91 TPY for the furnace area and the refining operation, and dividing by the annual production from 2008 of 149,564 tons. We note that variability was only applied in establishing technologybased emissions from the main stack in order to establish a plant-wide emission limit. Because the emission levels required from the refining operation and furnace area stacks are based on acceptable risk, we conclude it is not appropriate to consider variability in establishing limits for these emission

We are proposing that the plant-wide lead emission limit apply to new and existing facilities that are subject to the MACT. By default this would include any new, controlled lead processing source not currently covered, including lead processing by other than the current techniques. We are requesting comment on the appropriateness of applying the plant-wide lead emission limit to any future new lead processing technique.

For the existing facility, compliance with the plant-wide stack emission limit would be demonstrated in the same manner as discussed above in section V.C.1 for the furnace area and refining stack limit (i.e., stack testing on a quarterly basis). We are proposing stack testing on a quarterly basis as opposed to testing on an annual basis since this allows the facility the opportunity to adjust their emissions throughout the year to be in compliance, rather than to find they are out of compliance at the end of the year, thereby risking violations. This schedule also coincides with other quarterly monitoring and reporting required of the facility. Also as discussed in section V.C.1, new primary lead processing facilities would be required to demonstrate compliance using lead continuous emission monitoring systems (CEMS).

E. Variability

In assessing sources' performance, EPA may consider variability both in identifying which performers are "best" and in assessing their level of performance. *Brick MACT*, 479 F. 3d at 881–82; see also *Mossville Envt'l Action Now* v. *EPA*, 370 F.3d 1232, 1241–42 (D.C. Cir 2004) (EPA must exercise its judgment, based on an evaluation of the relevant factors and available data, to determine the level of emissions control that has been achieved by the best performing sources considering these sources' operating variability).

Variability in lead producers' performance has a number of causes. For emissions of lead compounds that are controlled by baghouses, the variability is chiefly due to variations in

performance of the control device for which both run-to-run and test-to-test variability must be accounted.²³

In determining the contribution to a plant-wide emission limit of the main stack, we considered annual emissions discharged from the air pollution control devices that control lead emissions. For this rule, we used the 2008 emissions reported by Doe Run to the State of Missouri.

We assessed variability using a statistical formula designed to estimate an emissions level that is equivalent to the source's performance based on future compliance tests. Specifically, the calculated limit is an upper prediction limit (UPL) calculated with the Student's t-test using the TINV function in Microsoft Excel®. The Student's t-test has also been used in other EPA rulemakings (e.g., NESHAP for Portland Cement Manufacturing [75 FR 54970, September 9, 2010]; NSPS for Hospital/Medical/Infectious Waste Incinerators [74 FR 51368, October 6, 2009]; NESHAP for Industrial, Commercial, and Institutional Boilers and Process Heaters-Proposed [75 FR 32006, June 4, 2010]) in accounting for variability. A prediction interval for a future observation is an interval that will, with a specified degree of confidence, contain the next (or some other pre-specified) randomly selected observation from a population. In other words, the prediction interval estimates what the upper bound of future values will be, based upon present or past samples taken. The UPL consequently

represents the value which we can expect the mean of future observations (3-run average for lead) to fall below within a specified level of confidence, based upon the results of an independent sample from the same population. In other words, if we were to randomly select a future test condition from any of these sources (i.e., average of 3 runs or 30-day average) we can be 95 percent confident that the reported level will fall at or below the UPL value. Use of the UPL is appropriate in this rulemaking because it sets a limit any single or future source can meet based on the sources past performance.

This formula uses a pooled variance (in the s² term) that encompasses all the data-point to data-point variability. Where variability was calculated using the UPL statistical approach, we used the sample standard deviation calculated from the emissions data distributions for lead. The standard deviation is the common measure of the dispersion of the data set around an average. We note here that the methodology accounts for both short-term and long-term variability and encompasses run-to-run and test-to-test variability.

We adopted a form of the UPL equation that has been used in more recent rulemakings. See 75 FR 54970 (September 9, 2010), 75 FR 32020 (June 4, 2010) and 75 FR 31905 (June 4, 2010). The UPL used in this proposed rule is calculated by:

$$UPL = \bar{x} + t(0.99, n-1) \times \sqrt{s^2 \times \left(\frac{1}{n} + \frac{1}{m}\right)}$$

Where:

 $\bar{x} = 2008$ annual emissions

n = the number of test runs

$$\label{eq:model} \begin{split} m = \text{the number of test runs in the} \\ \text{compliance average} \end{split}$$

 s^2 = observed variance

 $t = student \ t \ distribution \ statistic$

This calculation was performed using the following Excel functions: 95 percent UPL = 2008 annual emissions + [STDEV (Test Runs) \times TINV (2 \times probability, n-1 degrees of freedom) \times SQRT ((1/n) + (1/m))], for a one-tailed t-value, probability of 0.05, and sample size of n.

F. What other actions are we proposing?

As discussed in Section III.C. above, EPA is proposing to remove provisions in the existing standard that would have exempted sources from complying with the standard during periods of startup, shutdown and malfunction. Specifically we are proposing revisions to subpart TTT Table 1 and rule provisions to remove applicability of the General Provisions with regard to SSM and remove the exemption for bag leak detection alarm time attributable to SSM events from determining compliance with the total alarm time limit. In addition, we are proposing to

imprecision of stack test methods and laboratory analysis. 72 FR 54877 (Sept. 27, 2007). Test-to-test variability results from variability in pollution device control efficiencies over time (depending on many factors, including for fabric filters the point promulgate an affirmative defense to civil penalties for exceedances of emission limits caused by malfunctions, as well as criteria for establishing the affirmative defense.

EPA has attempted to ensure that we have not included in the proposed regulatory language any provisions that are inappropriate, unnecessary, or redundant in the absence of the SSM exemption. We are specifically seeking comment on whether there are any such provisions that we have inadvertently incorporated or overlooked.

in the maintenance cycle in which a fabric filter is tested). Test-to-test variability can be termed long-term variability. 72 FR 54878.

²³ Run-to-run variability is essentially within-test variability, and encompasses variability in individual runs comprising the compliance test, and includes uncertainties in correlation of monitoring parameters and emissions, and

VI. Proposed Action

A. What actions are we proposing as a result of the residual risk reviews?

Consistent with CAA section 112 (f)(2), we are proposing to amend the MACT standard for primary lead processing to include a lead concentration in air limit of 0.15 µg/m3 (based on 3-month rolling averages) to be measured at locations approved by the Administrator to address the risks from all fugitive dust emissions addressed in 40 CFR 63.1544. We are also proposing to remove refining and casting operations from § 63.1544 and to require that emissions from these operations be vented to one or more stacks. Finally, we are proposing to establish an emission cap of 0.91 TPY for the furnace area stack and the refining operation stacks. These limits were established based on the level of reductions in lead emissions from the three sources that are necessary to show that the lead NAAQS will not be exceeded within the 50 km modeled domain. We believe the NAAQS level represents an acceptable level of risk and that the proposed limits are necessary to ensure that risks from these sources are acceptable. We are proposing that the risk posed by lead emissions from the main stack and by emissions of all other HAP is acceptable.

We are proposing that compliance with the emission limits applicable to the furnace area and refinery stacks would be demonstrated based on stack testing for existing facilities and, for new facilities, using CEMS after promulgation of performance specifications for a CEMS capable of measuring lead emissions.

We are proposing that compliance with the lead concentration in air limit would be demonstrated using a compliance monitoring system approved by the Administrator.

We are also proposing that the Primary Lead Smelting standard, as we have proposed to revise it to ensure an acceptable level of risk, will also protect public health with an ample margin of safety. With regard to lead emissions from fugitive dust sources and from the furnace and refining area stacks, we have not identified any feasible controls beyond those needed to meet the proposed emission limits that will provide an acceptable level of risk. The standards we are proposing to ensure an acceptable level of risk for lead emissions will also reduce the risk from cadmium and will also reduce emissions of all other metal HAP known to be emitted from this source category because the controls that will reduce lead emissions are the same controls

that will reduce emissions of these other metal HAP. The cancer risk from cadmium emissions will be reduced from 30-in-1 million to less than 1-in-1 million. Therefore, we are proposing that the existing MACT, as it would be modified based on our proposed requirements for lead emissions, would provide an ample margin of safety with respect to emissions from all metal HAP.

With regard to lead emissions from the main stack, we have identified developments in practices, processes and control technologies since promulgation of the MACT standard in 1999, and are proposing a reduced emission limit for the main stack based on these improvements. Since the main stack does not pose an unacceptable risk at its current emissions level, we are not proposing reductions for this emission point under 112(f)(2). However, we are proposing a reduced emission limit under 112(d)(6) due to the improvements we identified.

B. What actions are we proposing as a result of the technology reviews?

For the Primary Lead Smelting source category, we have determined that there have been developments in practices, processes, or control technologies since the promulgation of the MACT standards that are feasible for the one facility in this source category to implement at the main stack. The proposed limit is consistent with the current demonstrated performance of the facility based on obligations adopted by the State and reflected in the 2002 SIP and 2007 SIP revision for Doe Run.

We are proposing that a performance of 15.11 TPY has been demonstrated for emissions from the main stack, taking into consideration variability of emissions from that stack. The existing MACT lead emissions standard that is applicable to emissions from the main stack is a plant-wide emission limit that also applies to emissions from the furnace-area stack. We are proposing to revise the plant-wide limit to reflect the 15.11 TPY limit for the main stack as well as the emissions limits we are proposing for the furnace-area and refinery stacks under CAA section 112(f)(2). Thus, we are proposing to revise the plant-wide emissions limit from 1 pound of lead per ton of lead produced, to 0.22 pound of lead per ton of lead produced and the new limit would include emissions from the refinery stack as well as emissions from the main stack and the furnace area stack. Compliance with this limit would be demonstrated quarterly with stack testing. For new facilities, compliance

would be demonstrated using lead CEMS.

C. What other actions are we proposing?

As described above, we are proposing to amend the applicability section for the MACT rule to tailor it to the definition of the source category we established under CAA section 112(c)(1). See "Documentation for Development of Initial Source Category List—Final Report", USEPA/OAQPS, EPA-450/3-91-030, July, 1992. In support of this applicability provision clarification, we are also proposing to replace the definition of "primary lead smelter" with a definition of "primary lead processor". The "primary lead processor" definition would include any facility that produces lead from processing of lead sulfide ore by pyrometallurgical (smelting) or any other technique. We are also proposing to add definitions of "secondary lead smelters", "lead refiners", and "lead remelters" to clarify the meaning of those terms in the second sentence of the applicability provision.

We propose to amend the Primary Lead Smelting MACT standards to remove the language that exempts bag leak detection system alarm time incurred during periods of SSM from inclusion in the allowable alarm time. This change is being made to ensure the rule is consistent with the court's ruling in Sierra Club v. EPA, 551 F.3d 1019 (D.C. Cir. 2008). We are also proposing minor modifications throughout the rule to incorporate plain language and to make editorial and clarifying revisions. In addition, we are proposing changes to Table 1 of the rule to reflect revisions to SSM requirements.

D. Compliance Dates

We are proposing that the requirements under CAA section 112(f)(2) for the one existing source, if finalized, must be implemented no later than two years after the effective date of this rule. Consistent with CAA section 112(f)(4)(B), we are proposing that a two-year compliance period is necessary so the facility has adequate time to install additional controls and demonstrate compliance, including the time necessary to purchase, install and test replacement bags, or if the facility decides to add a new baghouse in series with an existing baghouse, seek bids, select a vendor, install and test the new equipment; prepare and submit the required monitoring plan to monitor lead concentrations in air; purchase, install and conduct quality assurance and quality control measures on compliance monitoring equipment and; conduct site remediation necessary to

reduce fugitive emissions. A two-year compliance period is also consistent with the schedule of required actions contained in the Consent Decree.

In addition, we are proposing that the plant-wide limit that would reflect reductions required for the main stack pursuant to CAA section 112(d)(6) and for the furnace area and refinery stacks pursuant to CAA section 112(f)(2) must be met no later than two years after the effective date of this rule. Because these limits reflect the reductions from the furnace area and refinery stacks required under section 112(f)(2), we believe a two-year compliance timeframe is needed for the same reasons provided above.

VII. Request for Comments

We are soliciting comments on all aspects of this proposed action. All

comments received during the comment period will be considered. In addition to general comments on this proposed actions, we are also interested in any additional data that may help to reduce the uncertainties inherent in the risk assessments. We are specifically interested in receiving corrections to the dataset used for risk modeling. Such data should include supporting documentation in sufficient detail to allow characterization of the quality and representativeness of the data or information. Please see the following section for more information on submitting data.

VIII. Submitting Data Corrections

The facility-specific data used in the source category risk analyses and demographic analyses are available for download on the RTR Web Page at

http://www.epa.gov/ttn/atw/rrisk/ rtrpg.html. The data files include detailed information for each HAP emissions release point for the facility included in the source category.

If you believe the data are not representative or are inaccurate, please identify the data in question, provide your reason for concern, and provide any "improved" data that you have, if available. When you submit data, we request that you provide documentation of the basis for the revised values to support your suggested changes. To submit comments on the data downloaded from the RTR Web page, complete the following steps:

(1) Within this downloaded file, enter suggested revisions to the data fields appropriate for that information. The data fields that may be revised include the following:

Data element	Definition		
Control Measure	Are control measures in place? (yes or no).		
Control Measure Comment			
Delete	Indicate here if the facility or record should be deleted.		
Delete Comment	Describes the reason for deletion.		
Emission Calculation Method Code For Revised Emissions			
Emission Process Group	Enter the general type of emission process associated with the specified emission point.		
Fugitive Angle	Enter release angle (clockwise from true North); orientation of the y-dimension relative to true North, measured positive for clockwise starting at 0 degrees (maximum 89 degrees).		
Fugitive Length			
Fugitive Width			
Malfunction Emissions	Enter total annual emissions due to malfunctions (TPY).		
Malfunction Emissions Max Hourly			
North American Datum	, , ,		
	NAD83 is assumed.		
Process Comment	Enter general comments about process sources of emissions.		
REVISED Address			
REVISED City			
REVISED County Name			
REVISED Emission Release Point Type	Enter revised Emission Release Point Type here.		
REVISED End Date			
REVISED Exit Gas Flow Rate	Enter revised Exit Gas Flowrate here (ft ³ /sec).		
REVISED Exit Gas Temperature	Enter revised Exit Gas Temperature here (F).		
REVISED Exit Gas Velocity	Enter revised Exit Gas Velocity here (ft/sec).		
REVISED Facility Category Code			
REVISED Facility Name	,		
REVISED Facility Registry Identifier			
REVISED HAP Emissions Performance Level Code			
REVISED Latitude	Enter revised Latitude here (decimal degrees).		
REVISED Longitude	` ,		
REVISED MACT Code			
REVISED Pollutant Code			
REVISED Routine Emissions			
REVISED SCC Code	, ,		
REVISED Stack Diameter			
REVISED Stack Height			
REVISED Start Date			
REVISED State			
REVISED Tribal Code			
REVISED Zip Code			
Shutdown Emissions			

Data element	Definition
Stack Comment	Enter general comments about emission release points. Enter total annual emissions due to startup events (TPY). Enter maximum hourly startup emissions here (lb/hr). Enter date facility stopped operations.

- 2. Fill in the commenter information fields for each suggested revision (*i.e.*, commenter name, commenter organization, commenter e-mail address, commenter phone number, and revision comments).
- 3. Gather documentation for any suggested emissions revisions (*e.g.*, performance test reports, material balance calculations, *etc.*).
- 4. Send the entire downloaded file with suggested revisions in Microsoft® Access format and all accompanying documentation to Docket ID Number EPA-HQ-OAR-2004-0305 (through one of the methods described in the ADDRESSES section of this preamble). To expedite review of the revisions, it would also be helpful if you submitted a copy of your revisions to the EPA directly at RTR@epa.gov in addition to submitting them to the docket.
- 5. If you are providing comments on a facility, you need only submit one file for that facility, which should contain all suggested changes for all sources at that facility. We request that all data revision comments be submitted in the form of updated Microsoft® Access files, which are provided on the http://www.epa.gov/ttn/atw/rrisk/rtrpg.html Web page.

IX. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a significant regulatory action because it raises novel legal and policy issues. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

The information collection requirements in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR number 1856.07.

We are proposing new paperwork requirements to the Primary Lead

Smelting source category in the form of monitoring for lead concentrations in air and increased frequency for stack testing as described in 40 CFR 63.1547(k) (compliance monitoring) and 40 CFR 63.1546 (stack testing). These requirements are described in section VI.A and B. Although these are additional requirements under today's proposed rule, they are consistent with existing monitoring and testing currently conducted by the facility to meet MACT and SIP requirements. Therefore, we do not believe that the additional paperwork required by these proposed changes would constitute an undue burden to the facility.

We estimate one regulated entity is currently subject to subpart TTT and will be subject to all proposed standards. This facility will have no capital costs associated with the information collection requirements in

the proposed rule.

The estimated recordkeeping and reporting burden after the effective date of the proposed rule is estimated to be 1,323 labor hours at a cost of \$465,503. This estimate includes the cost of reporting, including reading instructions, and information gathering. Recordkeeping cost estimates include reading instructions, planning activities, monitoring plan development, conducting compliance monitoring, sampling and analysis and maintenance of rolling 3-month average data. The average hours and cost per regulated entity would be 1,323 hours and \$465,503 based on one facility response per year. Burden is defined at 5 CFR 1320.3(b).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, EPA has established a public docket for this rule, which includes this ICR, under Docket ID number EPA-HQ-OAR-2004-0305. Submit any comments related to the ICR to EPA and OMB. See ADDRESSES section at the beginning of this notice for where to submit comments to EPA.

Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after February 17, 2011, a comment to OMB is best assured of having its full effect if OMB receives it by March 21, 2011. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's proposed rule on small entities, small entity is defined as: (1) A small business that is a small industrial entity as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-forprofit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed rule will not impose any requirements on small entities. This proposed rule is currently applicable to one operating facility that does not meet the definition of a small entity.

We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This proposed rule does not contain a federal mandate under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. The proposed rule would not result in expenditures of \$100 million or more for State, local, and tribal governments, in aggregate, or the private sector in any 1 year. The proposed rule imposes no enforceable duties on any State, local or tribal governments or the private sector. Thus, this proposed rule is not subject to the requirements of sections 202 or 205 of the UMRA.

This proposed rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments because it contains no requirements that apply to such governments nor does it impose obligations upon them.

E. Executive Order 13132: Federalism

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. None of the facilities subject to this action are owned or operated by State governments, and, because no new requirements are being promulgated, nothing in this proposal will supersede State regulations. Thus, Executive Order 13132 does not apply to this proposed

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Subject to the Executive Order 13175 (65 FR 67249, November 9, 2000) EPA may not issue a regulation that has tribal implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by tribal governments, or EPA consults with tribal officials early in the process of developing the proposed regulation and develops a tribal summary impact statement. EPA

has concluded that this proposed rule will not have tribal implications, as specified in Executive Order 13175. It will not have substantial direct effect on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

ÉPA specifically solicits additional comment on this proposed action from

tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This proposed rule is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in Executive Order 12866. However, the Agency does believe there is a disproportionate risk to children. Modeled ambient air lead concentrations from the one facility in this source category are in excess of the NAAQS for lead, which was set to "provide increased protection for children and other at-risk populations against an array of adverse health effects, most notably including neurological effects in children, including neurocognitive and neurobehavioral effects." 73 FR 67007. However, the control measures proposed in this notice will result in lead concentration levels that are in compliance with the lead NAAQS, thereby mitigating the risk of adverse health effects to children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a "significant energy action" as defined under Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), because it is not likely to have significant adverse effect on the supply, distribution, or use of energy. This action will not create any new requirements for sources in the energy supply, distribution, or use sectors.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

To examine the potential for any environmental justice issues that might be associated with each source category, we evaluated the distributions of HAPrelated cancer and non-cancer risks across different social, demographic, and economic groups within the populations living near the facilities where these source categories are located. The methods used to conduct demographic analyses for this rule are described in section IV.A of the preamble for this rule. The development of demographic analyses to inform the consideration of environmental justice issues in EPA rulemakings is an evolving science. The EPA offers the demographic analyses in today's rulemaking as examples of how such analyses might be developed to inform such consideration, and invites public comment on the approaches used and the interpretations made from the results, with the hope that this will support the refinement and improve utility of such analyses for future rulemakings.

In the case of Primary Lead
Processing, we focused on populations
within 50 km of the one facility in this
source category with emission sources
subject to the MACT standard. More
specifically, for these populations we

evaluated exposures to HAP which could result in cancer risks of 1-in-1 million or greater, or population exposures to ambient air lead concentrations above the level of the NAAOS for lead. We compared the percentages of particular demographic groups within the focused populations to the total percentages of those demographic groups nationwide. The results of this analysis are documented in section V.B.1 (see Table 6), as well as in a technical report located in the docket for this rulemaking. In brief, although our analyses show that there is the potential for adverse environmental and human health effects from emissions of lead, it does not indicate any significant potential for disparate impacts to the specific demographic groups analyzed (see section V.B.1). Notably however, the proposed rule would require additional control measures to address the identified environmental and health risks and would therefore, decrease risks to any populations exposed to these sources.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Reporting and recordkeeping requirements, Lead.

Dated: January 31, 2011.

Lisa P. Jackson,

Administrator.

For reasons set out in the preamble, title 40, chapter I, of the Code of Federal Regulations is proposed to be amended:

PART 63—[AMENDED]

1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

2. Section 63.1541 is revised to read as follows:

§ 63.1541 Applicability.

(a) The provisions of this subpart apply to any facility engaged in producing lead metal from ore concentrates. The category includes, but is not limited to, the following smelting processes: Sintering, reduction, preliminary treatment, refining and casting operations, process fugitive sources, and fugitive dust sources. The sinter process includes an updraft or downdraft sintering machine. The reduction process includes the blast furnace, electric smelting furnace with a converter or reverberatory furnace, and slag fuming furnace process units. The preliminary treatment process includes the drossing kettles and dross reverberatory furnace process units. The refining process includes the refinery process unit. The provisions of this

subpart do not apply to secondary lead smelters, lead refiners, or lead remelters.

- (b) Table 1 of this subpart specifies the provisions of subpart A of this part that apply and those that do not apply to owners and operators of primary lead processors.
 - 3. Section 63.1542 is amended by:
- a. Adding in alphabetical order definitions for "Affirmative defense," "Lead refiner," "Lead remelter," "Primary lead processor," and "Secondary lead smelter".

b. Removing the definition for "Primary lead smelter".

c. Revising the definitions for "Fugitive dust source," "Furnace area," "Malfunction," "Materials storage and handling area," "Plant roadway," "Process fugitive source," "Refining and casting area," Sinter machine area," and "Tapping location".

§ 63.1542 Definitions.

* * * * *

Affirmative defense means, in the context of an enforcement proceeding, a response or defense put forward by a defendant, regarding which the defendant has the burden of proof, and the merits of which are independently and objectively evaluated in a judicial or administrative proceeding.

Fugitive dust source means a stationary source of hazardous air pollutant emissions at a primary lead processor resulting from the handling, storage, transfer, or other management of lead-bearing materials where the source is not part of a specific process, process vent, or stack. Fugitive dust sources include roadways, storage piles, materials handling transfer points, and materials transport areas.

Furnace area means any area of a primary lead processor in which a blast furnace or dross furnace is located.

Lead refiner means any facility that refines lead metal that is not located at a primary lead processor.

Lead remelter means any facility that remelts lead metal that is not located at

a primary lead processor.

Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control and monitoring equipment, process equipment, or a process to operate in a normal or usual manner which causes, or has the potential to cause, the emission limitations in an applicable standard to be exceeded. Failures that are caused in part by poor maintenance or careless operation are not malfunctions.

Materials storage and handling area means any area of a primary lead processor in which lead-bearing materials (including ore concentrate, sinter, granulated lead, dross, slag, and flue dust) are stored or handled between process steps, including areas in which materials are stored in piles, bins, or tubs, and areas in which material is prepared for charging to a sinter machine or smelting furnace or other lead processing operation.

Plant roadway means any area of a primary lead processor that is subject to vehicle traffic, including traffic by forklifts, front-end loaders, or vehicles carrying ore concentrates or cast lead ingots. Excluded from this definition are employee and visitor parking areas, provided they are not subject to traffic by vehicles carrying lead-bearing materials.

Primary lead processor means any facility engaged in the production of lead metal from lead sulfide ore concentrates through the use of pyrometallurgical or other techniques.

Process fugitive source means a source of hazardous air pollutant emissions at a primary lead processor that is associated with lead smelting, processing or refining but is not the primary exhaust stream and is not a fugitive dust source. Process fugitive sources include sinter machine charging locations, sinter machine discharge locations, sinter crushing and sizing equipment, furnace charging locations, furnace taps, and drossing kettle and refining kettle charging or tapping locations.

Refining and casting area means any area of a primary lead processor in which drossing or refining operations occur, or casting operations occur.

Secondary lead smelter means any facility at which lead-bearing scrap material, primarily, but not limited to, lead-acid batteries, is recycled into elemental lead or lead alloys by smelting.

Sinter machine area means any area of a primary lead processor where a sinter machine, or sinter crushing and sizing equipment is located.

Tapping location means the opening through which lead and slag are removed from the furnace.

4. Section 63.1543 is revised to read as follows:

§ 63.1543 Standards for process and process fugitive sources.

(a) No owner or operator of any existing, new, or reconstructed primary lead processor shall discharge or cause to be discharged into the atmosphere lead compounds in excess of 0.22

pounds per ton of lead metal produced from the aggregation of emissions discharged from air pollution control devices used to control emissions at primary lead processing facilities, including the sources listed in paragraphs (a)(1) through (a)(10) of this section.

- (1) Sinter machine;
- (2) Blast furnace;
- (3) Dross furnace;
- (4) Dross furnace charging location;
- (5) Blast furnace and dross furnace tapping location;
 - (6) Sinter machine charging location;
 - (7) Sinter machine discharge end;
- (8) Sinter crushing and sizing equipment;
 - (9) Sinter machine area; and
- (10) Refining and casting, and furnace area.
- (b) No owner or operator of any existing, new, or reconstructed primary lead processor shall discharge or cause to be discharged into the atmosphere lead compounds in excess of 0.91 tons per year from the air pollution control devices used to control emissions from furnace area and refining and casting operations.
- (c) The process fugitive sources listed in paragraphs (a)(4) through (a)(8) of this section must be equipped with a hood and must be ventilated to a baghouse or equivalent control device. The hood design and ventilation rate must be consistent with American Conference of Governmental Industrial Hygienists recommended practices.
- (d) The sinter machine area must be enclosed in a building that is ventilated to a baghouse or equivalent control device at a rate that maintains a positive in-draft through any doorway opening.
- (e) Except as provided in paragraph (f) of this section, following the initial tests to demonstrate compliance with paragraphs (a) and (b) of this section, the owner or operator of a primary lead processor must conduct compliance tests for lead compounds on an quarterly basis (no later than 100 days following any previous compliance test).
- (f) If the 12 most recent compliance tests demonstrate compliance with the emission limit specified in paragraphs (a) and (b) of this section, the owner or operator of a primary lead processor shall be allowed up to 12 calendar months from the last compliance test to conduct the next compliance test for lead compounds.
- (g) The owner or operator of a primary lead processor must maintain and operate each baghouse used to control emissions from the sources listed in paragraphs (a)(1) through (a)(10) of this section such that the alarm on a bag leak

detection system required under § 63.1547(c)(8) does not sound for more than five percent of the total operating time in a 6-month reporting period.

- (h) The owner or operator of a primary lead processor must record the date and time of a bag leak detection system alarm and initiate procedures to determine the cause of the alarm according to the corrective action plan required under § 63.1547(f) within 1 hour of the alarm. The cause of the alarm must be corrected as soon as practicable.
- (i) At all times, the owner or operator must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. Determination of whether such operation and maintenance procedures are being used will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.
- 5. Section 63.1544 is revised to read as follows:

§ 63.1544 Standards for fugitive dust sources.

- (a) No owner or operator of any existing, new or reconstructed primary lead processor shall discharge or cause to be discharged into the atmosphere lead compounds that cause the concentration of lead in air to exceed 0.15 $\mu g/m^3$ on a 3-month rolling average measured at locations approved by the Administrator.
- (b) At all times, the owner or operator must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. Determination of whether such operation and maintenance procedures are being used will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.
- 6. Section 63.1545 is revised to read as follows:

§ 63.1545 Compliance dates.

(a) Each owner or operator of an existing primary lead processor must achieve compliance with the

- requirements of this subpart no later than [DATE TWO YEARS FROM PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].
- (b) Each owner or operator of a new primary lead processor must achieve compliance with the requirements of this subpart no later than [DATE 60 DAYS AFTER PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER] or startup, whichever is later
- 7. Section 63.1546 is revised to read as follows:

§ 63.1546 Performance testing.

- (a) The following procedures must be used to determine quarterly compliance with the emissions standard for lead compounds under § 63.1543(a) and (b) for existing sources:
- (1) Each owner or operator of existing sources listed in § 63.1543(a)(1) through (10) must determine the lead compound emissions rate, in units of pounds of lead per hour according to the following test methods in appendices of part 60 of this chapter:
- (i) Method 1 to appendix A-1 of 40 CFR part 60 must be used to select the sampling port location and the number of traverse points.
- (ii) Methods 2 and 2F of appendix A–1 and Method 2G of appendix A–2 of 40 CFR part 60 must be used to measure volumetric flow rate.
- (iii) Methods 3, 3A, 3B of appendix A–2 of 40 CFR part 60 must be used for gas analysis.
- (iv) Method 4 of appendix A–3 of 40 CFR part 60 must be used to determine moisture content of the stack gas.
- (v) Method 12 of appendix A–5 or Method 29 of appendix A–8 of 40 CFR part 60 must be used to determine lead emissions rate of the stack gas.
- (2) A performance test shall consist of at least three runs. For each test run with Method 12 of appendix A–5 or Method 29 of appendix A–8 of 40 CFR part 60, the minimum sample time must be 60 minutes and the minimum volume must be 1 dry standard cubic meter (35 dry standard cubic feet).
- (3) Performance tests shall be completed quarterly, once every 3 months, to determine compliance.
- (4) The lead emission rate in pounds per quarter is calculated by multiplying the quarterly lead emission rate in pounds per hour by the quarterly plant operating time, in hours as shown in Equation 1:

$$E_{Pb} = ER_{Pb} \times QPOT$$
 (Eq. 1)

Where:

 E_{Pb} = quarterly lead emissions, pounds per quarter;

 ER_{Pb} = quarterly lead emissions rate, pounds per hour; and

- QPOT = quarterly plant operating time, hours per quarter.
- (5) The lead production rate, in units of tons per quarter, must be determined based on production data for the previous quarter according to the procedures detailed in paragraphs (a)(5)(i) through (iv) of this section:

(i) Total lead products production multiplied by the fractional lead content must be determined in units of tons.

(ii) Total copper matte production multiplied by the fractional lead content must be determined in units of tons.

(iii) Total copper speiss production multiplied by the fractional lead content must be determined in units of tons.

(iv) Total quarterly lead production must be determined by summing the values obtained in paragraphs (a)(5)(i) through (a)(5)(iii) of this section.

(6) To determine compliance with the production-based lead compound emission rate in § 63.1543(a), the quarterly production-based lead compound emission rate, in units of pounds of lead emissions per ton of lead produced, is calculated as shown in Equation 2 by dividing lead emissions by lead production.

$$CE_{Pb} = \frac{E_{Pb}}{P_{Pb}} \tag{Eq. 2}$$

Where:

CE_{Pb} = quarterly production-based lead compound emission rate, in units of pounds of lead emissions per ton of lead produced;

 E_{Pb} = quarterly lead emissions, pounds per quarter; and

 P_{Pb} = quarterly lead production, tons per quarter.

(7) To determine quarterly compliance with the emissions standard for lead compounds under § 63.1543(b), sum the lead compound emission rates for the current and previous three quarters for the sources in § 63.1543 (a)(10) to determine compliance with § 63.1543(b), as determined in accordance with paragraphs (a)(1) through (a)(4) of this section.

(b) Owner and operators must perform an initial compliance test to demonstrate compliance with the sinter building in-draft requirements of § 63.1543(d) at each doorway opening in accordance with paragraphs (b)(1) through (b)(4) of this section.

(1) Use a propeller anemometer or equivalent device.

(2) Determine doorway in-draft by placing the anemometer in the plane of the doorway opening near its center.

(3) Determine doorway in-draft for each doorway that is open during

normal operation with all remaining doorways in their customary position during normal operation.

(4) Do not determine doorway in-draft when ambient wind speed exceeds 2 meters per second.

- (c) Performance tests shall be conducted under such conditions as the Administrator specifies to the owner or operator based on representative performance of the affected source for the period being tested. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.
- 8. Section 63.1547 is revised to read as follows:

§ 63.1547 Monitoring requirements.

- (a) Owners and operators of primary lead processors must prepare, and at all times operate according to, a standard operating procedures manual that describes in detail the procedures for inspection, maintenance, and bag leak detection and corrective action for all baghouses that are used to control process, process fugitive, or fugitive dust emissions from any source subject to the lead emission standards in §§ 63.1543 and 63.1544, including those used to control emissions from general ventilation systems.
- (b) The standard operating procedures manual for baghouses required by paragraph (a) of this section must be submitted to the Administrator or delegated authority for review and approval.
- (c) The procedures specified in the standard operating procedures manual for inspections and routine maintenance must, at a minimum, include the requirements of paragraphs (c)(1) through (c)(8) of this section.
- (1) Weekly confirmation that dust is being removed from hoppers through visual inspection or equivalent means of ensuring the proper functioning of removal mechanisms.

(2) Daily check of compressed air supply for pulse-jet baghouses.

(3) An appropriate methodology for monitoring cleaning cycles to ensure proper operation.

(4) Monthly check of bag cleaning mechanisms for proper functioning through visual inspection or equivalent means.

(5) Quarterly visual check of bag tension on reverse air and shaker-type baghouses to ensure that bags are not kinked (kneed or bent) or laying on their sides. Such checks are not required for shaker-type baghouses using selftensioning (spring loaded) devices. (6) Quarterly confirmation of the physical integrity of the baghouse through visual inspection of the baghouse interior for air leaks.

(7) Quarterly inspection of fans for wear, material buildup, and corrosion through visual inspection, vibration detectors, or equivalent means.

(8) Except as provided in paragraph (h) of this section, continuous operation of a bag leak detection system.

(d) The procedures specified in the standard operating procedures manual for maintenance must, at a minimum, include a preventative maintenance schedule that is consistent with the baghouse manufacturer's instructions for routine and long-term maintenance.

(e) The bag leak detection system required by paragraph (c)(8) of this section must meet the specifications and requirements of (e)(1) through (e)(8) of this section.

(1) The bag leak detection system must be certified by the manufacturer to be capable of detecting particulate matter emissions at concentrations of 10 milligram per actual cubic meter (0.0044 grains per actual cubic foot) or less.

(2) The bag leak detection system sensor must provide output of relative particulate matter loadings, and the owner or operator must continuously record the output from the bag leak detection system.

(3) The bag leak detection system must be equipped with an alarm system that will sound when an increase in relative particulate loading is detected over a preset level, and the alarm must be located such that it can be heard or otherwise determined by the

appropriate plant personnel.

(4) Each bag leak detection system that works based on the triboelectric effect must be installed, calibrated, and maintained in a manner consistent with guidance provided in the U.S. Environmental Protection Agency guidance document "Fabric Filter Bag Leak Detection Guidance" (EPA-454/R-98-015). Other bag leak detection systems must be installed, calibrated, and maintained in a manner consistent with the manufacturer's written specifications and recommendations.

(5) The initial adjustment of the system must, at a minimum, consist of establishing the baseline output by adjusting the sensitivity (range) and the averaging period of the device, and establishing the alarm set points and the alarm delay time.

(6) Following initial adjustment, the owner or operator must not adjust the sensitivity or range, averaging period, alarm set points, or alarm delay time, except as detailed in the approved SOP required under paragraph (a) of this

section. In no event shall the sensitivity be increased by more than 100 percent or decreased more than 50 percent over a 365-day period unless a responsible official certifies that the baghouse has been inspected and found to be in good operating condition.

- (7) For negative pressure, induced air baghouses, and positive pressure baghouses that are discharged to the atmosphere through a stack, the bag leak detector must be installed downstream of the baghouse and upstream of any wet acid gas scrubber.
- (8) Where multiple detectors are required, the system's instrumentation and alarm may be shared among detectors
- (f) The standard operating procedures manual required by paragraph (a) of this section must include a corrective action plan that specifies the procedures to be followed in the event of a bag leak detection system alarm. The corrective action plan must include at a minimum, procedures to be used to determine the cause of an alarm, as well as actions to be taken to minimize emissions, which may include, but are not limited to, the following.
- (1) Inspecting the baghouse for air leaks, torn or broken bags or filter media, or any other condition that may cause an increase in emissions.
- (2) Sealing off defective bags or filter media
- (3) Replacing defective bags or filter media, or otherwise repairing the control device.
- (4) Sealing off a defective baghouse compartment.
- (5) Cleaning the bag leak detection system probe, or otherwise repairing or maintaining the bag leak detection system.
- (6) Shutting down the process producing the particulate emissions.
- (g) The percentage of total operating time the alarm on the bag leak detection system sounds in a 6-month reporting period must be calculated in order to determine compliance with the five percent operating limit in § 63.1543(h). The percentage of time the alarm on the bag leak detection system sounds must be determined according to paragraphs (g)(1) through (g)(3) of this section.
- (1) For each alarm where the owner or operator initiates procedures to determine the cause of an alarm within 1 hour of the alarm, 1 hour of alarm time must be counted.
- (2) For each alarm where the owner or operator does not initiate procedures to determine the cause of the alarm within 1 hour of the alarm, alarm time will be counted as the actual amount of time taken by the owner or operator to

initiate procedures to determine the cause of the alarm.

(3) The percentage of time the alarm on the bag leak detection system sounds must be calculated as the ratio of the sum of alarm times to the total operating time multiplied by 100.

- (h) Baghouses equipped with HEPA filters as a secondary filter used to control process or process fugitive sources subject to the lead emission standards in § 63.1543 are exempt from the requirement in paragraph (c)(8) of this section to be equipped with a bag leak detector. The owner or operator of an affected source that uses a HEPA filter must monitor and record the pressure drop across the HEPA filter system daily. If the pressure drop is outside the limit(s) specified by the filter manufacturer, the owner or operator must take appropriate corrective measures, which may include, but not be limited to, the following:
- (1) Inspecting the filter and filter housing for air leaks and torn or broken filters.
- (2) Replacing defective filter media, or otherwise repairing the control device.
- (3) Sealing off a defective control device by routing air to other comparable control devices.

(4) Shutting down the process producing the particulate emissions.

- (i) Owners and operators must monitor sinter machine building in-draft to demonstrate continued compliance with the operating standard specified in § 63.1543(d) in accordance with either paragraph (i)(1), (i)(2), or (i)(3) of this section.
- (1) Owners and operators must check and record on a daily basis doorway indraft at each doorway in accordance with the methodology specified in § 63.1546(b).
- (2) Owners and operators must establish and maintain baseline ventilation parameters which result in a positive in-draft according to paragraphs (i)(2)(i) through (i)(2)(iv) of this section.
- (i) Owners and operators must install, calibrate, maintain, and operate a monitoring device that continuously records the volumetric flow rate through each separately ducted hood; or install, calibrate, maintain, and operate a monitoring device that continuously records the volumetric flow rate at the control device inlet of each exhaust system ventilating the building. The flow rate monitoring device(s) can be installed in any location in the exhaust duct such that reproducible flow rate measurements will result. The flow rate monitoring device(s) must have an accuracy of plus or minus 10 percent over the normal process operating range

and must be calibrated according to manufacturer's instructions.

- (ii) During the initial demonstration of sinter building in-draft, and at any time the owner or operator wishes to reestablish the baseline ventilation parameters, the owner or operator must continuously record the volumetric flow rate through each separately ducted hood, or continuously record the volumetric flow rate at the control device inlet of each exhaust system ventilating the building and record exhaust system damper positions. The owner or operator must determine the average volumetric flow rate(s) corresponding to the period of time the in-draft compliance determinations are being conducted.
- (iii) The owner or operator must maintain the volumetric flow rate(s) at or above the value(s) established during the most recent in-draft determination at all times the sinter machine is in operation. Volumetric flow rate(s) must be calculated as a 15-minute average.
- (iv) If the volumetric flow rate is monitored at the control device inlet, the owner or operator must check and record damper positions daily to ensure they are in the positions they were in during the most recent in-draft determination.
- (3) An owner or operator may request an alternative monitoring method by following the procedures and requirements in § 63.8(f) of the General Provisions.
- (j) Each owner or operator of new or modified sources listed under § 63.1543 (a)(1) through (a)(10) must install, calibrate, maintain, and operate a continuous emission monitoring system (CEMS) for measuring lead emissions and a continuous emission rate monitoring system (CERMS) subject to Performance Specification 6 of Appendix B to part 60.

(1) Each owner or operator of a source subject to the emissions limits for lead compounds under § 63.1543(a) and (b) must install a CEMS for measuring lead emissions within 180 days of promulgation of performance specifications for lead CEMS.

(i) Prior to promulgation of performance specifications for CEMS used to measure lead concentrations, an owner or operator must use the procedure described in § 63.1546(a)(1) through (a)(7) of this section to determine compliance.

(ii) [Reserved]

(2) If a CEMS used to measure lead emissions is applicable, the owner or operator must install a CERMS with a sensor in a location that provides representative measurement of the exhaust gas flow rate at the sampling location of the CEMS used to measure lead emissions, taking into account the manufacturer's recommendations. The flow rate sensor is that portion of the system that senses the volumetric flow rate and generates an output proportional to that flow rate.

(i) The CERMS must be designed to measure the exhaust gas flow rate over a range that extends from a value of at least 20 percent less than the lowest expected exhaust flow rate to a value of at least 20 percent greater than the highest expected exhaust gas flow rate.

(ii) The CERMS must be equipped with a data acquisition and recording system that is capable of recording values over the entire range specified in paragraph (b)(2)(i) of this section.

(iii) Each owner or operator must perform an initial relative accuracy test of the CERMS in accordance with the applicable Performance Specification in Appendix B to part 60 of the chapter.

- (iv) Each owner or operator must operate the CERMS and record data during all periods of operation of the affected facility including periods of startup, shutdown, and malfunction, except for periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, and required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments.
- (3) Each owner or operator must calculate the lead emissions rate in tons per year by summing all hours of CEMS data for a year to determine compliance with 63.1543(b).
- (i) When the CERMS are unable to provide quality assured data the following applies:
- (A) When data are not available for periods of up to 48 hours, the highest recorded hourly emission rate from the previous 24 hours must be used.
- (B) When data are not available for 48 or more hours, the maximum daily emission rate based on the previous 30 days must be used.
 - (ii) [Reserved]
- (k) The owner or operator of each source subject to § 63.1544(a) must operate a continuous monitoring system for the measurement of lead compound concentrations in air.
- (1) The owner or operator must operate compliance monitors sufficient in number, location, and frequency of sample collection to detect expected maximum concentrations of lead compounds in air due to emissions from the affected source(s) in accordance with a written plan as described in (k)(2) of this paragraph and approved by the Administrator. The plan must

include descriptions of the sampling and analytical methods used. The plan may take into consideration existing monitoring being conducted under a state monitoring plan in accordance with part 58 of this chapter.

(2) The owner or operator must submit a written plan describing and explaining the basis for the design and adequacy of the compliance monitoring network, the sampling, analytical, and quality assurance procedures, and any other related procedures, and the justification for any seasonal, background, or other data adjustments within 45 days after the effective date of this subpart.

(3) The Administrator at any time may require changes in, or expansion of, the monitoring program, including additional sampling and analytical protocols and network design.

- (l) If all rolling three-month average concentrations of lead in air measured by the compliance monitoring system are less than 50 percent of the lead concentration in air limit in § 63.1544(a) for three consecutive years, the owner or operator may submit a revised plan to reduce the monitoring sampling and analysis frequency (e.g., from daily to weekly). For any subsequent period, if any rolling three-month average lead concentration in air measured at any monitor in the monitoring system exceeds 50 percent of the concentration limit in § 63.1544(a), the owner or operator must resume monitoring pursuant to paragraph (k)(1) of this section at all monitors until another three consecutive years of lead concentration in air measurements less than 50 percent of the lead concentration in air limit is demonstrated.
- 9. Section 63.1548 is revised to read as follows:

§ 63.1548 Notification requirements.

(a) The owner or operator of a primary lead processor must comply with the notification requirements of § 63.9 of subpart A, General Provisions as specified in Table 1 of this subpart.

(b) The owner or operator of a primary lead processor must submit the standard operating procedures manual for baghouses required under § 63.1547(a) to the Administrator or delegated authority along with a notification that the primary lead processor is seeking review and approval of the manual and procedures. Owners or operators of existing primary lead processors must submit this notification no later than November 6, 2000. The owner or operator of a primary lead processor that commences construction or reconstruction after April 17, 1998,

must submit this notification no later than 180 days before startup of the constructed or reconstructed primary lead processor, but no sooner than September 2, 1999.

(c) The owner or operator of a primary lead processor must submit the compliance monitoring network plan required under § 63.1547(k)(2) to the Administrator or delegated authority along with a notification that the primary lead processor is seeking review and approval of the plan. Owners or operators of existing primary lead processors must submit this notification no later than 45 days after promulgation of this subpart. The owner or operator of a new, reconstructed, or modified primary lead processor must submit this notification no later than 180 days before startup of the constructed or reconstructed primary lead processor.

10. Section 63.1549 is revised to read as follows:

§ 63.1549 Recordkeeping and reporting requirements.

(a) The owner or operator of a primary lead processor must comply with the recordkeeping requirements of § 63.10 of subpart A, General Provisions as specified in Table 1 of this subpart.

(b) In addition to the general records required by paragraph (a) of this section, each owner or operator of a primary lead processor must maintain for a period of 5 years, records of the information listed in paragraphs (b)(1) through (b)(10) of this section.

(1) Production records of the weight and lead content of lead products, copper matte, and copper speiss.

(2) Records of the bag leak detection system output.

(3) An identification of the date and time of all bag leak detection system alarms, the time that procedures to determine the cause of the alarm were initiated, the cause of the alarm, an explanation of the actions taken, and the date and time the cause of the alarm was corrected.

(4) Any recordkeeping required as part of the requirements described in the compliance monitoring system plan required under § 63.1547(k)(2).

(5) Any recordkeeping required as part of the practices described in the standard operating procedures manual for baghouses required under § 63.1547(a).

(6) If an owner or operator chooses to demonstrate continuous compliance with the sinter building in-draft requirement under § 63.1543(d) by employing the method allowed in § 63.1547(i)(1), the records of the daily doorway in-draft checks, an

- identification of the periods when there was not a positive in-draft, and an explanation of the corrective actions taken.
- (7) If an owner or operator chooses to demonstrate continuous compliance with the sinter building in-draft requirement under § 63.1543(d) by employing the method allowed in § 63.1547(i)(2), the records of the output from the continuous volumetric flow monitor(s), an identification of the periods when the 15-minute volumetric flow rate dropped below the minimum established during the most recent indraft determination, and an explanation of the corrective actions taken.
- (8) If an owner or operator chooses to demonstrate continuous compliance with the sinter building in-draft requirement under § 63.1543(d) by employing the method allowed in § 63.1547(i)(2), and volumetric flow rate is monitored at the baghouse inlet, records of the daily checks of damper positions, an identification of the days that the damper positions were not in the positions established during the most recent in-draft determination, and an explanation of the corrective actions taken.
- (9) Records of the occurrence and duration of each malfunction of operation (*i.e.*, process equipment) or the air pollution control equipment and monitoring equipment.
- (10) Records of actions taken during periods of malfunction to minimize emissions in accordance with §§ 63.1543(i) and 63.1544(e), including corrective actions to restore malfunctioning process and air pollution control and monitoring equipment to its normal or usual manner of operation.
- (c) Records for the most recent 2 years of operation must be maintained on site. Records for the previous 3 years may be maintained off site.
- (d) The owner or operator of a primary lead processor must comply with the reporting requirements of § 63.10 of subpart A, General Provisions as specified in Table 1 of this subpart.
- (e) In addition to the information required under § 63.10 of the General Provisions, the owner or operator must provide semi-annual reports containing the information specified in paragraphs (e)(1) through (e)(9) of this section to the Administrator or designated authority.
- (1) The reports must include records of all alarms from the bag leak detection system specified in § 63.1547(e).
- (2) The reports must include a description of the actions taken following each bag leak detection system alarm pursuant to § 63.1547(f).

- (3) The reports must include a calculation of the percentage of time the alarm on the bag leak detection system sounded during the reporting period pursuant to § 63.1547(g).
- (4) If an owner or operator chooses to demonstrate continuous compliance with the sinter building in-draft requirement under § 63.1543(d) by employing the method allowed in § 63.1547(i)(1), the reports must contain an identification of the periods when there was not a positive in-draft, and an explanation of the corrective actions taken.
- (5) If an owner or operator chooses to demonstrate continuous compliance with the sinter building in-draft requirement under § 63.1543(d) by employing the method allowed in § 63.1547(i)(2), the reports must contain an identification of the periods when the 15-minute volumetric flow rate(s) dropped below the minimum established during the most recent indraft determination, and an explanation of the corrective actions taken.
- (6) If an owner or operator chooses to demonstrate continuous compliance with the sinter building in-draft requirement under § 63.1543(d) by employing the method allowed in § 63.1547(i)(2), and volumetric flow rate is monitored at the baghouse inlet, the reports must contain an identification of the days that the damper positions were not in the positions established during the most recent in-draft determination, and an explanation of the corrective actions taken.
- (7) The reports must contain a summary of the records maintained as part of the practices described in the standard operating procedures manual for baghouses required under § 63.1547(a), including an explanation of the periods when the procedures were not followed and the corrective actions taken.
- (8) The reports must contain a summary of the compliance monitoring results for the required reporting period, including an explanation of any periods when the procedures outlined in the compliance monitoring system plan required by § 63.1547(k)(2) were not followed and the corrective actions taken.
- (9) If there was a malfunction during the reporting period, the report shall also include the number, duration, and a brief description for each type of malfunction which occurred during the reporting period and which caused or may have caused any applicable emission limitation to be exceeded. The report must also include a description of actions taken by an owner or operator during a malfunction of an affected

- source to minimize emissions in accordance with §§ 63.1543(i) and 63.1544(b), including actions taken to correct a malfunction.
- 11. Section 63.1550 is revised to read as follows:

§ 63.1550 Delegation of authority.

- (a) In delegating implementation and enforcement authority to a State under section 112(1) of the Act, the authorities contained in paragraph (b) of this section must be retained by the Administrator and not transferred to a State.
- (b) Authorities which will not be delegated to States: No restrictions.
- 12. Section 63.1551 is added to read as follows:

§ 63.1551 Affirmative defense for exceedance of emission limit during malfunction.

In response to an action to enforce the standards set forth in this subpart you may assert an affirmative defense to a claim for civil penalties for exceedances of such standards that are caused by malfunction, as defined in 40 CFR 63.2. Appropriate penalties may be assessed, however, if you fail to meet your burden of proving all the requirements in the affirmative defense. The affirmative defense shall not be available for claims for injunctive relief.

- (a) To establish the affirmative defense in any action to enforce such a limit, you must timely meet the notification requirements in paragraph (b) of this section, and must prove by a preponderance of evidence that:
 - (1) The excess emissions:
- (i) Were caused by a sudden, short, infrequent, and unavoidable failure of air pollution control and monitoring equipment, process equipment, or a process to operate in a normal or usual manner; and
- (ii) Could not have been prevented through careful planning, proper design or better operation and maintenance practices; and
- (iii) Did not stem from any activity or event that could have been foreseen and avoided, or planned for; and
- (iv) Were not part of a recurring pattern indicative of inadequate design, operation, or maintenance; and
- (2) Repairs were made as expeditiously as possible when the applicable emission limitations were being exceeded. Off-shift and overtime labor were used, to the extent practicable to make these repairs; and
- (3) The frequency, amount and duration of the excess emissions (including any bypass) were minimized to the maximum extent practicable during periods of such emissions; and

- (4) If the excess emissions resulted from a bypass of control equipment or a process, then the bypass was unavoidable to prevent loss of life, severe personal injury, or severe property damage; and
- (5) All possible steps were taken to minimize the impact of the excess emissions on ambient air quality, the environment and human health; and
- (6) All emissions monitoring and control systems were kept in operation if at all possible; and
- (7) All of the actions in response to the excess emissions were documented by properly signed, contemporaneous operating logs; and

- (8) At all times, the facility was operated in a manner consistent with good practices for minimizing emissions; and
- (9) A written root cause analysis has been prepared to determine, correct and eliminate the primary causes of the malfunction and the excess emissions resulting from the malfunction event at issue. The analysis shall also specify, using best monitoring methods and engineering judgment, the amount of excess emissions that were the result of the malfunction.
- (b) Notification. The owner or operator of the facility experiencing an exceedance of its emission limit(s) during a malfunction shall notify the

Administrator by telephone or facsimile (FAX) transmission as soon as possible, but no later than two business days after the initial occurrence of the malfunction, if it wishes to avail itself of an affirmative defense to civil penalties for that malfunction. The owner or operator seeking to assert an affirmative defense shall also submit a written report to the Administrator within 30 days of the initial occurrence of the exceedance of the standard in this subpart to demonstrate, with all necessary supporting documentation, that it has met the requirements set forth in paragraph (a) of this section.

12. Table 1 to Subpart TTT of Part 63 is revised to read as follows:

TABLE 1 TO SUBPART TTT OF PART 63—GENERAL PROVISIONS APPLICABILITY TO SUBPART TTT

Reference	Applies to subpart TTT	Explanation
§ 63.1 § 63.2 § 63.3 § 63.4 § 63.5 § 63.6(a), (b), (c) § 63.6 (d) § 63.6(e)(1)(ii) § 63.6(e)(1)(iii) § 63.6(e)(1)(iiii) § 63.6(e)(2)	Yes. Yes. Yes. Yes. No	Section reserved. See § 63.1543(i) and § 63.1544(b) for general duty requirement. Section reserved.
§ 63.6(e)(3) § 63.6(f)(1) § 63.6(g) § 63.6(i) § 63.6(j) § 63.7(a)—(d) § 63.7(e)(1)	No. Yes. No Yes. Yes.	No opacity limits in rule. See § 63.1546(c).
§ 63.7(e)(2)-(e)(4) § 63.7(f), (g), (h) § 63.8(a)-(b) § 63.8(c)(1)(i) § 63.8(c)(1)(iii) § 63.8(c)(1)(iiii) § 63.8(c)(2)-(d)(2) § 63.8(d)(3)	Yes. Yes. Yes. No. Yes.	
§ 63.8(e)–(g) § 63.9(a), (b), (c), (e), (g), (h)(1) through (3), (h)(5) and (6), (i) and (j)	Yes. No. No	Reserved.
§ 63.10(b)(2)(i)	No. No	See § 63.1549(b)(9) and (10) for recordkeeping of occurrence and duration of malfunctions and recordkeeping of actions taken during malfunction.
\$ 63.10(b)(2)(iii) \$ 63.10(b)(2)(iv)—(b)(2)(v) \$ 63.10(b)(2)(vi)—(b)(2)(xiv) \$ 63.10(c)(1)—(9) \$ 63.10(c)(10)—(11)	No. Yes. Yes.	See § 63.1549(b)(9) and (10) for recordkeeping of malfunctions.
§ 63.10(c)(12)–(c)(14) § 63.10(c)(15) § 63.10(d)(1)–(4)		

TABLE 1 TO SUBPART TTT OF PART 63—GENERAL PROVISIONS APPLICABILITY TO SUBPART TTT—Continued

Reference	Applies to subpart TTT	Explanation
§ 63.10(d)(5)	No	See § 63.1549(e)(9) for reporting of malfunctions.
§ 63.10(e)–((f)	Yes.	
§ 63.11	No	Flares will not be used to comply
§ 63.12 through 63.15	Yes.	with the emission limits.

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