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National Emission Standards for Hazardous Air Pollutant Emissions for Primary Lead Processing; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2004–0305; FRL–9491–2]

RIN 2060–AQ43

National Emission Standards for Hazardous Air Pollutant Emissions for Primary Lead Processing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action finalizes the residual risk and technology review conducted for the Primary Lead Processing source category regulated under national emission standards for hazardous air pollutants (NESHAP). This action finalizes amendments to the NESHAP that include revision of the rule's title and applicability provision, revisions to the stack emission limits for lead, work practice standards to minimize fugitive dust emissions, and the modification and addition of testing and monitoring and related notification, recordkeeping, and reporting requirements. It also finalizes revisions to the regulatory provisions related to emissions during periods of startup, shutdown, and malfunction and makes minor non-substantive changes to the rule.

DATES: This final action is effective on November 15, 2011.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2004–0305. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (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 form. Publicly available docket materials are available either electronically through *http://www.regulations.gov,* or in hard copy at the EPA Docket Center, EPA West Building, Room Number 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket and Information Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Mr. Nathan Topham, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; *telephone number:* (919) 541–0483; *fax number:* (919) 541–3207; and *email address: topham.nathan@epa.gov.* For additional contact information, see the following **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION: For specific information regarding the modeling methodology, contact Dr. Michael Stewart, Office of Air Quality Planning and Standards, Health and Environmental Impacts Division, Air Toxics Assessment Group (C504–06), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; *telephone number:* (919) 541–7524; *fax number:* (919) 541–0840; and *email address: stewart.michael@epa.gov.* For information about the applicability of this NESHAP to a particular entity, contact the appropriate person listed in Table 1 to this preamble.

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

NESHAP for:	OECA Contact [1]	OAQPS Contact [2]
Primary Lead Processing	Maria Malave, (202) 564–7027, *malave.maria@epa.gov.*	Nathan Topham, (919) 541–0483, *topham.nathan@epa.gov.*

[1] EPA's Office of Enforcement and Compliance Assurance.
[2] EPA's Office of Air Quality Planning and Standards.

Background Information Document. On February 17, 2011 (76 FR 9410), the EPA proposed revisions to the Primary Lead Smelting NESHAP based on evaluations performed by the EPA in order to conduct our risk and technology review. In this action, we are finalizing decisions and revisions for the rule. Some of the significant comments and our responses are summarized in this preamble; a summary of the other public comments on the proposal, and the EPA's responses to those comments, is available in Docket ID No. EPA–HQ–OAR–2004–0305. A red-line version of the regulatory language that incorporates the changes in this action is available in the docket.

Organization of This Document. The following outline is provided to aid in locating information in the preamble.

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I. General Information

A. Does this action apply to me?

Regulated Entities. Categories and entities potentially regulated by this action include:

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

NESHAP and source category	NAICS [1] code	MACT [2] code
Primary Lead Processing	331419	0204

[1] North American Industry Classification System.
[2] Maximum Achievable Control Technology.

Table 2 is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by the final action for the source category listed. To determine whether your facility would be affected, you should examine the applicability criteria in the appropriate national emission standards for hazardous air pollutants (NESHAP). As defined in the source category listing report published by the 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.[1] To be consistent with the 1992 listing, the EPA is revising the applicability of the Primary Lead Smelting NESHAP to apply to any facility that produces lead metal from lead ore concentrates and is changing the title of the rule to reference Primary Lead Processing. For clarification purposes, all reference to lead emissions in this preamble means ''lead compounds'' (which is a hazardous air pollutant) and all reference to lead production means elemental lead (which is not a hazardous air pollutant) as provided under Clean Air Act (CAA) section 112(b)(7)).

If you have any questions regarding the applicability of any aspect of the Primary Lead Processing NESHAP, please contact the appropriate person listed in Table 1 of this preamble in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. Where can I get a copy of this document?

In addition to being available in the docket, an electronic copy of this final action will also be available on the World Wide Web (www) through the Technology Transfer Network (TTN). Following signature, a copy of the final action will be posted on the TTN's policy and guidance page for newly proposed and promulgated rules at the following address: *http://www.epa.gov/ttn/caaa/new.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. Judicial Review

Under section 307(b)(1) of the CAA, judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by January 17, 2012. Under section 307(b)(2) of the CAA, the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that ''[o]nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review.'' This section also provides a mechanism for us to convene a proceeding for reconsideration, ''[i]f the person raising an objection can demonstrate to the EPA that it was impracticable to raise such objection within [the period for public comment] or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule.'' Any person seeking to make such a demonstration to us should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, Ariel Rios Building, 1200 Pennsylvania Ave. NW., Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

II. Background

Section 112 of the CAA establishes a two-stage regulatory process to address emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, after the EPA has identified categories of sources emitting one or more of the HAP listed in section 112(b) of the CAA, section 112(d) calls for us to promulgate NESHAP for those sources. ''Major sources'' are those that emit, or have the potential to emit, any single HAP at a rate of 10 tons per year (TPY) or more, 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.

For MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as floor requirements and may not be based on cost considerations. See CAA section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control that is achieved in practice by the best controlled similar source. The MACT standards for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer

[1] USEPA. *Documentation for Developing the Initial Source Category List—Final Report,* USEPA/OAQPS, EPA–450/3–91–030, July, 1992.

than 30 sources). In developing MACT, we must also consider control options that are more stringent than the floor, under CAA section 112(d)(2). 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. In promulgating MACT standards, CAA section 112(d)(2) directs us to consider the application of measures, processes, methods, systems, or techniques that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or processes to eliminate emissions; collect, capture, or treat HAP when released from a process, stack, storage, or fugitive emissions point; and/or are design, equipment, work practice, or operational standards.

In the second stage of the regulatory process, we undertake two different analyses, as required by the CAA: section 112(d)(6) of the CAA calls for us 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; and within 8 years after promulgation of the technology standards, CAA section 112(f) calls for us to evaluate the risk to public health remaining after application of the technology-based standards and to revise the standards, if necessary, to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. In doing so, the EPA may adopt standards equal to existing MACT standards if the EPA determines that the existing standards are sufficiently protective. *NRDC* v. *EPA,* 529 F.3d 1077, 1083 (DC Cir. 2008).

On February 17, 2011, the EPA published a proposed rule in the **Federal Register** for the Primary Lead Smelting NESHAP, 40 CFR part 63 subpart TTT, that took into consideration the residual risk and technology review (RTR) analyses for that source category. This action provides the EPA's final determinations pursuant to the RTR provisions of CAA section 112 for the Primary Lead Processing source category. Specifically, as a result of our analyses, we are revising the requirements of the NESHAP to ensure public health and the environment are protected consistent with section 112(f) and that emission reductions are consistent with what is economically and technically feasible under section 112(d)(6). In addition, we are taking the following actions:

- Revising the requirements in the NESHAP related to emissions during periods of startup, shutdown, and malfunction (SSM).
- Revising the title of the rule and amending the applicability section consistent with the definition of the source category adopted in 1992, to provide that the NESHAP applies to any facility processing lead ore concentrate to produce lead metal.
- Replacing the definition of ''primary lead smelter'' with a definition of ''primary lead processor'' and adding definitions of ''secondary lead smelters,'' ''lead refiners,'' and ''lead remelters.''
- Incorporating the use of plain language into the rule.
- Addressing technical and editorial corrections in the rule.
- Responding to the January 2009 petition for rulemaking from the Natural Resources Defense Council (NRDC) that the original primary lead NESHAP should have included an emission standard for organic HAP and announcing our intention to collect additional data needed to develop a standard for organic HAP.

We note that the Doe Run Herculaneum Smelter, the only facility in the source category, is subject to a Consent Decree requiring submission of a facility-wide cleanup plan by January 1, 2013, shutdown of their sintering operations by the end of 2013, and shutdown of the blast furnace by April 30, 2014. The Consent Decree will achieve drastic reductions in emissions of lead and other pollutants and will provide substantial environmental and public health benefits. The Herculaneum area has also been designated as a nonattainment area for the 2008 National Ambient Air Quality Standards (NAAQS) for lead. Attainment of the 2008 Lead NAAQS (which is demonstrated based on three years of data at or below the level of the NAAQS) is required by December 2015. The State of Missouri is required to submit its attainment demonstration State Implementation Plan (SIP) by June 30, 2012.

III. Summary of the Final Rule

A. What are the final rule amendments for the Primary Lead Processing source category?

The National Emission Standards for Hazardous Air Pollutant Emissions: Primary Lead Smelting was promulgated on June 6, 1999 (64 FR 30204), and codified at 40 CFR part 63, subpart TTT. The primary lead processing industry consists of facilities that produce lead metal from ore concentrates. The source category covered by this MACT standard currently includes only one operating facility, The Doe Run Company in Herculaneum, Missouri.

For the reasons provided in the proposed rule and in the support documents in the docket, we have determined that the risks associated with this source category are unacceptable and are therefore promulgating requirements to reduce the risk to an acceptable level. Once risk is reduced to an acceptable level, we analyze whether there are additional controls that will provide an ample margin of safety, considering cost, energy, safety, and other relevant factors. We have concluded that there are no additional cost-effective controls available beyond those that we are requiring to reduce risk to an acceptable level and thus the same controls to ensure an acceptable level of risk will also provide an ample margin of safety. To satisfy section 112(f) of the CAA, we are, therefore, revising the existing MACT standard to include:

- An emission cap of 1.2 TPY for the furnace area stack and the refining operation stacks, combined.[2]
- Work practice standards to minimize fugitive dust emissions.

To satisfy section 112(d)(6) of the CAA, we are revising the existing MACT standard to include a reduction of the lead emission limit for the main stack. The MACT standard is being lowered from the current 1.0 pound per ton of lead produced to 0.97 pound of lead per ton of lead produced based on a determination that developments in practices, processes, or control technologies since promulgation of the MACT standards demonstrate that the facility can meet a reduced emission limit from the main stack pursuant to CAA section 112(d)(6).

In addition to our reviews under sections 112(f) and 112(d)(6) of the CAA, we are promulgating the following:

- The revision of the applicability section of the rule consistent with the definition of the source category adopted in 1992, subpart TTT which applies to any facility that produces lead metal from lead concentrate ore.
- Changes to the Primary Lead Processing MACT standards to

[2] EPA notes that it is setting a combined emission limit for these sources because, as noted in the proposal (76 FR 9432), and the risk assessment documents to support the proposed and final rulemakings, these sources have overlapping points of maximum lead impact.

eliminate the SSM exemption. These changes revise Table 1 in 40 CFR part 63, subpart TTT to indicate that several requirements of the 40 CFR part 63 General Provisions related to periods of SSM do not apply. We are adding provisions to the Primary Lead Processing MACT standards requiring sources to operate in a manner that minimizes emissions, removing the SSM plan requirement, clarifying the required conditions for performance tests, and revising the SSM-associated recordkeeping and reporting requirements to require reporting and recordkeeping for periods of malfunction. We are also adding provisions to provide an affirmative defense against civil penalties for exceedances of emission standards caused by malfunctions, as well as criteria for establishing the affirmative defense.

• Replacement of the word ''shall'' with the word ''must'' in the regulatory text. We are also replacing ''thru'' with ''through.'' We are replacing the definition of ''primary lead smelter'' with a definition of ''primary lead processor'' and adding definitions of ''secondary lead smelters,'' ''lead refiners,'' and ''lead remelters.''

These revisions to the Primary Lead Processing MACT standard are expected to result in emissions reductions in lead and other hazardous air pollutants and increased compliance costs to the industry. No economic impacts on small businesses are expected as a result of the revisions to the rule. We have determined that the one facility in this source category can meet the applicable emissions standards at all times, including periods of startup and shutdown, in compliance with the current MACT standards.

B. What are the requirements during periods of startup, shutdown, and malfunction?

The United States Court of Appeals for the District of Columbia Circuit vacated portions of two provisions in the EPA's CAA Section 112 regulations governing the emissions of HAP during periods of startup, shutdown, and malfunction (SSM). *Sierra Club* v. *EPA,* 551 F.3d 1019 (DC Cir. 2008), *cert. denied, 130 S. Ct. 1735 (U.S. 2010).* Specifically, the Court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), that are part of a regulation, commonly referred to as the ''General Provisions Rule,'' that the EPA 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 have eliminated the SSM exemption in this rule. Consistent with *Sierra Club* v. *EPA,* the EPA has established standards in this rule that apply at all times. We have also revised Table 1 (the General Provisions table) in several respects. For example, we have eliminated that incorporation of the General Provisions' requirement that the source develop an SSM plan. We have also eliminated or revised certain recordkeeping and reporting that related to the SSM exemption. The EPA has attempted to ensure that we have not included in the regulatory language any provisions that are inappropriate, unnecessary, or redundant in the absence of the SSM exemption.

In establishing the standards in this rule, the EPA has taken into account startup and shutdown periods and, for the reasons explained below, has not established 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 startup or shutdown. Also, compliance with the standards requires averaging of emissions over three-month periods, 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 promulgated.

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 usual manner * * *'' (40 CFR 63.2). The EPA has determined that CAA section 112 does not require that emissions that occur during periods of malfunction be factored into development of CAA section 112 standards. Under section 112, emission standards for new sources must be no less stringent than the level ''achieved'' by the best controlled similar source and for existing sources generally must be no less stringent than the average emission limitation ''achieved'' by the best performing 12 percent of sources in the category. There is nothing in section 112 that directs the Agency to consider malfunctions in determining the level ''achieved'' by the best performing or best controlled sources when setting emission standards. Moreover, while the EPA accounts for variability in setting emissions standards consistent with the section 112 caselaw, nothing in that caselaw requires the Agency to consider malfunctions as part of that analysis. Section 112 uses the concept of ''best controlled'' and ''best performing'' unit in defining the level of stringency that section 112 performance standards must meet. Applying the concept of ''best controlled'' or ''best performing'' to a unit that is malfunctioning presents significant difficulties, as malfunctions are sudden and unexpected events.

Further, accounting for malfunctions would be difficult, if not impossible, given the myriad different types of malfunctions that can occur across all sources in the category and given the difficulties associated with predicting or accounting for the frequency, degree, and duration of various malfunctions that might occur. As such, the performance of units that are malfunctioning is not ''reasonably'' foreseeable. *See, e.g., Sierra Club* v. *EPA,* 167 F.3d 658, 662 (DC Cir. 1999) (EPA typically has wide latitude in determining the extent of data-gathering necessary to solve a problem. We generally defer to an agency's decision to proceed on the basis of imperfect scientific information, rather than to ''invest the resources to conduct the perfect study.''). *See also, Weyerhaeuser* v. *Costle,* 590 F.2d 1011, 1058 (DC 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.''). In addition, the goal of a best controlled or best performing source is to operate in such a way as to avoid malfunctions of the source and accounting for malfunctions could lead to standards that are significantly less stringent than levels that are achieved by a well-performing non-malfunctioning source. The EPA's approach to malfunctions is consistent with section 112 and is a reasonable interpretation of the statute.

In the event that a source fails to comply with the applicable CAA section 112(d) standards as a result of a malfunction event, the 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. The 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, the EPA recognizes that even equipment that is properly designed and maintained can sometimes fail and that such failure can sometimes cause 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)). The EPA is therefore adding 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 Primary Lead Processing (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 have added 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 Primary Lead Processing. (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 reasonable 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, 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 section 63.1543(i) and 63.1544(d), 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 22.27).

The EPA included an affirmative defense in the final rule in an attempt to balance a tension, inherent in many types of air regulation, to ensure adequate compliance while simultaneously recognizing that despite the most diligent of efforts, emission limits may be exceeded under circumstances beyond the control of the source. The EPA must establish emission standards that ''limit the quantity, rate, or concentration of emissions of air pollutants on a continuous basis.'' 42 U.S.C. 7602(k) (defining ''emission limitation and emission standard''). *See generally Sierra Club* v. *EPA,* 551 F.3d 1019, 1021 (DC Cir. 2008) Thus, the EPA is required to ensure that section 112 emissions limitations are continuous. The affirmative defense for malfunction events meets this requirement by ensuring that even where there is a malfunction, the emission limitation is still enforceable through injunctive relief. While ''continuous'' limitations, on the one hand, are required, there is also caselaw indicating that in many situations it is appropriate for the EPA to account for the practical realities of technology. For example, in *Essex Chemical* v. *Ruckelshaus,* 486 F.2d 427, 433 (DC Cir. 1973), the DC Circuit acknowledged that in setting standards under CAA section 111 ''variant provisions'' such as provisions allowing for upsets during startup, shutdown and equipment malfunction ''appear necessary to preserve the reasonableness of the standards as a whole and that the record does not support the 'never to be exceeded' standard currently in force.'' See also, *Portland Cement Association* v. *Ruckelshaus, 486 F.2d 375* (DC Cir. 1973). Though intervening caselaw such as *Sierra Club* v. *EPA* and the CAA 1977 amendments undermine the relevance of these cases today, they support EPA's view that a system that incorporates some level of flexibility is reasonable. The affirmative defense simply provides for a defense to civil penalties for excess emissions that are proven to be beyond the control of the source. By incorporating an affirmative defense, the EPA has formalized its approach to upset events. In a Clean Water Act setting, the Ninth Circuit required this type of formalized approach when regulating ''upsets beyond the control of the permit holder.'' *Marathon Oil Co.* v. *EPA,* 564 F.2d 1253, 1272–73 (9th Cir. 1977). *But see, Weyerhaeuser Co.* v. *Costle,* 590 F.2d 1011, 1057–58 (DC Cir. 1978) (holding that an informal approach is adequate). The affirmative defense provisions give the EPA the flexibility to both ensure that its emission limitations are ''continuous'' as required by 42 U.S.C. section 7602(k), and account for unplanned upsets and thus support the reasonableness of the standard as a whole.

C. What are the effective and compliance dates of the standards?

The revisions to the MACT standards being promulgated in this action are effective on November 15, 2011. For the MACT standards being addressed in this action, the compliance date for the revised SSM requirements is the effective date of the standards, November 15, 2011. The compliance date for the revised emission standard in section 16.1543(a) is January 17, 2012. The compliance date for the revised requirements in section 16.1544 is February 13, 2012. The compliance date for the new refining and furnace area stack emission limit is 2 years from the effective date of the standard, November 15, 2013.

IV. Summary of Significant Changes Since Proposal

A. Changes to the Risk Assessment Performed Under Section 112(f) of the Clean Air Act

As noted above, in February of 2011 EPA published the notice of proposed rulemaking: National Emission Standards for Hazardous Air Pollutants: Primary Lead Smelting. In the proposed rulemaking, EPA presented a number of options for additional controls on the primary lead smelting source category, which currently includes only one facility operating in the United States. In the proposed rule, EPA solicited comment on these options as well as on all the analyses and data the options were based upon, including the risk methods and results presented in the draft document: Draft Residual Risk

Assessment for the Primary Lead Smelting Source Category.

During the public comment period for the proposed rule, the one facility in the source category, The Doe Run Company, submitted substantially updated emissions, meteorological, facility boundary, as well as other relevant information bearing on the risk assessment (see docket number: EPA–HQ–OAR–2004–0305 for Doe Run's public comments). As a result, to support this final rulemaking EPA revised its analyses to reflect the information received during the public comment period for the proposed rule. Revised methods, model inputs, and risk results are presented in the report: ''Residual Risk Assessment for the Primary Lead Smelting Source Category'' which is available in the docket for this rulemaking. In addition, a discussion of the updated emissions information used in the final risk assessment can be found in the Technical Support Document for the final rule, which can also be found in the docket for this rulemaking.

Table 3 presents the results of the final baseline risk assessment, with respect to the risks due to lead emissions, broken down by emission point. In the baseline scenario, we estimate that approximately 1,550 people may be exposed to lead concentrations above the NAAQS. Results indicate that emissions from the refining stacks and furnace area stacks can likely result in exceedences of the NAAQS for lead beyond the fenceline of the facility.[3] These results also indicate that fugitive dust emissions could result in exposures approximately equal to the level of the NAAQS at the location of maximum impact. The results also indicate that emissions from the main stack do not likely result in exceedences of the NAAQS for lead beyond the fenceline of the facility because emissions are highly dispersed due to the height of the main stack.

TABLE 3—SUMMARY OF LEAD CONCENTRATIONS RELATIVE TO THE NAAQS BASED ON ESTIMATED ACTUAL 2009 EMISSIONS

Emission point	2009 Emissions (tpy)	Offsite impact [3]
Main stack [1]	68.3	0.9 times the NAAQS.
Refining stacks [2]	9.1	8 times the NAAQS.
Furnace area stack: (Controlled blast and drossing fugitives)	2.5	2 times the NAAQS.
Fugitive dust	1.0	1 times the NAAQS.

[1] Results presented for the main stack in this table consider the good engineering practice (GEP) stack height of 330 feet (as was done in the SIP and in modeling submitted by the Doe Run Company in its public comments on the proposed rulemaking). The actual height of the main stack is approximately 550 feet, and thus the impact would likely be lower had actual stack height been modeled.

[2] Emission sources controlled by baghouses 8 and 9 at the Doe Run facility.

[3] For a given emission point, the model receptor location with the highest modeled 3-month ambient lead concentration was determined. This highest 3-month ambient lead concentration was then divided by the NAAQS (0.15 $\mu g/m^3$) for lead to determine the maximum offsite impact for a given emission point.

Consistent with the risk assessment to support the proposed rulemaking, the risk assessment to support the final rulemaking also indicates that risks are unacceptable. This decision considers all the risk estimates presented in the risk assessment document, but is primarily based on lead emissions from the furnace area stack and the refining operations stacks. We note that while the risk assessment supporting the proposed rulemaking estimated that a combined emission limit for the furnace area and refining operations should be set at 0.91 tons of lead per year to ensure that risks are acceptable, the updated risk assessment estimates that a combined emission limit of 1.2 tons of lead per year will ensure that ambient lead concentrations from those emission points do not result in lead levels in the ambient air above the level of the NAAQS for lead, thereby resulting in acceptable lead risk. In our ample margin of safety analysis, we identified no cost-effective controls that are capable of achieving emission levels below 1.2 tons per year, as described in the technical support document. Thus, the EPA is promulgating a combined lead emission limit for the furnace area and refining operations stacks at 1.2 tons per year.[4] In addition, the risk assessment projected ambient lead concentrations from fugitive dust emissions to be very close to the NAAQS for lead at the location of maximum impact; thus with respect to fugitive dust emissions, since only minimal (if any) reductions beyond those already in place are needed to ensure lead levels in the air do not exceed the NAAQS, the EPA believes that the work practice standards being promulgated in this rule, which are more stringent than currently required by the 1999 NESHAP, will ensure an acceptable level of risk.

Moreover, since this NESHAP includes work practice standards to minimize fugitive dust emissions, and since ambient monitoring for lead is already conducted very close to this facility and in the local community to demonstrate whether the area is attaining the lead NAAQS, we have decided that fenceline monitoring to specifically demonstrate that the source has adopted sufficient work practice standards to ensure fugitive emissions do not cause exceedances of the NAAQS is not necessary.

In addition to the updated lead risk assessment results presented above, we also note that there were changes to our cancer, acute, and PB–HAP multipathway screening analyses for non-lead HAP as a result of the new risk analysis performed for the final rule. With respect to our updated cancer risk assessment, we estimate that the maximum individual risk (MIR) of cancer is 20 in a million (as compared to 30 in a million based on the risk assessment to support the proposed rule), and that the cancer incidence is 0.008, or 1 excess cancer case every 125 years (as compared to 0.0008 based on the risk assessment to support the proposed rule). In addition, the refined worst-case acute hazard quotient (HQ) value is 2.0 (based on the REL for arsenic), driven by arsenic emissions from the main stack (as compared to 0.6 based on the REL for arsenic and driven by arsenic fugitive dust emissions as indicated by the risk assessment to

[3] For the reasons noted in the proposed rulemaking, 76 FR at 9421, we used the level of the lead NAAQS as the level above which we think an unacceptable risk is presented to the public.

[4] EPA notes that it is setting a combined emission limit for these sources because, as noted in the proposal (76 FR 9432), and the risk assessment documents to support the proposed and final rulemakings, these sources have overlapping points of maximum lead impact.

support the proposed rule). Finally, while the worst-case multipathway screen to support the proposed rule indicated that no non-lead PB–HAP exceeded screening levels for potential multipathway effects, in the risk assessment to support the final rulemaking, the worst-case multipathway screening level was exceeded with respect to cadmium emissions. This is the result of the revised emissions information provided by the company during the comment period, which indicated higher cadmium emissions from the main stack than were assumed for purposes of the risk assessment performed for the proposed rule.

In considering the updated non-lead risk results presented above, we note that while cancer incidence increased in our updated risk assessment, cancer incidence remains very low with 1 excess cancer case being estimated every 125 years.

With respect to the worst-case acute HQ value of 2 based on the REL for arsenic due to emissions from the main stack, we note that this is a conservative, worst-case analysis of the potential for acute health effects. We also note that in contrast to the risk analysis to support the proposed rulemaking, the final risk analysis modeled the main stack at the good engineering practice (GEP) stack height of 330 feet rather than the actual stack height of 550 feet. Thus it is very likely that the maximum potential worst-case HQ value is significantly lower than 2.

Finally, with respect to the exceedence of the worst-case multipathway screening level for cadmium, we note that this only indicates the potential for cadmium exposures above the chronic noncancer reference dose (RfD) for cadmium. That is, while in general, emission rates below the worst-case multipathway screening level indicate no significant potential for multipathway related health effects, emission levels above this worst-case screening level only indicate the potential for multipathway-related health risks of concern based on a worst-case scenario. We were not able to refine our multi-pathway analysis beyond the worst-case screening assessment. As a result, based on worst case screening, we cannot state whether or not there are going to be multipathway risks at true exposure levels, we can only say that worst case modeling suggests there could be potential risks. However, due to the highly conservative nature of this screening assessment and the uncertainties related to the results, we have concluded that, after implementation of the controls required by this rule, risks will be acceptable, considering the combination of potential multipathway risks, cancer risks, chronic non-cancer risks, and acute non-cancer risks. We also reviewed whether there were cost-effective controls that could further reduce risks as part of our ample margin of safety analysis. The controls we are requiring to address lead emissions also reduce emissions of non-lead HAP. We were unable to identify any technically feasible cost effective additional controls that would further reduce emissions of lead and non-lead HAP. We are therefore determining that the standards we are promulgating today provide an ample margin of safety to protect public health.

In summary, the final rule includes an emission standard of 1.2 tons per year of lead emissions from refining and furnace area stacks, combined. The standard also includes a requirement for the facility to employ work practice standards to minimize fugitive dust emissions, including cleaning plant roadways, stabilization of material during storage and handling, and ensuring that doorways to process areas remain closed. In summary, we conclude that these standards being promulgated today will ensure risks are acceptable and public health is protected with an ample margin of safety and that there will not be an adverse environmental effect from HAP emissions from the one lead processing facility in this source category.

B. Changes to the Technology Review Performed Under Section 112(d)(6) of the Clean Air Act

In the proposed rule, the main stack was subject to an emission limit of 0.22 pounds of lead per ton of lead produced based on our section 112(d)(6) technology review. That proposed limit was based on information that indicated the source had significantly lower emissions than the emission limit of 1 pound of lead per ton of lead produced (lb/ton) required in the 1999 MACT standard. However, in comments received on the proposed rule, The Doe Run Company indicated that the proposed emission limit of 0.22 lb/ton under Section 112(d)(6) could not be met and that the data on which that emission limit was based were not accurate. The facility provided a 2009 stack emissions test for the main stack that indicated that emissions at the facility are significantly higher than we assumed as the basis for the proposed limit. For purposes of our analysis for the final rule, the EPA recalculated the emissions performance achieved for the main stack as demonstrated by the 2009 and 2008 stack tests and considered an estimate of emission variability in order to determine whether it was appropriate to revise the emission limit based on what the source was able to achieve in practice. Based on the revised analysis, we are promulgating an emission limit for the main stack of 0.97 pounds of lead per ton of lead produced.

We have also changed the compliance date for the main stack to reflect compliance ''as expeditiously as possible'' under section 112(i)(3) of the CAA. The compliance date for the 0.97 lb/ton limit is 60 days from the date of publication of the final rule.

C. Other Changes Since Proposal

The EPA has decided not to include the refining and furnace area emissions as part of a facility wide emission limit as was proposed. We received comments from Doe Run on the proposed rule that inclusion of these sources in the production based emission limit in section 63.1543(a) was not necessary and that these sources would simultaneously be required to comply with the standard for refining and furnace area emissions proposed under section 112(f) and the production based limit proposed under section 112(d)(6). We agree with the commenters and we are establishing a separate emission limit of 1.2 tons per year of lead emissions that applies to the combined emissions of the refining and furnace area stacks. The emission standard limits the combined emissions from these two stacks because the revised risk assessment indicated that the location of maximum impact for these two stacks overlapped at the same receptor. A production based emission limit will continue to apply to sources in section 63.1543(a)(1)–(9).

As mentioned earlier, we are not finalizing a requirement for fenceline monitoring to ensure that fugitive dust emissions do not cause an exceedance of the NAAQS offsite. The revised modeling showed substantially lower ambient concentrations due to fugitive dust emissions relative to the modeling performed for the proposed rule. We estimate current fugitive dust emissions result in maximum lead levels offsite that are approximately equal to the NAAQS. We are promulgating work practice standards beyond what is required by the 1999 rule that must be implemented by the source in order to ensure that fugitive emissions will not result in an exceedance of the NAAQS and thus result in an unacceptable risk. We expect that after implementation of this revised NESHAP, fugitive dust emissions from primary lead processing

facilities will not result in exposures levels above the NAAQS. Since the risk levels are much lower than we had estimated at proposal, and since we are promulgating specific work practice requirements to minimize fugitive dust emissions, we have determined that the proposed fenceline monitoring requirement is not necessary to show compliance with this NESHAP. Furthermore, there are already several monitors nearby that measure ambient lead levels and that should provide sufficient indication of whether fugitive lead emissions have been sufficiently reduced.

In recent rules promulgated under section 112 and 129, the EPA has revised certain terms and conditions of the affirmative defense in response to concerns raised by various commenters. The EPA is adopting those same revisions in this rule. Specifically, the EPA is revising the affirmative defense language to delete ''short'' from 63.1551(a)(1)(i), because other criteria in the affirmative defense require that the source assure that the duration of the excess emissions ''were minimized to the maximum extent practicable.'' The EPA is also deleting the term ''severe'' in the phrase ''severe personal injury'' in 63.1551(a)(4) because we do not think it is appropriate to make the affirmative defense available only when bypass was unavoidable to prevent severe personal injury. In addition, the EPA is revising 63.1551(a)(6) to add ''consistent with good air pollution control practice for minimizing emissions.'' The EPA is also revising the language of 63.1551(a)(9) to clarify that the purpose of the root cause analysis is to determine, correct, and eliminate the primary cause of the malfunction. The root cause analysis itself does not necessarily require that the cause be determined, corrected or eliminated. However, in most cases, the EPA believes that a properly conducted root cause analysis will have such results. In addition, the EPA is revising 63.1551(b) to state that a written report must be submitted within 45 days of the initial occurrence of the malfunction and that the source may seek an extension of up to an additional 30 days.

V. Summary of Significant Comments and Responses

In the proposed action, we requested public comments on all aspects of the proposal, including our residual risk reviews and resulting proposed standards, our technology reviews and resulting proposed standard, and our proposed amendments to delete the startup and shutdown exemptions and the malfunction exemption and to establish an affirmative defense for malfunctions.

We received written comments from 16 commenters. Our responses to some of the significant public comments are provided below. Responses to the comments that are not in the preamble have been placed in the docket. See *Summary of Public Comments and Responses for Primary Lead Processing NESHAP* (October 2011), for summaries of other comments and our responses to them.

A. Timeline for Compliance

Comment: Two commenters opposed the compliance timing and supported extending the compliance date beyond two years for several reasons. One commenter stated that according to the time line in the proposed rule, the facility will operate in its current form for only a few months after the compliance date of the rule. This creates a dilemma for the State and facility in terms of implementation, planning, resources and compliance. The commenter suggested that the implementation and attainment schedules for this MACT rule should correspond to those of the 2008 NAAQS.

One commenter identified three provisions they suggest could be used to allow more than 2 years for compliance: (1) 112(i)(3)(A) establishes 3 years for compliance for section 112 standards, (2) 112(i)(5) allows exemption for up to 6 years for facilities demonstrating 90 percent reduction in HAP prior to first proposal of a section 112(d) standard, and (3) 112(h)(3) allows an alternative means of compliance in some circumstances. The commenter stated that the import of the underlying statutory authority relates to the compliance period for existing sources. Under the EPA practice, a three-year compliance period applies to section 112(d) MACT standards, while a two-year period applies to section 112(f) standards. Although the EPA seems to have reflexively applied the section 112(f) period, this approach is not foreordained in the present circumstances. Specifically, section 112(i)(3)(A), which allows a three-year compliance period for any section 112 standard, merits consideration in light of the various proposed MACT standards, including a plant-wide section 112(d)(6) standard. With regard to the authority under section 112(i)(5), the commenter states that emissions have been reduced from 140 tons in the year 2000 to less than 14 tons in 2009, representing a decrease of over 90%. With regard to section 112(h)(3), the commenter believes that the two year compliance period has serious adverse economic effects on the company and the new hydrometallurgical process can be considered an alternative means of emission limitation.

The commenter also stated that the circumstances of this case present a unique challenge in determining an appropriate compliance deadline for a new primary lead smelting MACT standard. The commenter stated that there were several differences from the typical MACT rulemaking: Instead of multiple sources within a category, there is only one facility in the category; by virtue of a federally enforceable consent decree, the facility must terminate its present operations by April 30, 2014; and assuming a final rule issues on October 31, 2011, and a two-year compliance deadline, the compliance period would be at most six months prior to stoppage of many of the current operations. If forced to achieve compliance that would last only for such a short period, the facility would face severe economic hardship that could jeopardize its ability to finance and to build a new hydrometallurgical lead production process that would largely eliminate lead emissions. These circumstances raise questions as to the legal necessity as well as the feasibility and practicality of implementing a two-year compliance deadline.

Further, it was incorrectly assumed that a two-year compliance period is consistent with the schedule of required actions contained in the Consent Decree, when the opposite is true. Requiring MACT standard compliance six months before the required termination of Doe Run's existing lead smelting seriously erodes several Consent *Decree goals:* Introducing a new hydrometallurgical lead production process that minimizes lead emissions, assuring continued primary lead production in the United States, and promoting the development of the most technologically advanced lead production process in the world.

Finally, the commenter stated that the primary lead RTR proposal effectively accelerates the compliance date for the lead NAAQS for the Doe Run facility. According to the commenter a two-year compliance timeframe relies, in part, on the various steps that must be undertaken to implement a plan to monitor lead concentration in air. But this reliance is also misplaced because it requires Doe Run to comply with the new Lead NAAQS in 2013, or more than two years before the Lead NAAQS itself requires compliance. No statutory authority supports such accelerated compliance for the lead NAAQS or preemption of the SIP process. In short,

the two-year timeframe rests on faulty grounds: Factually, it is inconsistent with the Consent Decree requirements, and legally, it unlawfully attempts to speed up the previously-established compliance timeframe for the lead NAAQS.

Response: Section 112(i)(3) establishes the compliance timeframe for any standard issued under section 112 for existing sources and provides that the compliance date shall be as expeditiously as practicable but no later than 3 years following the effective date of the standard. Section 112(f)(4), however, expressly provides more specific requirements for standards issued under section 112(f) and thus for section 112(f) standards those more prescriptive requirements govern in place of the compliance requirements in section 112(i)(3). Specifically, section 112(f)(4) provides that a source cannot emit an air pollutant in violation of a standard issued under subsection (f) except that the standard will not apply until 90 days after its effective date. It also provides that the Administrator may grant a waiver for a period of up to 2 years from the effective date if necessary for the installation of controls and if measures will be taken in the interim to ensure public health is protected from imminent endangerment. Thus, for standards applicable to the furnace and refinery area emissions and the work practice standards to address fugitive emissions, which were issued under section 112(f), the compliance period may not exceed two years from the effective date of the standard. We are providing 90 days for compliance with the work practice standards and two years for compliance with the standards applicable to the furnace and refinery area stacks.

The main stack emission limit, proposed under 112(d)(6), is subject to the section 112(i)(3) compliance provisions. We are establishing an emission standard of 0.97 lb Pb/ton of lead produced that would replace the existing standard of 1 lb Pb/ton of lead produced. This standard is based on the level of emissions that the source is already achieving in practice and thus no additional controls would be needed to meet that emission limit for the main stack. For that reason, we are requiring compliance with the new limit for the main stack within 60 days of the effective date of this final rule as this timeframe constitutes compliance ''as expeditiously as practicable.''

Concerning section 112(i)(5), the provision only applies to standards promulgated pursuant to section 112(d) (and not 112(f)) and also only where a source achieves a 90% reduction (95% in the case of HAPs that are particulate matter) prior to the proposal of the section 112(d) standard. Thus, this provision does not apply to the standards established under 112(f) in this final rule. With regard to the emission standard proposed for the main stack, stack test data indicate that the main stack emissions are substantially higher than the 14 tons per year value cited by the commenter. Based on performance test data, the facility has not achieved the reductions in emissions required to apply the alternative compliance dates in section 112(i)(5).

Section 112(h)(3) allows the Administrator through notice and comment rulemaking to accept an alternative means of emission limit in place of a work practice standard established under 112(h)(1) if the owner or operator of a source establishes that such alternative means will achieve reductions at least equivalent to those that would be achieved by the work practice standard. It is unclear precisely what the commenter is suggesting with regard to this provision. However, it seems they may be suggesting that the new hydrometallurgical process that they plan to install after they close the pyrometallurgical processes should be considered an alternative means of compliance with the work practice standard. It is unclear how this process would address the emissions covered by the work practice standards we are establishing which are intended to address current fugitive dust emissions from the facility. Those emissions are almost exclusively from lead entrenched in open areas and the installation of a new process for lead processing would not appear to affect those emissions. Moreover, we understand that the new hydrometallurgical process won't be operational until sometime after the compliance date for the work practice standards we are requiring. Thus, even if that process would address in whole or in part the fugitive dust emissions addressed through the work practice standards, it would not be an appropriate substitute in the absence of being able to achieve the necessary reductions within the compliance period. We note that our determination here does not preclude Doe Run from submitting additional information that may further support a demonstration under section 112(h)(3) and for which we could take further action in a separate rulemaking.

As to the concerns the commenter raises about this situation being unique, we do not disagree. However, the statute is clear that the maximum compliance period for standards issued pursuant to section 112(f) is two years. The commenter submits no facts or information that supports a legal basis for providing a longer period for compliance for the refining and furnace area stack limits and for the work practice standards to minimize fugitive dust emissions.

Finally, we note that the Lead NAAQS does not apply to a specific facility but rather is a level that must be met within the designated nonattainment area. However, we recognize that Doe Run is the only stationary industrial source creating the Jefferson County lead nonattainment area and the reductions required under the rule will help bring the area into attainment with the lead NAAQS. However, this regulation does not preempt the SIP process; the State of Missouri is still required to submit a state implementation plan demonstrating how the area will attain and maintain the lead NAAQS. In doing so, the State may rely on any reductions required under this regulation. Finally, we note that this regulation does not ''speed up'' the compliance timeframe for meeting the Lead NAAQS. The CAA requires areas to attain the various NAAQS as expeditiously as practicable, but no later than specified dates. For the 2008 lead NAAQS, areas are required to attain the standard as expeditiously as practicable, but no later than December 31, 2015. The Act not only contemplates but requires, if practicable, for areas to attain the 2008 lead NAAQS earlier than December 31, 2015.

Additionally, we are not requiring fenceline monitoring as part of the final NESHAP amendments. Therefore, the commenter's concerns related to potential conflict between monitoring for the NAAQS and this NESHAP are no longer relevant.

Comment: One commenter stated that the proposed emission standards and ambient standard had negative implications for determining compliance under the proposed two-year compliance period and the ''plantwide reductions'' that are ''required under section 112(f)(2).'' 76 FR at 9437/1. According to the commenter, the only plant-wide reduction proposed in the rule is the plant wide limit of 0.22 pounds per ton produced while the other two new numerical standards are the 0.91 tpy limit for furnace area and refining and casting operations and the 0.15 $\mu g/m^3$ limit for ambient lead concentrations.

The commenter stated that the three proposed numerical standards present a confusing regulatory regime as to which standard ultimately controls for determining compliance. If, for

example, Doe Run achieves an aggregate emission of 0.22 lb/ton on a facility wide basis but exceeds 0.91 tpy for its furnace and refining and casting operations, would it be in compliance?

Of the three numerical standards, the commenter stated that only the 0.91 tpy limit can arguably be linked to Section 112(f), and even that is unclear. The 0.91 tpy standard is derived from the Lead NAAQS risk analysis. Despite this starting point, this standard is subsumed in the proposed 0.22 lb/ton plant-wide limit which arose under the section 112(d)(6) technology review, adjusted for ''variability in the operations and emissions.'' While an effort is made to differentiate the components of the 0.22 lb/ton standard as to which portion fits under what statutory authority, this single plant-wide emission standard rests on the section 112(d)(6) review. Although not explicitly stated, this plant-wide standard offers more than an ample margin of safety.

Response: We have decided not to include a facility-wide limit that would include the refining and furnace area stacks as well as to the main stack. Instead, the 1.2 tpy emissions standard we are promulgating under section 112(f) will apply to combined emissions from the refining and furnace area stacks. The 0.97 lb/ton emission standard that we are promulgating pursuant to section 112(d)(6) will replace the 1.0 lb/ton limit in the original MACT rule and will apply to the same sources subject to the limit in the original MACT rule. Additionally, we have eliminated the fenceline monitoring requirement from the final rule. These changes should alleviate the regulatory confusion that could arise over the limits in the proposal. Furthermore, we believe a plant-wide limit is not necessary to address the residual risk and technology review requirements of the Act. As provided in the preamble to the proposed and final rules, we evaluated each of the emission stacks separately to determine whether additional controls are necessary under section 112(f) or 112(d)(6) and a plant-wide limit is not needed under either of those statutory requirements.

B. The EPA's Authority Under Section 112 of the Clean Air Act

Comment: One commenter stated that the modification to the applicability provision does not comport with how smelting is defined and used and that the source category listing was intended to cover smelting only, not other processes. The commenter lists several issues supporting this position:

- The opening phrase of the first sentence ''The Primary Lead Smelting source category,'' describes and limits ''any facility'' to mean those involving smelting; and the ''includes, but is not limited to'' language does not apply to any lead producing process, but only to ''the following smelting processes.''
- The list of processes identified all involve pyrometallurgical activities: Sintering process, blast furnace, electric smelting furnace, reverberatory furnace, slag fuming furnace, drossing kettles, and dross reverberatory furnace.
- The plain meaning of that language evidences intent to cover any and all types of pyrometallurgical processes for producing lead but shows no attempt to encompass other, as yet unknown, lead production processes.
- Isolating the phrase ''including, not limited to'' from the company it keeps to justify an expansive reading goes well beyond the meaning of the listing as a whole and thus cannot stand.

The commenter also stated that the proposed change in applicability is inconsistent with the statutory structure for formulating source categories: ''To the extent practicable, the categories and subcategories listed under this subsection shall be consistent with the list of source categories established pursuant to section 7411 of this title and part C of this subchapter.'' The commenter cited several instances in the statute where Primary Lead Smelting is referred to as a pyrometallurgical process. In summation, the commenter states that the statutory directive of CAA section 112(c)(1) to assure consistency between a source category definition and how the same terms are used in other parts of the Act demonstrates that the statutory and regulatory use of ''primary lead smelting'' and ''primary lead smelter'' was consistently designed to cover only pyrometallurgical processes. The EPA's assertion that the originally formulated primary lead smelting source category has a ''broader definition'' is inconsistent with the original source category language and the pyro-oriented definitions applied to primary lead smelting/smelter found throughout the statute and regulations.

The commenter also stated that the EPA's effort to recast the primary lead smelting category is barred by the failure to show a major source would be present. The new hydrometallurgical process bears no resemblance to the current pyrometallurgical process, other than feedstock and end product. The new process will have drastically reduced lead emissions and is presented as a minor source in the Doe Run Air Construction Permit Application for the New Lead Technology submitted to the Missouri Department of Natural Resources.

Response: Section 112(c)(1) describes the process for creating the source category list. To the extent that the commenter is concerned that the source category listing for primary lead was not issued consistent with the requirements of section 112(c)(1), such claim is untimely. We disagree with the commenter that the source category description must be read to be limited to pyrometallurgical processes. The source category description was intended to include all processes used to produce lead metal from ore concentrates, as evidenced by the first sentence of the category description. While it is true that at the time of the source category listing, the hydrometallurgical process described by the commenter did not exist, the language left open the possibility that other lead metal production processes might be developed in the future and would be covered under the source category listing.

Although, the source category name in the 1999 NESHAP was ''primary lead smelting'' rather than ''primary lead processing,'' it was given that title because, at that time smelting was the only technology used to process lead ore into lead metal. However, the three-word title should not be read as limiting the broader language in the description of the source category, which provides the full evidence of EPA's intent of what should be included in the source category.

Recently, during the development of this RTR rulemaking, we became aware of a new primary lead processing and production technology (*i.e.,* hydrometallurgical process). It is our understanding that even after this new technology is in place, the facility plans to continue operating some of the same thermal processes in use now and subject to the NESHAP (such as refining and casting) which continue to have the potential to emit significant amounts of lead. We also note that this facility will continue to have the potential for fugitive emissions. For these reasons, we conclude that it is appropriate and necessary to update the title for the MACT standard and the applicability section of the standard, consistent with the description of the listed source category, to ensure these emissions points continue to be subject to emissions standards. However, it is also important to note that the rule being promulgated today has no requirements that apply to the hydrometallurgical processes themselves, since this process currently does not exist at this facility.

As noted in the response to comments, if a new process such as the hydrometallurgical process is developed and put into use in the future, then EPA would consider what standards to propose for such process after such process is operational.

We believe section 112(d)(1) provides the authority for this revision to the standard. That provision requires EPA to ''promulgate regulations establishing emission standards for each category or subcategory of major sources and area sources'' of the hazardous air pollutants listed in section 112(b)(1). Because EPA's initial promulgation of the MACT standard did not fully describe the source category, and thus did not regulate all potential sources within the source category, we believe it is now appropriate to revise the applicability provision to fully cover the sources as provided under the source category listing.

Comment: A commenter stated that the proposed rule does not suggest that the new lead production processes should be listed as area sources. If the EPA could make the necessary ''adverse effects finding'' for including a hydrometallurgical lead production process as an area source, a separate NESHAP would be required for a new area source. The EPA lacks authority to subsume a new area source into the Primary Lead Smelting major source category, as it would require in the proposed rule. Therefore, the EPA must show that either Doe Run's new lead production process or the entire Doe Run facility after the new process is operational would or could emit more than 10 tpy of lead if the facility is to remain a major source category and the proposed rule offers no documented evidence that Doe Run's hydrometallurgical lead production process or the Herculaneum facility after the new process becomes operational would constitute a major source. The commenter contended that neither the new process nor the entire Herculaneum facility would be a major source. Plant-wide emissions at Doe Run's facility after the new process becomes operational are estimated to approximate 0.65 tpy. Absent the presence of a major source at Doe Run's facility, the new lead production process cannot be treated as a major source category.

Response: As explained in detail elsewhere, the EPA has the authority to impose additional requirements on emission points already subject to an emission standard and to impose requirements on previously unregulated emission points in performing a risk and technology review. The EPA has exercised that authority here by establishing emission limitations for activities previously only subject to work practice requirements. The commenter's arguments to the contrary notwithstanding, the revised applicability definition will result in a source category containing a major source, the Doe Run facility. Doe Run is currently a major source of lead emissions and will be a major source of such emissions on the date by which it must initially comply with the newly established emission limits for refining activities. Thus, regardless of the level of its emissions following conversion to the hydrometallurgical process, Doe Run must meet the newly established emission limits by the specified date(s). As noted elsewhere, a new hydrometallurgical process is not subject to an emission limit under the existing MACT standard as it now exists or following the changes resulting from this rulemaking; we would consider an appropriate emission limit for the hydrometallurgical process once that process is a demonstrated technology.

Comment: Another commenter stated that the EPA appropriately proposes to update the applicability of the MACT to cover Doe Run's new type of facility.

Response: We agree with this comment.

Comment: Two commenters stated that the EPA cannot use section 112(f) authority to establish an ambient air standard because this type of standard is not an ''emission standard.''

The commenters stated that the NAAQS does not fit within the meaning of ''emission standard'' as used in CAA sections 112(d)(6) or (f)(2), the EPA's stated authority for the proposed rule. Section 112(f)(2) is entitled ''Emission standards'' and the second sentence, where the ''ample margin of safety'' factor is found, has ''emission standard'' as its subject; these specific references clarify the use of ''standards'' elsewhere in the subsection means ''emission standard.'' Likewise, section 112(d)(6) gives the Administrator authority to revise ''emission standards.'' Both subsections limit the EPA's rule-promulgating authority to setting ''emission standards.''

According to commenters, Congress defined ''emission standard'' in CAA section 302(k) to ''mean a requirement established by the * * * Administrator which limits the quantity, rate or concentration of emissions of air pollutants on a continuous basis, including any requirement relating to the operation or maintenance of a source * * * and any design, equipment, work practice or operational standard promulgated under this chapter.'' The language can only be reasonably read to allow a standard applicable to emissions from specific source(s). The lead (or any other) NAAQS, by definition, is not targeted to specific source(s), but applies generally to the national ambient air. See, *e.g.,* CAA section 109(a)(1)(A) (''regulations prescribing a national primary ambient air quality standard * * * for each air pollutant'').

The commenters stated that the contrasting language highlights that the lead NAAQS does not qualify as an emission standard within the meaning of section 112. The NAAQS addresses ambient air rather than emissions from a source, and as a result the NAAQS does not put any limits on the quantity, rate, or concentration of emissions from a particular source or on its operation, maintenance, design, or work practices, all of which are central to the section 112(f)(2) mandate or on the practices, processes, and control technologies related to sources central to section 112(d)(6). Further, a NAAQS limits ambient air lead without regard to source category or types of sources, while the MACT standards are particularized to control emissions at specific sources. Thus, the primary lead smelting emission standards differ from the secondary lead smelting emission standards, but the same lead ambient air standards apply throughout the country without regard to such distinctions. In short, the lead NAAQS does not fit the meaning of ''emission standard'' as used in section 112 and therefore cannot be properly used as the MACT standard here.

One commenter stated further that this error is not cured by the wording of proposed section 63.1544(a), which states: ''No owner * * * 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.'' As such, proposed section 63.1544(a) measures ambient air levels for compliance (''concentration of lead in air * * * at locations'') in what appears to match the source monitoring of ambient air required for the Lead NAAQS. See 73 FR at 67052, section 50.16(a) and at 67059, section 58.10; see also 76 FR at 9436/1 (proposing that compliance ''be demonstrated using a compliance monitoring system''). As such, proposed section 63.1544(a) does not limit the quantity, rate, or concentration of emissions from a specified source or take into account developments in practices, processes, and control technologies. Compare 40 CFR

63.1544(a)(2010) (requiring ''manual that describes in detail the measures that will be put in place to control fugitive dust emissions from the sources''). Measuring ambient air at locations presumably near the source does not fall within the standards allowed by CAA section 112, and, in any event, is redundant to the same monitoring and limitations already established under the Lead NAAQS. Consequently, the proposed rule exceeds the statutory authority granted by section 112, and therefore cannot be adopted.

One commenter stated that the proposal requests comments on a work practices standard operating procedure (SOP) alternative to ambient air monitoring. As opposed to using the Lead NAAQS, which is not an emission standard under Section 112, the alternative SOP proposal is consistent with the MACT directive that emission reductions be tied to specific sources.

One commenter stated that the proposed ambient lead standard is procedurally flawed because the EPA fails to explain the legal basis for imposing such a standard under section 112(f). The agency's legal authority is of central relevance to this aspect of the proposal and the failure to clearly describe the legal basis for the standard violates the EPA's obligation under section 307(d)(3)(C) to set forth the ''major legal interpretations'' that underlie the proposal.

Response: The commenters mistake the purpose of the fenceline monitoring requirement in the proposed rule. The proposed rule established emissions standards from the main, furnace area, and refinery operations stacks and further provided that fugitive dust emissions would need to be addressed by work practice standards (as is allowed under section 112(h)(1)). Finally, we proposed a fenceline monitoring requirement to ensure that the work practice standards adequately address fugitive dust emissions consistent with the requirements of section 112(f). However, we have eliminated the fenceline monitoring requirement in the final rule. Instead, we are specifying work practice standards to minimize fugitive dust emissions. Because we are not requiring fenceline monitoring in this final rule, the commenter's concerns related to redundant monitoring requirements need not be addressed.

We disagree with the suggestion that we do not provide the legal basis for our proposed rule. The preamble clearly explains that we are addressing residual risk for this source category under section 112(f) and clearly explains the rationale for the proposed rule and the basis for the proposed requirements. (See 76 FR 9412–9414 for a discussion of the statutory authority underlying the proposed revisions to the standard.) With regard to fugitive dust emissions, we are establishing a requirement for work practice standards consistent with section 112(h)(1) in lieu of an emission standard because these fugitive dust emissions, which are predominantly from materials handling and roadways cannot be captured and vented to a stack for which we could establish an emission limit.

Comment: One commenter stated that the CAA limits the EPA's ability to regulate pollutants subject to NAAQS (''criteria pollutants'') to that regime and does not allow supplemental (or supplanting) regulation of them under NESHAP. The commenter cited CAA section 112(b)(2) that states in relevant part: ''No air pollutant which is listed under section 7408(a) of this title may be added to the list under this section'' with certain exceptions not relevant here. Section 7408(a) provides the statutory authority for setting NAAQS. Also, CAA section 112(b)(7) removes elemental lead from consideration as a HAP. According to the commenter, the prohibition is not only clear, but also expansive: The statute ''unqualifiedly prohibits listing a criteria pollutant as a HAP, that is, regardless of the reason.'' *Nat'l Lime Ass'n* v. *EPA,* 233 F.3d 625, 638 (DC Cir. 2000).

Response: As we recognized in the preamble to the proposed rule, under section 112(b)(7) elemental lead may not be listed as a HAP under section 112 and the references to ''lead'' in the proposed rule referred to ''lead compounds'' which are expressly listed as a HAP in CAA section 112(b)(1). 76 FR 9412. Because lead compounds are a listed HAP, we are required to regulate them under section 112, as we did when we established the original MACT standard for primary lead in 1999. 64 FR 30194. The lead emitted from primary lead processing is lead compounds with elemental lead present only in trace amounts.[5] The commenter did not provide any data to refute this. Thus, we disagree with the commenter that we are attempting to regulate in contravention of section 112(b)(7) in this action.

The *National Lime* opinion cited by the commenters addressed a different issue than the one being at issue here. In that case, the issue was whether the EPA could use a NAAQS pollutant (particulate matter) as a surrogate for HAP metal emissions. While certain HAP listed in 112(b)(1) are considered particulate matter, ''particulate matter'' is not listed on the 112(b)(1) list. In that case, the court rejected the argument by the National Lime Association that the EPA was regulating particulate matter ''through the back door.'' In the present situation, the EPA is not regulating lead ''through the back door'' in this rulemaking.

Comment: One commenter stated that the EPA unlawfully refused to set a standard for organic HAP. According to the commenter, the EPA must set an emission standard for the organic HAP listed on the section 112(b)(1) list that this source category emits. Specifically, the commenter argues that:

> ''[w]hen EPA performs a section 112(d)(6) review, it must consider the ongoing legality and effectiveness of the existing standard. Explicitly, in the current rulemaking EPA must ''review, and revise as necessary'' the existing MACT standard. 42 U.S.C. section 7412(d)(6). It is clearly ''necessary'' for EPA to close inherently unlawful gaps in the original MACT, by setting a standard for an uncontrolled HAP. Indeed, EPA has recognized the need and done this during its section 112(d)(6) review in its recent rulemaking for Marine Tank Vessel Loading Operations and Group I Polymers and Resins where it proposed a standard for previously uncontrolled subcategories of these sources. *See* Proposed Rule, 75 Fed. Reg. 65068, 65115, 65106 (Oct. 21, 2010). EPA has no legal basis for failing to set a MACT standard now for the uncontrolled HAPs for the primary lead source category.''

Response: We disagree with the commenter that section 112(d)(6) mandates that the EPA must correct any deficiency in an underlying MACT standard when it conducts the ''technology review'' under that section. We believe that section 112 does not expressly address this issue, and the EPA has discretion in determining how to address a purported flaw in a promulgated standard. The ''as necessary'' language cited by the

[5] Harrison, R.M. and Williams, C.R. (1981). Environmental Science and Technology, Vol. 15:10, p. 1197–1204.; Ohmsen, G.S. (2001). Journal of the Air and Waste Management Association, Vol. 51, p. 1443–1451.; Uzu, G., Sobanska, S., Sarret, G., Sauvain, J.J., Pradère, P., and Dumat, C. (2011). Journal of Hazardous Materials, Vol. 186, p. 1018–1027.; Spear, T.M., Svee, W., Vincent, J.H., and Stanisich, N. (1998). Environmental Health Perspectives, Vol. 106:9, p. 565–571.; Czaplicka, M., and Buzek, Ł. (2011). Water, Air, & Soil Pollution, Vol. 218, p. 157–163.; Sobanska, S., Ricq, N., Laboudigue, A., Guillermo, R., Brémard, C., Laureyns, J., Merlin, J.C., Wignacourt, J.P. (1999). Environmental Science and Technology, Vol. 33, p. 1334–1339.; Harrison, R.M. and Williams, C.R. (1983). The Science of the Total Environment, Vol. 31, p. 129–140.; Batonneau, Y., Bremard, C., Gengembre, L., Laureyns, J., Maguer, A.L., Maguer, D.L., Perdrix, E., and Sobanska, S. (2004). Environmental Science and Technology, Vol. 38, p. 5281–5289.; Foster, R.L. and Lott, P.F. (1980). Environmental Science and Technology, Vol. 14:10, p. 1240–1244.

commenter must be read in the context of the provision, which focuses on the review of developments that have occurred since the time of the original promulgation of the MACT standard and thus should not be read as a mandate to correct flaws that existed at the time of the original promulgation. In several recent rulemakings, we have chosen to fix underlying defects in existing MACT standards under sections 112(d)(2) and (3), the provisions that directly govern the initial promulgation of MACT standards (see National Emission Standards for Hazardous Air Pollutants From Petroleum Refineries, October 28, 2009, 74 FR 55670; and National Emission Standards for Hazardous Air Pollutants: Group I Polymers and Resins; Marine Tank Vessel Loading Operations; Pharmaceuticals Production; and the Printing and Publishing Industry, April 21, 2011, 76 FR 22566). (We note that the commenter incorrectly states that we revised those standards under 112(d)(6)). We believe that our approach is reasonable because using those provisions ensures that the process and considerations are those associated with initially establishing a MACT standard, and it is reasonable to make corrections following the process that would have been followed if we had not made an error at the time of the original promulgation.

Nevertheless, based on our review of the commenter's 2009 petition and their additional comments on this proposed rulemaking, we agree that the Primary Lead Smelting NESHAP should have included an emission standard for organic HAP. We have evaluated available data and believe that we need additional data in order to set an emission standard for organic HAP that is representative of current operations and emissions. We intend to collect the needed data and propose a MACT emission standard under section 112(d)(2) and (3) of the CAA. Accordingly, we are not taking final action on the 2009 petition with respect to the issue of setting a standard or standards for organic HAP and will address that petition once we have gathered the necessary data.

C. Primary Lead Processing Risk Assessment

Comment: One commenter stated that the EPA failed to consider or account for cumulative risk and that there is no rational or scientific basis to dismiss consideration of the cumulative risk of exposures to HAPs due to uncertainties. The commenter urged that these uncertainties require protective action rather than inaction. The commenter stated that the EPA's Science Advisory Board (SAB) in May 2010 urged the EPA to use the RTR rulemaking process to do this as well as perform a sensitivity analysis to identify the major uncertainties in both the human health and ecological risk assessments. According to the commenter, the SAB and numerous other scientific experts have developed, and are in the process of developing, cutting edge methods to perform these assessments and that the EPA, as the lead environmental agency of the United States, has a responsibility to show leadership in this process. It should rely on the significant information already available and also use the current and future RTR rulemakings to further advance this process.

The commenter stated that it could be done on a site-specific basis or for the industry as a whole. Uncertainty in estimates of HAP in ambient air has been characterized, so the data available from the National-Scale Air Toxics Assessments (NATA) would allow a defensible estimate of what might be expected from other sources.

Response: We disagree with the commenter that our risk assessments do not consider cumulative risk. We note that our assessment of cancer risks is, in fact, cumulative, summing the risks associated with all carcinogens emitted by the facility. Similarly, the use of the target organ specific hazard index (TOSHI) for chronic non-cancer effects evaluates the cumulative effects of HAP on a given target organ. Further, our assessment for Primary Lead Processing is cumulative in that it considers all emission points within the fenceline (since they are all covered by the MACT). Moreover, the level of the lead NAAQS, which we used as the metric for defining unacceptable risk, was set based on all air-related exposures in its derivation and thus is also a cumulative standard. We note that for the present rulemaking, our consideration of cumulative risks for the Doe Run facility is the same as that for the industry as a whole since Doe Run is the only facility within the source category.

We further disagree with the commenter's assertion that a comprehensive quantitative assessment of risks from all sources outside the source category is required under the statute. If such were in fact the case, the task of completing such a requirement would take an interminable length of time. Instead, to provide the quantitative risk information necessary to inform RTR regulatory decisions, the EPA conducts a comprehensive assessment of the risks associated with exposure to the HAPs emitted by the source category (*i.e.,* those emissions that can actually be affected by the specific rulemaking) and supplements that with additional information about other possible concurrent and relevant risks that is readily available. In some cases, we have additional information about HAP emissions that are outside the scope of the particular rulemaking but within the boundaries of the subject facilities. In other cases, we may have ambient HAP monitoring data that can be considered as part of the regulatory decision-making. In still other cases, we may have very little additional risk information that can be considered. In all cases, however, when we consider additional information about risks, we also consider its attendant uncertainties, and information which carries significant uncertainties generally carries much less weight in the overall regulatory decision.

All of the quantitative risk assessment information about HAP emissions from the source category under consideration is also considered in the manner prescribed by the decision framework set forth by the CAA for residual risk decision-making (*i.e.,* the Benzene decision framework), and this means that the general guidelines of risk acceptability have been developed in a way that they already take into account the impossibility of accurately quantifying the health risks posed by outside forces on every individual in the population. They do this by noting that the guidelines apply in ''the world in which we live,'' a world which is acknowledged to be ''not risk-free,'' but rather a world which is full of risks, many of which can simply not be quantified. This acknowledgment allows the EPA to make risk-based decisions by focusing on the risks associated with the emissions that are themselves the subject of regulation being considered, and not get distracted by the daunting task of assessing all the other concurrent potential risks that may or may not be relevant and can't be impacted by the regulation in question anyway.

Comment: Two commenters took issue with the modeling methodology used for the RTR proposal and disagreed with the risk results based on a number of concerns.

One commenter stated that the RTR modeling characterized the maximum air lead concentrations near the facility to be fifty times the 2008 NAAQS which is inconsistent with both recent air quality monitoring data and Missouri's 2007 attainment demonstration modeling and stated that the proposed RTR modeling overestimated the maximum air lead concentration by at

least a factor of five. The commenter stated that the inaccuracies of the EPA's proposed modeling analysis will be in conflict with future baseline and attainment demonstration modeling based on more accurate data, especially since the RTR proposes to correlate the MACT standard with the 2008 NAAQS. The commenter recommended that the EPA remodel this facility using higher quality input data that are more representative of current operations at the Herculaneum facility, to obtain results that better reflect the actual monitored 3-month lead concentrations. Alternately, the commenter stated that the EPA should either defer to appropriate air quality monitoring information or to the modeling run used for the 2007 SIP revision attainment demonstration as the basis for this RTR. Some commenters also suggested using AERMOD modeling followed by LEADPOST, rather than using HEM–3 to ultimately calculate 3-month rolling average lead concentrations.

Two commenters identified specific issues with regard to the modeling approach and input data including:

- The ratio of modeled results to monitored data should not exceed a factor of two. The commenter provided specific corrections and analysis of data.
- The NAAQS attainment demonstration model developed by the State of Missouri and the RTR modeling, although conducted for different purposes, are both based on compliance with the same standard for the same geographic location. Therefore, the output of both dispersion models, whether for residual risk assessment or SIP development, should reflect the maximum ambient air lead concentration. The commenter stated that any data limitations should be addressed with input from the commenter.
- Improvements from the 2007 SIP for the fugitive emissions from the sinter plant and blast furnace building do not appear to be reflected in the run script of the model, resulting in concentrations up to fifty times the NAAQS. The commenter stated that actual monitoring data from 2010 show a maximum three-month average ambient air concentration of 1.12 μg/m^3 at the Main Street site. This actual monitored value is in line with the MDNR modeled estimate from the 2007 SIP revision and is recommended to be the basis for the risk assessment.
- The EPA did not provide a modeling protocol for their dispersion modeling, or all of the modeling inputs, post processing and other data in the docket for public review. Therefore, a complete, replicable public review of the model and assessment of the proposed RTR could not be made. The commenter identified several specific modeling parameters and data elements that were not correctly applied during the proposal modeling run which could have significantly affected the results including model control options, run script parameters, volume sources modeled as point sources, inaccurate fenceline/boundary locations, incorrect elevations for sources and receptors, and old census data information for receptor centroids.

Response: Because of the availability of newer emissions data, more detailed site-specific meteorological data, as well as updated facility boundary and other information provided by Doe Run in comments on the proposed rule, we have remodeled the facility with these newer data. We remodeled using AERMOD in the default mode to estimate monthly lead concentrations, and we used the building and particle data submitted by one commenter to model building downwash and plume depletion. We used the LEADPOST processor to calculate 3-month rolling averages. In addition, using the updated facility boundary information, the EPA also removed census blocks that would now be considered onsite. The methods and results of this modeling effort can be found in the document: Residual Risk Assessment for the Primary Lead Smelting Source Category, which is available in the docket for this rulemaking. The EPA notes that the results of this modeling effort are similar to results submitted by the Doe Run Company to the State as part of a SIP (this Doe Run modeling effort was also submitted to the EPA as part of its public comments). Moreover, the EPA notes that a comparison of modeled lead concentrations at the sites of six lead monitors are within 50 percent of measured concentrations at those monitors. These results are similar to a model-to-monitor comparison submitted by Doe Run in its public comments.

We note that the docket included all of the input files and documentation needed to reproduce the modeling that was performed for the proposal risk assessment.

Comment: With respect to using the NAAQS to evaluate potential multipathway risks from lead, one commenter stated that the risk assessment used to set the NAAQS was based on quantitative studies of young children and that while ''the Lead NAAQS obviously applies to all ages, that was a qualitative risk management decision made as a matter of policy'' and that ''the task at hand is to provide a quantitative risk assessment of the maximum non-adverse facility-level emissions rate for all ages, which cannot be done on the basis of a risk assessment that studied children only.

Response: The lead NAAQS was a public health policy judgment considering the available health evidence and risk analyses as well as the uncertainties associated with the health evidence and risk analyses. We disagree with the commenter that the lead NAAQS cannot be used in a quantitative manner. The review of the lead NAAQS clearly resulted in a quantitative standard: 3-month maximum lead concentration not to exceed a level of 0.15 μg/m^3. This standard was set to protect public health, including the health of sensitive populations, with an adequate margin of safety. As the commenter notes, the lead NAAQS applies in all areas of the United States and is meant to protect the public health with an adequate margin of safety regardless of the age of the individuals living in a particular area.

Comment: One commenter stated that rather than finalizing this proposal as it stands, the best available science directs the EPA to set a residual risk standard that incorporates protective health benchmarks and assures that children living near the facility will not face an unacceptable neurological effect, such as the loss of IQ points. This includes protecting children against a blood lead level change of 1.0 μg/dL or more, a benchmark used by California for the blood lead level change that is associated with a child's loss of one IQ point. Because there is no safe level of lead exposure and because lead persists in the environment, resulting in reservoirs in soils and dusts, the EPA has an obligation to control emissions from this source category promptly and in a precautionary manner. The commenter stated that the EPA should consider requiring zero lead emissions. At a minimum, the EPA should set a standard that would ensure that the ambient air concentration for lead in the local community does not exceed the level of 0.02 μg/m^3 as a one-month average, in order to protect children. As this is the level the Children's Health Protection Advisory Committee had recommended for the lead NAAQS, the EPA must also set additional protections beyond this ambient air limit in order to provide an ''ample margin of safety.''

Response: In order to assess multipathway risks associated with emissions of lead, the EPA compared modeled rolling three month average lead concentrations estimated from emissions from the one source in this category to the NAAQS for lead. As

noted above, we believe that this is a reasonable approach given that the NAAQS is a health based standard set to protect the public health, including the health of sensitive sub-populations (such as children) with an adequate margin of safety. Moreover, the risk assessment supporting the NAAQS considered direct inhalation exposures and indirect air-related multi-pathway exposures from industrial sources like primary and secondary lead smelting operations. We conclude that the level of the NAAQS presents an acceptable level of risk from lead in ambient air. Moreover, we are promulgating emissions limits (for the furnace area and refining operation stacks) to reduce emissions and promulgating specific work practice standards to minimize fugitive emissions to ensure that emissions do not result in exceedances of the NAAQS. As part of our ''ample margin of safety'' analysis, we examined whether there were additional cost effective controls available to further reduce emissions and risks. As explained elsewhere in this notice and in other supporting documents available in the docket, we have not identified any additional cost effective controls to reduce emissions further and provide further risk reductions.

With respect to the California benchmark for protecting children, the EPA has a hierarchy of appropriate health benchmark values. In general, this hierarchy places greater weight on EPA derived health benchmarks than those from other agencies (*http://www.epa.gov/ttn/atw/nata1999/99pdfs/healtheffectsinfo.pdf*). For the reasons provided above, we believe that the lead NAAQS level establishes an appropriate benchmark for addressing the acceptable level of risk and we disagree with the commenter that we should instead use an ambient concentration of 0.02 $\mu g/m^3$ based on a one month average.[6]

Comment: With regard to the source category's emissions of two dozen other hazardous air pollutants, including cadmium and arsenic, one commenter stated that the EPA should determine that this health risk is also unacceptable. With thousands of people exposed to a lifetime risk of cancer above 1 in a million, and with at least 200 exposed to a lifetime risk of up to 30 in a million, the EPA must recognize that this risk is too high for this local community. The EPA should set a standard that would reduce cancer risks to an acceptable level and ensure an ample margin of safety from non-lead emissions.

Response: With respect to cancer risk, section 112 provides for EPA to follow the benzene decision framework for determining acceptability. Under that framework, cancer risk less than 100 in a million is generally considered acceptable, although this is not a bright line and EPA examines a variety of health factors to make its determination. Once we concluded that the risk from non-lead HAP was acceptable, we then considered whether there were additional cost-effective controls that would further reduce risk from the other HAP emitted in order to provide an ample margin of safety. Because the controls for other HAP were the same as the controls for lead, we determined (for the same reason we did for lead) that there were no additional cost effective controls and that the acceptable level of HAP emissions also provided an ample margin of safety.

Comment: One commenter stated that they oppose the use of the lead NAAQS assessment instead of a multi-pathway risk assessment because the lead NAAQS provides an inappropriate level of protection, *i.e.,* the lead NAAQS requires an adequate margin of safety while a residual risk standard requires an ample margin of safety. The commenter stated that a residual risk standard should provide a level of protection that is higher than the NAAQS. Moreover, the commenter noted that the NAAQS is set to protect sensitive populations while residual risk rules are set to protect the greatest number of individuals possible from unacceptable risk. The proposed rule based on the lead NAAQS will not provide as high a level of protection as required by CAA section 112(f)(2).

Response: We disagree with the commenter that the lead NAAQS assessment should not be considered as part of our residual risk analysis because it provides an inappropriate level of protection. The lead NAAQS is set at a level to protect public health, including the health of sensitive populations, most critical for lead, the health of children. That does not suggest that non-sensitive populations are not protected, but rather that the NAAQS is set at a level that will not only protect the general population but also those who are more sensitive to lead exposures. In the proposed rule, the level of the NAAQS, which protects public health with an adequate margin of safety, was used to determine whether or not there was unacceptable risk. Once we determined a level of emissions that results in risks being acceptable, under the two-step residual risk decision process, the EPA then considered whether there were additional controls that might further reduce risk to achieve an ample margin of safety considering cost and feasibility. We did not identify any additional cost-effective controls beyond those that would need to be implemented to ensure an acceptable level of risk. Thus, with regard to the two stack emissions points (the furnace area stack and the refinery stacks) for which we are requiring action to ensure an acceptable level of risk, and for fugitive dust emissions, for which we are specifying work practice standards, we have concluded that there are no additional cost-effective controls and that an ample margin of safety will be provided by the same controls that ensure an acceptable level of risk. Moreover, there are no additional cost effective controls to further reduce emissions from the main stack beyond those controls that are already applied. Therefore, an ample margin of safety will be provided by the current level of control for the main stack. A more detailed presentation of the economic analysis of additional controls for the refining, furnace area, and main stacks can be found in the technical support document, which is available in the docket.

Comment: One commenter stated that the EPA has not appropriately accounted for or prevented environmental risks from lead or non-lead emissions as required by section 112(f)(2)(A). According to the commenter, using the NAAQS to assess ecological risk is problematic and EPA's approach of assuming that ''when exposure levels are not anticipated to adversely affect human health, they also are not anticipated to adversely affect the environment,'' 76 FR at 9425, is illogical and unlawful. Further, based on the information the EPA has gathered about the local environment around the Doe Run facility, the EPA cannot assume that there would be no effects either to wildlife or to natural resources in the environment either from inhalation or air deposition of HAP emissions, exacerbated by persistence and bioaccumulation. As the EPA's own Scientific Advisory Board has stated: ''The assumption that ecological receptors will be protected if human health is protected is incorrect.'' SAB May 2010 at 48.

Response: The EPA is unaware of any data indicating a direct atmospheric impact of non-lead HAP emitted from this source category on receptors such as plants, birds, and wildlife. Given that there is no information supporting that

[6] This level is well below the background ambient lead levels measured in the area during the SIP process. See docket ID EPA–HQ–OAR–2006–0735–5204.

there is an effect, we find it appropriate to assume that exposure levels not expected to harm humans are also not expected to harm ecological receptors.

Although the ecological effects of lead are well documented, there was a lack of evidence at the time of the last lead NAAQS review linking various ecological effects to specific levels of lead in the air. It was determined that the evidence did not provide a sufficient basis for establishing a separate secondary standard, but that revising the secondary standard to be equal to the revised primary standard would provide substantial additional protection to ecological receptors from the effects of lead. Thus, we find it appropriate to consider the secondary lead NAAQS when evaluating the potential for adverse environmental effects.

Comment: One commenter generally stated that the EPA must not use the secondary NAAQS as a benchmark to determine whether there will be environmental effects and that the use of the lead NAAQS to evaluate ecologic risks is inappropriate. The commenter states that the EPA should recognize that the establishment of the Secondary lead NAAQS at the same level of the Primary Lead NAAQS was a risk management decision, rather than a decision quantitatively founded in risk assessment. The commenter cited that in establishing the lead NAAQS, the EPA introduced its approach by describing the ''substantial limitations in the evidence, especially the lack of evidence linking various effects to specific levels of ambient Pb'' (U.S. EPA, 2008. P. 67007), and ultimately concluded that the secondary lead NAAQS should be set equal to the primary lead NAAQS.

In contrast, in this proposed rule, the EPA concludes that ''ambient lead concentrations above the lead NAAQS indicates potential for adverse environmental effects'' (76 FR 9421).

Response: The secondary lead NAAQS was set to protect against adverse welfare effects (including adverse environmental effects) and has the same averaging time, form, and level as the primary standard. Thus, we find it appropriate to consider the secondary lead NAAQS when considering the potential for adverse environmental effects. The commenter is correct that we stated in the proposed rule that ''ambient lead concentrations above the lead NAAQS indicates potential for adverse environmental effects.'' This statement is entirely consistent with the idea that the secondary lead NAAQS was set at a level above which there may be adverse environmental effects but does not support a conclusion that there are adverse environmental effects below that level that must be addressed as part of this residual risk determination. As we have noted previously, there are not sufficient data supporting that a lower level is necessary to protect against an environmental risk.

Comment: One commenter stated that in evaluating potential multipathway risks from PB–HAP other than lead, the EPA used *de minimis* emission rates to screen for potentially significant multi-pathway impacts, but for lead, this method was abandoned. The commenter disagrees with this approach, stating, ''This comparison mirrors NAAQS source monitoring for attainment purposes in its use of the national ambient air lead level as the benchmark. As such, it is not a proper surrogate for ''facility-level *de minimis* emission rates'' used as the chronic reference benchmarks for CAA section 112 risk assessments.''

Response: The EPA disagrees that comparing modeled 3-month rolling average lead concentrations to the NAAQS for lead mirrors source monitoring for NAAQS attainment purposes and that this approach is not a proper surrogate for facility-level *de minimis* emission rates used as the chronic reference benchmarks for CAA section 112 risk assessments. In general, determining attainment for the lead NAAQS is based on aggregate ambient monitoring of all potential sources of lead in a given area. In contrast, the Primary Lead Smelting Risk Assessment and Preamble clearly state that 3-month rolling average lead concentrations are based on modeled lead concentrations from lead emissions from the one facility in the source category. 76 FR 9421. Thus, for example, while for NAAQS attainment purposes ambient lead concentrations resulting from lead haul roads outside the facility boundary would contribute to the overall 3-month rolling average ambient lead concentration measured at a nearby ambient lead monitor, for purposes of the risk assessment to support this rulemaking, these types of offsite emission sources were not included when modeling 3-month rolling lead concentrations (*i.e.,* only emission sources from within the facility boundary were used as inputs into the dispersion model to estimate resulting modeled 3-month average lead concentrations).

The NAAQS for lead was set to protect, with an adequate margin of safety, human health, including 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). In developing the NAAQS for lead, because of the multi-pathway, multi-media impacts of lead, the risk assessment supporting the NAAQS considered direct inhalation exposures and indirect air-related multi-pathway 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). The EPA believes that the lead NAAQS is a reasonable benchmark to evaluate the potential for multipathway health effects from lead.

Finally, as noted in the risk assessment document, there is no RfD or other comparable chronic health benchmark value for lead compounds. That is, in 1988, the 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.'' The EPA's IRIS assessment for Lead and compounds (inorganic) (CASRN 7439–92–1), *http://www.epa.gov/iris/subst/0277.htm.*

Comment: One commenter stated that the EPA must include a plain language statement of health risks and benefits of the proposed rule. As part of its rulemaking proposal, the EPA should include a plain statement of the health impacts and risks at issue. For example, the commenter stated that the MIR and chronic and risk numbers are not easily

understandable by the general public; the IQ point losses at stake or how it is setting a standard to address these are not discussed, and the types of cancer or the nature of the health disorders or other adverse effects that most of these types of HAP emissions present to the public are not discussed. The commenter stated that this type of ''[e]xpanded discussion is important to understanding the 'real-world' risk, including dealing with health disparities.'' SAB May 2010 at 50.

A full elaboration of the types of health impacts at issue here, ranging from significant IQ loss (due to lead emissions), to a high lifetime cancer risk (from non-lead emissions), for this particular community, is needed to inform the EPA's and the public's consideration of what level of risk is acceptable or unacceptable, and what standard is required to provide an ample margin of safety.

Response: The EPA strives to communicate its health and risk information to the public in a manner that is concise, informative, and readily understandable. In the risk assessment document, we discuss the various metrics used to characterize risk associated with the source category (*e.g.,* see section 2.3 of the risk assessment document for a discussion of the MIR). Moreover, while the commenter is correct that we do not discuss in detail the neurological effects associated with exposure to lead (*e.g.,* loss of IQ points in children), we do reference the final lead NAAQS decision, which does discuss in detail the health effects associated with lead exposure. With regard to how the proposed controls limit the health risks associated with lead exposure, we noted in the preamble of the proposed rule that the proposed controls would ensure that the facility's contribution to ambient concentrations of lead were at or below the NAAQS for lead and that this represents an acceptable level of risk since the lead NAAQS was set to protect public health, including the health of sensitive populations (*e.g.,* children), from the adverse health effects associated with lead exposure. Moreover, although the requirements that we are promulgating in today's action are somewhat different than the proposed requirements, we believe that the requirements that we are promulgating will also ensure that the facility's contribution to ambient concentrations of lead will not present an unacceptable level of risk. In addition, as discussed previously, we have not identified any additional cost-effective controls and we therefore conclude that the same level of controls to achieve acceptable risks will also provide an ample margin of safety.

With regard to discussing specific types of cancers potentially associated with exposure to a given HAP, we note that the cancer unit risk estimates used in the risk assessment are not associated with specific types of cancers, but rather with the risk of cancer in general. Moreover, since many of the cancer studies the unit risk estimates take into account are animal studies, there is appreciable uncertainty as to whether the same types of cancers would be seen in humans. Thus, we find it appropriate to express the results of our cancer assessment in terms of general cancer risk.

VI. Impacts of the Final Rule

The revisions to the Primary Lead Processing MACT standard will ensure that emissions from the one source in this source category do not present an unacceptable level of risk and will also provide an ample margin of safety. The estimated reductions include as much as 10 tons per year of lead from the furnace area and refining operations stacks. We also expect reductions will be achieved with the additional work practices, but we have not been able to quantify those reductions. These controls and work practices will also reduce emissions of other HAP emitted from the facility. The costs of these controls and work practices were not directly considered in the decision because these controls and practices are necessary to ensure that risks are acceptable. The EPA evaluated control practices and technology and associated costs in determining that the same requirements needed to achieve acceptable risks would also provide an ample margin of safety. In addition, we considered other available practices, processes and control technologies. For the same reason we concluded that no additional controls were necessary to provide an ample margin of safety, we concluded that there were no additional cost effective developments in practices, processes or control technologies for any sources other than the main stack.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review, and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a ''significant regulatory action.'' This action is a significant regulatory action because it raises novel legal and policy issues. Accordingly, the EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866 and Executive Order 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0414.

The information requirements are based on notification, recordkeeping, and reporting requirements in the NESHAP General Provisions (40 CFR part 63, subpart A), which are mandatory for all operators subject to national emission standards. These recordkeeping and reporting requirements are specifically authorized by section 114 of the CAA (42 U.S.C. 7414). All information submitted to the EPA pursuant to the recordkeeping and reporting requirements for which a claim of confidentiality is made is safeguarded according to agency policies set forth in 40 CFR part 2, subpart B.

This final rule includes new paperwork requirements for increased frequency for stack testing as described in 40 CFR 63.1546.

When a malfunction occurs, sources must report the event according to the applicable reporting requirements of 40 CFR part 63, subpart TTT. An affirmative defense to civil penalties for exceedances of emission limits that are caused by malfunctions is available to a source if it can demonstrate that certain criteria and requirements are satisfied. 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) and where the source took necessary actions to minimize emissions. In addition, the source must meet certain notification and reporting requirements. For example, the source must prepare a written root cause analysis and submit a written report to the Administrator documenting that it has met the conditions and requirements for assertion of the affirmative defense.

The EPA is adding affirmative defense to the estimate of burden in the ICR. To provide the public with an estimate of the relative magnitude of the burden

associated with an assertion of the affirmative defense position adopted by a source, the EPA has provided administrative adjustments to the ICR that show what the notification, recordkeeping, and reporting requirements associated with the assertion of the affirmative defense might entail. The EPA's estimate for the required notification, reports, and records, including the root cause analysis, totals $3,141, and is based on the time and effort required of a source to review relevant data, interview plant employees, and document the events surrounding a malfunction that has caused an exceedance of an emission limit. The estimate also includes time to produce and retain the record and reports for submission to the EPA. The EPA provides this illustrative estimate of this burden, because these costs are only incurred if there has been a violation, and a source chooses to take advantage of the affirmative defense.

Given the variety of circumstances under which malfunctions could occur, as well as differences among sources' operation and maintenance practices, we cannot reliably predict the severity and frequency of malfunction-related excess emissions events for a particular source. It is important to note that the EPA has no basis currently for estimating the number of malfunctions that would qualify for an affirmative defense. Current historical records would be an inappropriate basis, as source owners or operators previously operated their facilities in recognition that they were exempt from the requirement to comply with emissions standards during malfunctions. Of the number of excess emission events reported by source operators, only a small number would be expected to result from a malfunction (based on the definition above), and only a subset of excess emissions caused by malfunctions would result in the source choosing to assert the affirmative defense. Thus, we believe the number of instances in which source operators might be expected to avail themselves of the affirmative defense will be extremely small. For this reason, we estimate no more than 2 or 3 such occurrences for all sources subject to 40 CFR part 63, subpart TTT over the 3-year period covered by this ICR. We expect to gather information on such events in the future, and will revise this estimate as better information becomes available.

For the Primary Lead Processing MACT standard, the ICR document prepared by the EPA, which has been revised to include the amendments to the standards, has been assigned the EPA ICR number 1856.08. Burden changes associated with these amendments result from the reporting and recordkeeping requirements of the affirmative defense provisions added to the rule. The change in respondents' annual reporting and recordkeeping burden associated with these amendments for this collection (averaged over the first 3 years after the effective date of the standards) is estimated to be 30 labor hours at a cost of $3,141 per year for the affirmative defense reporting. There will be no capital costs associated with the information collection requirements of the final rule. There is no estimated change in annual burden to the Federal government for these amendments. 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. In addition, EPA is amending the table in 40 CFR part 9 of currently approved OMB control numbers for various regulations to list the regulatory citations for the information requirements contained in this final rule.

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 impact of these final rules on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's 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-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of these final rules on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final action will not impose any requirements on small entities. The costs associated with the new requirements in these final rules are not expected to present an undue burden to this industry as discussed above.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates 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 action imposes no enforceable duty on any State, local or tribal governments or the private sector. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA.

These rules are also not subject to the regulatory requirements that might significantly or uniquely affect small governments. They contain no requirements that apply to such governments or impose obligations upon them.

E. Executive Order 13132: Federalism

This action 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. These final rules primarily affect private industry, and do not impose significant economic costs on State or local governments. Thus, Executive Order 13132 does not apply to this action.

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

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). 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.

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

This action 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 promulgated 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 in Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not likely to have a significant adverse energy 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. Further, we have concluded that these final rules are not likely to have any adverse energy effects.

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 the EPA to use voluntary consensus standards (VCS) in its regulatory activities, unless to do so would be inconsistent with applicable law or otherwise impractical. VCS are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by VCS bodies. NTTAA directs the EPA to provide Congress, through OMB, explanations when the agency decides not to use available and applicable VCS.

This action does not involve technical standards. Therefore, the EPA did not consider the use of any VCS.

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.

The EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations, because it does not decrease the level of protection provided to human health or the environment, but in fact decreases emissions of lead. To examine the potential for any environmental justice issues that might be associated with this rule, 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 that is currently operating in this source category. Our analyses also show that, although there is potential for an adverse environmental and human health effects from emission of lead, it does not indicate any significant potential for disparate impacts to the specific demographic groups analyzed.

The 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.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801, *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that, before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to publication of the final rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). The final rules will be effective on November 15, 2011.

List of Subjects for 40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: November 4, 2011.

Lisa P. Jackson,

Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency amends title 40, chapter I, of the Code of Federal Regulations as follows:

PART 63—[AMENDED]

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

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

Subpart TTT—[Amended]

■ 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 adding a definition for ''Affirmative defense,'' ''Lead refiner,'' ''Lead remelter,'' ''Primary lead processor,'' and ''Secondary lead smelter;'' removing the definition of ''Primary lead smelter;'' and revising the definitions of ''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'' to read as follows:

§ 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 0.97 pounds per ton of lead metal produced from the aggregation of emissions discharged from air pollution control devices used to control emissions from the sources listed in paragraphs (a)(1) through (9) 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; and

(9) Sinter machine 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 1.2 tons per year from the aggregation of 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 (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 a 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 (9) and (b) 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) Each owner or operator of a primary lead processor must prepare, and at all times operate according to, a standard operating procedures manual that describes in detail the measures that will be put in place to control fugitive dust emissions from the sources listed in paragraphs (a)(1) through (a)(5) of this section that incorporates each of the specific work practices listed in paragraphs (a)(1) through (a)(5) of this section:

(1) *Plant roadways.* (i) Paved plant roadways must be cleaned using a wet sweeper unless the temperature falls below 39 degrees Fahrenheit or when the application of water results in the formation of ice. During periods when the temperature is below 39 degrees Fahrenheit, paved plant roadways must be cleaned using a high efficiency dry sweeper.

(ii) Continuously operate a sprinkler system to wet plant roadways to prevent fugitive dust entrainment. This sprinkler system must be operated except during periods when the temperature is less than 39 degrees Fahrenheit or when the application of water results in formation of ice.

(2) *Material storage and handling area(s).* (i) Chemically stabilize inactive concentrate storage piles a minimum of once every month to reduce particulate from wind born re-suspension.

(ii) Finished sinter must be sufficiently wetted to ensure fugitive dust emissions are minimized prior to loading to railcars.

(3) *Sinter machine area(s).* (i) Personnel doors must be kept closed during operations except when entering or exiting the furnace building by the aid of door weights or similar device for automatic closure.

(ii) Large equipment doors must remain closed except when entering or existing the building using an automatic closure system or equivalent lock-and-key method.

(iii) It may be necessary to open doors subject to the requirements in § 63.1544(a)(3)(i) and (ii) to prevent heat stress or exhaustion of workers inside the sinter plant building. Records of such periods must be included in the report required under § 63.1549(e)(8).

(4) *Furnace area(s).* (i) Personnel doors must be kept closed during operations except when entering or exiting the furnace building by the aid of door weights or similar device for automatic closure.

(ii) Large equipment doors must remain closed except when entering or existing the building using an automatic closure system or equivalent lock-and-key method.

(iii) It may be necessary to open doors subject to the requirements in § 63.1544(a)(4)(i) and (ii) to prevent heat stress or exhaustion of workers inside the blast furnace building. Records of such periods must be included in the report required under § 63.1549(e)(8).

(5) *Refining and casting area(s).* (i) Personnel doors must be kept closed during operations except when entering or exiting the furnace building by the aid of door weights or similar device for automatic closure.

(ii) Large equipment doors must remain closed except when entering or existing the building using an automatic closure system or equivalent lock-and-key method.

(iii) It may be necessary to open doors subject to the requirements in § 63.1544(a)(5)(i) and (ii) to prevent heat stress or exhaustion of workers inside the refining and casting building. Records of such periods must be included in the report required under § 63.1549(e)(8).

(b) Notwithstanding paragraph (c) of this section, the standard operating procedures manual shall be submitted to the Administrator or delegated authority for review and approval.

(c) Existing manuals that describe the measures in place to control fugitive dust sources required as part of a State implementation plan for lead shall satisfy the requirements of paragraph (a) of this section provided they include all the work practices as described in paragraphs (a)(1) through (5) of this section and provided they address all the sources listed in paragraphs (a)(1) through (5) of this section.

(d) 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 in § 16.1543(a) no later than January 17, 2012. Each owner or operator of an existing primary lead processor must achieve compliance with the requirements of § 63.1544 no later than February 13, 2012. Each owner or operator of an existing primary lead processor must achieve compliance with the requirements in § 63.1543(b) and (e) of this subpart no later than November 15, 2013.

(b) Each owner or operator of a new primary lead processor must achieve compliance with the requirements of this subpart no later than January 17, 2012 or startup, whichever is later.

(c) Prior to the dates specified in § 63.1545(a), each owner or operator of an existing primary lead processor must continue to comply with the requirements of §§ 63.1543 and 63.1544 as promulgated in the June 4, 1999 NESHAP for Primary Lead Smelting.

(d) Each owner or operator of an existing primary lead processor must comply with the requirements of §§ 63.1547(g)(1) and (2), 63.1551, and Table 1 of Subpart TTT of Part 63 on November 15, 2011.

■ 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 (9) and (b) must determine the lead compound emissions rate, in units of pounds of lead per hour according to the following test methods in appendix A of part 60 of this chapter:

(i) Method 1 must be used to select the sampling port location and the number of traverse points.

(ii) Method 2, 2F, 2G must be used to measure volumetric flow rate.

(iii) Method 3, 3A, 3B must be used for gas analysis.

(iv) Method 4 must be used to determine moisture content of the stack gas.

(v) Method 12 or Method 29 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 or Method 29, 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:

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

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 (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.

$$CE_{Pb} = \frac{E_{Pb}}{P_{Pb}} \qquad \text{(Eq. 2)}$$

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(b), as determined in accordance with paragraphs (a)(1) through (4) of this section.

(b) Owners 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 (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 (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 self-tensioning (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 (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(g). The percentage of time the alarm on the bag leak detection system sounds must be determined according to paragraphs (g)(1) through (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), (2), or (3) of this section.

(1) Owners and operators must check and record on a daily basis doorway in-draft 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 (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 re-establish 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 (9) and (b) 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 (7) of this section to determine compliance.

(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 (j)(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.

■ 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.

■ 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 (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 practices described in the standard operating procedures manual for baghouses required under § 63.1547(a).

(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)(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.

(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), 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 in-draft determination, 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), 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.

(8) Records of the occurrence and duration of each malfunction of operation (*i.e.,* process equipment) or the air pollution control equipment and monitoring equipment.

(9) Records of actions taken during periods of malfunction to minimize emissions in accordance with §§ 63.1543(i) and 63.1544(d), 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 (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 in-draft 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 shall contain a summary of the fugitive dust control measures performed during the required reporting period, including an explanation of any periods when the procedures outlined in the standard operating procedures manual required by § 63.1544(a) were not followed and the corrective actions taken. The reports shall not contain copies of the daily records required to demonstrate compliance with the requirements of the standard operating procedures manuals required under §§ 63.1544(a) and 63.1547(a).

(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(d), 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(l) 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 at 40 CFR 63.2. Appropriate penalties may be assessed, however, if you fail to meet your burden of proving all of the requirements in the affirmative defense. The affirmative defense shall not be available for claims for injunctive relief.

(a) *Affirmative defense.* 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, 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, 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, consistent with safety and good air pollution control practices; 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, the purpose of which is 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 45 days of the initial occurrence of the exceedance of the standards in this subpart to demonstrate, with all necessary supporting documentation, that it has met the requirements set forth in paragraph (a) of this section. The owner or operator may seek an extension of this deadline for up to 30 additional days by submitting a written request to the Administrator before the expiration of the 45 day period. Until a request for an extension has been approved by the Administrator, the owner or operator is subject to the requirement to submit such report within 45 days of the initial occurrence of the exceedance.

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

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

Reference	Applies to subpart TTT	Comment
* * *	*	* * *
63.6(a), (b), (c)	Yes.	
63.6(d)	No	Section reserved.
63.6(e)(1)(i)	No	See 63.1543(i) and 63.1544(d) for general duty requirement.
63.6(e)(1)(ii)	No.	
63.6(e)(1)(iii)	Yes.	
63.6(e)(2)	No	Section reserved.
63.6(e)(3)	No.	
63.6(f)(1)	No.	
63.6(g)	Yes.	
63.6(h)	No	No opacity limits in rule.
63.6(i)	Yes.	
63.6(j)	Yes.	
§ 63.7(a)–(d)	Yes.	
§ 63.7(e)(1)	No	See 63.1546(c).
§ 63.7(e)(2)–(e)(4)	Yes.	
63.7(f), (g), (h)	Yes.	
63.8(a)–(b)	Yes.	
63.8(c)(1)(i)	No.	
63.8(c)(1)(ii)	Yes.	
63.8(c)(1)(iii)	No.	
63.8(c)(2)–(d)(2)	Yes.	
63.8(d)(3)	Yes, except for last sentence.	
63.8(e)–(g)	Yes.	
63.9(a), (b), (c), (e), (g), (h)(1) through (3), (h)(5) and (6), (i) and (j).	Yes.	
63.9(f)	No.	
63.9(h)(4)	No	Reserved.
63.10(b)(2)(i)	No.	
63.10(b)(2)(ii)	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)	Yes.	
63.10(b)(2)(iv)–(b)(2)(v)	No.	
63.10(b)(2)(vi)–(b)(2)(xiv)	Yes.	
63.(10)(b)(3)	Yes.	
63.10(c)(1)–(9)	Yes.	
63.10(c)(10)–(11)	No	See 63.1549(b)(9) and (10) for recordkeeping of malfunctions.
63.10(c)(12)–(c)(14)	Yes.	
63.10(c)(15)	No.	
63.10(d)(1)–(4)	Yes.	
63.10(d)(5)	No	See 63.1549(e)(9) for reporting of malfunctions.
63.10(e)–(f)	Yes.	
* * *	*	* * *

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