

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2010-0600; FRL-9291-3]

RIN 2060-AO91

National Emission Standards for Hazardous Air Pollutant Emissions: Group I Polymers and Resins; Marine Tank Vessel Loading Operations; Pharmaceuticals Production; and the Printing and Publishing Industry

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action for four national emission standards for hazardous air pollutants (NESHAP) that regulate 12 industrial source categories evaluated in our risk and technology review. The four NESHAP include: National Emissions Standards for Group I Polymers and Resins (Butyl Rubber Production, Epichlorohydrin Elastomers Production, Ethylene Propylene Rubber Production, Hypalon™ Production, Neoprene Production, Nitrile Butadiene Rubber Production, Polybutadiene Rubber Production, Polysulfide Rubber Production, and Styrene Butadiene Rubber and Latex Production); Marine Tank Vessel Loading Operations; Pharmaceuticals Production; and The Printing and Publishing Industry.

For some source categories, EPA is finalizing our decisions concerning the residual risk and technology reviews.

For the Marine Tank Vessel Loading Operations NESHAP and the Group I Polymers and Resins NESHAP, EPA is finalizing emission standards to address certain emission sources not previously regulated under the NESHAP. EPA is also finalizing changes to the Pharmaceuticals Production NESHAP to correct an editorial error. For each of the four NESHAP, EPA is finalizing revisions to the regulatory provisions related to emissions during periods of startup, shutdown, and malfunction and promulgating provisions addressing electronic submission of emission test results.

DATES: This final action is effective on April 21, 2011.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2010-0600. 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 Ms. Mary Tom Kissell, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Refining and Chemicals Group (E143-01), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541-4516; fax number: (919) 685-3219; and e-mail address: kissell.mary@epa.gov. For additional contact information, see the following **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION: For specific information regarding the modeling methodology, contact Ms. Elaine Manning, Office of Air Quality Planning and Standards, Health and Environmental Impacts Division, Air Toxics Assessment Group (C539-02), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541-5499; fax number: (919) 541-0840; and e-mail address: manning.elaine@epa.gov. For information about the applicability of these four 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
Group I Polymers and Resins	Marcia Mia (202) 564-7042, mia.marcia@epa.gov .	Nick Parsons, (919) 541-5372, parsons.nick@epa.gov .
Marine Tank Vessel Loading Operations	Maria Malave, (202) 564-7027, malave.maria@epa.gov .	Steve Shedd, (919) 541-5397, shedd.steve@epa.gov .
Pharmaceuticals Production	Marcia Mia, (202) 564-7042, mia.marcia@epa.gov .	Nick Parsons, (919) 541-5372, parsons.nick@epa.gov .
The Printing and Publishing Industry	Rafael Sanchez, (202) 564-7028, sanchez.rafael@epa.gov .	David Salman, (919) 541-5402, salman.dave@epa.gov .

¹ OECA stands for EPA's Office of Enforcement and Compliance Assurance.
² OAQPS stands for EPA's Office of Air Quality Planning and Standards.

Background Information Document. On October 21, 2010 (75 FR 65068), EPA proposed revisions to six NESHAP that regulate 16 industrial source categories evaluated in our risk and technology review. The six NESHAP and industrial source categories are: National Emissions Standards for Hazardous Air Pollutant Emissions: Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks; Group I Polymers and Resins; Marine Tank Vessel Loading Operations;

Pharmaceuticals Production; The Printing and Publishing Industry; and Steel Pickling—HCl Process Facilities and Hydrochloric Acid Regeneration. In this action, we are finalizing decisions for four of these NESHAP—Group I Polymers and Resins; Marine Tank Vessel Loading Operations; Pharmaceuticals Production; and The Printing and Publishing Industry. We will finalize our decisions for the Hard and Decorative Chromium Electroplating and Chromium

Anodizing Tanks NESHAP and the Steel Pickling—HCl Process Facilities and Hydrochloric Acid Regeneration in a future rulemaking.¹ A summary of the public comments on the proposal, and EPA's responses to the comments, is

¹ We addressed two additional source categories as part of this proposed rule, Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks and Steel Pickling—HCl Process Facilities and Hydrochloric Acid Regeneration, and we plan to take final action on those two source categories in June 2011.

available in Docket ID No. EPA-HQ-OAR-2010-0600.

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

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- I. National Technology Transfer and Advancement Act
- J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
- K. Congressional Review Act

A red-line version of the regulatory language that incorporates the changes in this action is available in the docket.

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
Group I Polymers and Resins:		
Butyl Rubber Production	325212	1307
Epichlorohydrin Elastomers Production	325212	1311
Ethylene Propylene Rubber Production	325212	1313
Hypalon™ Production	325212	1315
Neoprene Production	325212	1320
Nitrile Butadiene Rubber Production	325212	1321
Polybutadiene Rubber Production	325212	1325
Polysulfide Rubber Production	325212	1332
Styrene Butadiene Rubber and Latex Production	325212	1339
Marine Tank Vessel Loading Operations	4883	0603
Pharmaceuticals Production	3254	1201
The Printing and Publishing Industry	32311	0714

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 categories listed. To determine whether your facility would be affected, you should examine the applicability criteria in the appropriate NESHAP. If you have any questions regarding the applicability of any of these 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/atw/risk/rtrpg.html>. The TTN provides information and technology exchange in various areas of air pollution control.

Additional information is available on the residual risk and technology review (RTR) Web page at <http://www.epa.gov/ttn/atw/risk/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 Clean Air Act (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 June 20, 2011. Under section 307(b)(2) of the CAA, the requirements established by these final rules may not be challenged separately in any civil or criminal proceedings brought by 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 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 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 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, EPA may adopt standards equal to existing MACT standards if EPA determines that the existing standards are sufficiently protective. *NRDC v. EPA*, 529 F.3d 1077, 1083 (D.C. Cir. 2008).

On October 21, 2010, EPA published a proposed rule and supplemental notice of proposed rulemaking in the **Federal Register** for these four NESHAP that took into consideration the RTR analyses. For these NESHAP—Group I Polymers and Resins, Marine Tank Vessel Loading Operations, Pharmaceuticals Production, and The Printing and Publishing Industry—this action provides EPA’s final determinations pursuant to the RTR provisions of CAA section 112. In addition, we are promulgating amendments as follows:

- For the Marine Tank Vessel Loading Operations NESHAP and Group I Polymers and Resins NESHAP, pursuant

to CAA section 112(d)(2) and (3), EPA is finalizing revisions to address certain emission sources not currently regulated under the standards.

- For the Pharmaceuticals Production NESHAP, EPA is finalizing changes to correct an editorial error.

- For each of the four NESHAP, EPA is finalizing revisions to requirements in each NESHAP related to emissions during periods of startup, shutdown, and malfunction (SSM).

- For each of the four NESHAP, EPA is finalizing revisions to requirements in each NESHAP related to electronic reporting.

III. Summary of the Final Rules

A. What are the final rule amendments for the Group I Polymers and Resins source categories?

The National Emission Standards for Hazardous Air Pollutant Emissions: Group I Polymers and Resins were promulgated on September 5, 1996 (62 FR 46925), and codified at 40 CFR part 63, subpart U. The Group I Polymers and Resins MACT standards apply to major sources and regulate HAP emissions from nine source categories: Butyl Rubber Production, Epichlorohydrin Elastomers Production, Ethylene Propylene Rubber Production, Hypalon™ Production, Neoprene Production, Nitrile Butadiene Rubber (NBR) Production, Polybutadiene Rubber Production, Polysulfide Rubber Production, and Styrene Butadiene Rubber and Latex Production.

The Group I Polymers and Resins MACT standards regulate HAP emissions resulting from the production of elastomers (*i.e.*, synthetic rubber). An elastomer is a synthetic polymeric material that can stretch to at least twice its original length and then return rapidly to approximately its original length when released. Elastomers are produced via a polymerization/copolymerization process, in which monomers undergo intermolecular chemical bond formation to form a very large polymer molecule. Generally, the production of elastomers entails four processes: (1) Raw material (*i.e.*, solvent) storage and refining; (2) polymer formation in a reactor (either via the solution process, where monomers are dissolved in an organic solvent, or the emulsion process, where monomers are dispersed in water using a soap solution); (3) stripping and material recovery; and (4) finishing (*i.e.*, blending, aging, coagulation, washing, and drying).

Sources of HAP emissions from elastomers production include raw material storage vessels, front-end

process vents, back-end process operations, wastewater operations, and equipment leaks. The “front-end” processes include pre-polymerization, reaction, stripping, and material recovery operations; and the “back-end” process includes all operations after stripping (predominantly drying and finishing). Typical control devices used to reduce organic HAP emissions from front-end process vents include flares, incinerators, absorbers, carbon adsorbers, and condensers. Emissions from storage vessels are controlled by floating roofs or by routing them to a control device.

While emissions from back-end process operations can be controlled with control devices such as incinerators, the most common method of reducing these emissions is the pollution prevention method of reducing the amount of residual HAP that is contained in the raw product going to the back-end operations. Emissions from wastewater are controlled by a variety of methods, including equipment modifications (e.g., fixed roofs on storage vessels and oil water separators; covers on surface impoundments, containers, and drain systems), treatment to remove the HAP (steam stripping, biological treatment), control devices, and work practices.

Emissions from equipment leaks are typically reduced by leak detection and repair work practice programs, and in some cases, by equipment modifications.

For these five Group I Polymers and Resins² source categories—Epichlorohydrin Elastomers Production; Hypalon™ Production; Polybutadiene Rubber Production; Styrene Butadiene Rubber and Latex Production; and NBR Production—we have determined that the current MACT standards reduce risk to an acceptable level, provide an ample margin of safety to protect public health, and prevent adverse environmental effects. We are, therefore, re-adopting the existing MACT standards to satisfy section 112(f) of the CAA. We have also determined that there have been no significant developments in practices, processes, or control technologies since promulgation of the MACT standards, and that, therefore, it is not necessary to revise the MACT standard pursuant to CAA section 112(d)(6).³

² We previously re-adopted the existing MACT standards to satisfy section 112(f) of the CAA for four Group I Polymers and Resins source categories—Neoprene Rubber Production; Ethylene Propylene Rubber Production; Butyl Rubber Production; and Polysulfide Rubber Production. See 73 FR 76220, published December 16, 2008.

³ We note there are no longer any operating facilities in the United States that produce Hypalon™, and we do not anticipate that any will begin operation in the future.

We are eliminating the subcategories in the Butyl Rubber source category (Butyl Rubber and Halobutyl Rubber) because the technical differences that distinguished the subcategories when the original rule was developed no longer exist. The existing requirements for facilities producing either butyl rubber or halobutyl rubber as the primary product are identical, and, therefore, the removal of the subcategory distinction does not affect these requirements. The source category remains named Butyl Rubber Production. We are establishing standards at the MACT floor level of control for previously unregulated hydrochloric acid (HCl) emissions from front-end process vents in the Butyl Rubber and Ethylene Propylene Rubber source categories. We are also establishing standards at the MACT floor level of control for previously unregulated back-end process operations in the Epichlorohydrin Elastomers, NBR, Neoprene, and Butyl Rubber source categories.

The numerical emission standards that are being finalized in this action for new and existing major source facilities in the Group 1 Polymers and Resins source categories are shown in Table 3 of this preamble.

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Table 3 - Numerical Emission Standards for Existing and New Major Source of HAP in Group 1
Polymers and Resins Source Categories

Process Type	P&R I Source Category	Emissions Standard
Front-end process vents		Limit of Mg HCl per Mg elastomer produced
	Butyl Rubber Production	$\frac{(HCl \text{ emissions in } 2010 \frac{Mg}{yr}) * 1.74}{\text{butyl rubber produced in } 2010 \frac{Mg}{yr}}$
	Ethylene Propylene Rubber Production	$\frac{27 \frac{Mg}{yr}}{\text{ethylene propylene rubber produced in } 2010 \frac{Mg}{yr}}$
Back-end process operations		Limit of Mg organic HAP per Mg elastomer produced
	Butyl Rubber Production	$= \frac{(\text{controlled} + \text{bypassed} + \text{uncontrolled organic HAP emissions in } 2009 \frac{Mg}{yr}) * 1.35}{\text{butyl rubber produced in } 2009 \frac{Mg}{yr}}$
	Epichlorohydrin Elastomers Production	$= \frac{51 \frac{Mg}{yr}}{\text{epichlorohydrin elastomer produced in } 2009 \frac{Mg}{yr}}$
	Neoprene Rubber Production	$\frac{30 \frac{Mg}{yr}}{\text{neoprene rubber produced in } 2007 \frac{Mg}{yr}}$
	NBR Production	$\frac{2.4 \frac{Mg}{yr}}{\text{NBR produced in } 2000 \frac{Mg}{yr}}$

We are finalizing changes to the Group I Polymers and Resins MACT standards to eliminate the SSM exemption. These changes revise Table 1 in 40 CFR part 63, subpart U 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 Group I Polymers and Resins MACT standards to operate in a manner that minimizes emissions, removing the SSM plan requirement, removing the explanation of applicability of emissions standards during periods of SSM, revising the definition of initial start-up to remove references to malfunctions, clarifying the required conditions for performance tests, and revising the SSM-associated monitoring, 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.

We are also requiring the electronic submittal of performance test data to increase the ease and efficiency of data submittal and to improve data accessibility. Specifically, owners and operators of Group I Polymers and Resins facilities are required to submit electronic copies of applicable reports of performance tests to EPA's WebFIRE database through an electronic emissions test report structure called the Electronic Reporting Tool (ERT). This requirement to submit performance test data electronically to EPA does not require any additional performance testing, and applies only to those performance tests conducted using test methods that are supported by the ERT.

We anticipate that the front-end process vent limits will not require additional control to meet the floor-level standards for HCl emissions from front-end process operations at the facilities in the Butyl Rubber and Ethylene Propylene Rubber source categories. We anticipate that facilities in the Butyl Rubber, Epichlorohydrin Elastomers, Neoprene Rubber, and NBR source categories will not require additional control to meet the floor-level standards for the back-end process operations.

To demonstrate compliance with the front-end process vent HCl emissions provisions of the final rule, the facility owner or operator will be required to submit an initial notification of the calculated front-end HCl limit for the facility and to perform and record monthly calculations of the mass of HCl emissions and the mass of elastomer

product produced. These recorded monthly calculations are required to be submitted in the semi-annual compliance reports already required by existing provisions of the rule.

To demonstrate compliance with the back-end process operation provisions of the final rule, the facility owner or operator will be required to submit an initial notification of the calculated back-end limit for the facility, and to perform and record monthly calculations of the mass of HAP emissions and the mass of elastomer product produced. These recorded monthly calculations are required to be submitted in the semi-annual compliance reports already required by existing provisions of the rule.

The final changes to the Group I Polymers and Resins MACT standards are not expected to result in substantial emissions reduction or economic impacts. We have determined that facilities in the Group 1 Polymers and Resins categories can meet the applicable emissions limits at all times, including periods of startup and shutdown, with the exception of the organic HAP emissions limits applicable to front-end process vents at facilities in the Butyl Rubber and Ethylene Propylene Rubber source categories. We have determined that facilities in the Butyl Rubber and Ethylene Propylene Rubber source categories cannot meet the applicable organic HAP emission limits applicable to continuous front-end process vents during periods of shutdown. Therefore, we are establishing alternative emissions limits during these periods. No substantial changes in costs to industry are predicted.

B. What are the final rule amendments for the Marine Tank Vessel Loading Operations (MTVLO) source category?

MTVLO are loading operations conducted at marine terminals in which liquid commodities, such as crude oil, gasoline, and other fuels or chemicals, are pumped from the terminal's large, above-ground storage tanks through a network of pipes into a storage compartment (tank) on the vessel. Emissions occur as vapors are displaced from the tank as it is being filled. Most MTVLO facilities are either independent terminals or are associated with synthetic organic chemical manufacturers or with petroleum refineries (although MTVLO at petroleum refineries are part of the Petroleum Refinery source category).

For these MTVLO facilities, we have determined that the current MACT standards reduce risk to an acceptable level, provide an ample margin of safety

to protect public health, and prevent adverse environmental effects. We are, therefore, re-adopting the existing MACT standards to satisfy section 112(f) of the CAA. We have also determined that the costs of the only significant development in practices, processes, or control technologies since promulgation of the MACT standards is disproportionate to the emission reduction that would be achieved, and we are not adopting additional technology standards pursuant to CAA section 112(d)(6).

We are finalizing changes to the MTVLO MACT standards to require standards for two subcategories of MTVLO facilities for which the current MTVLO MACT standards do not include emission standards. These subcategories are facilities with MTVLO that emit less than 10/25 TPY of HAP that are located at a major source of HAP emissions and facilities located more than 0.5 miles from shore. For these source categories, we are adding a requirement for the facilities to perform submerged fill. This requirement is the MACT floor level of control.

We are finalizing changes to the MTVLO MACT standards to eliminate the SSM exemption. These changes revise Table 1 in 40 CFR part 63, subpart Y 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 MTVLO MACT standards to operate in a manner that minimizes emissions, clarifying the required conditions for performance tests, and revising the SSM-associated monitoring, 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.

Additionally, we are requiring the electronic submittal of performance test data to increase the ease and efficiency of data submittal and to improve data accessibility. Specifically, owners and operators of MTVLO are required to submit electronic copies of applicable reports of performance tests to EPA's WebFIRE database through an electronic emissions test report structure called the ERT. This requirement to submit performance test data electronically to EPA does not require any additional performance testing, and applies only to those performance tests conducted using test methods that are supported by the ERT. The final changes to the

MTVLO MACT standards will have little or no impact on HAP emissions or costs because facilities currently use submerged fill, as required by Coast Guard regulations.⁴

C. What are the final rule amendments for the Pharmaceuticals Production source category?

The pharmaceutical manufacturing process consists of chemical production operations that produce drugs and medications. These operations include chemical synthesis (deriving a drug's active ingredient) and chemical formulation (producing a drug in its final form). Emissions occur from breathing and withdrawal losses from chemical storage tanks, venting of process vessels, leaks from piping and equipment used to transfer HAP compounds (equipment leaks), and volatilization of HAP from wastewater streams.

For the reasons provided in the proposed rule and in the support documents in the docket, we have determined that the current MACT standards for Pharmaceutical Production facilities reduce risk to an acceptable level, provide an ample margin of safety to protect public health, and prevent adverse environmental effects. We are, therefore, re-adopting the existing MACT standards to satisfy section 112(f) of the CAA. We have also determined that there have been no significant developments in practices, processes, or control technologies since promulgation of the MACT standards, and that, therefore, it is not necessary to revise the MACT standards pursuant to CAA section 112(d)(6).

We are finalizing changes to the Pharmaceutical Production MACT standards to eliminate the SSM exemption. These changes revise Table 1 in 40 CFR part 63, subpart GGG to indicate that several requirements of the 40 CFR General Provisions related to periods of SSM do not apply. We are adding provisions to the Pharmaceuticals Production MACT standards to operate in a manner that minimizes emissions, removing the SSM plan requirement, removing the exemption provisions for periods of SSM in 40 CFR 63.1250(g), requiring that delay of equipment leak repair plans be contained in a separate document, clarifying the required conditions for performance tests, and revising the SSM-associated monitoring, 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.

We are also requiring the electronic submittal of performance test data to increase the ease and efficiency of data submittal and to improve data accessibility. Specifically, owners and operators of Pharmaceuticals Production facilities are required to submit electronic copies of applicable reports of performance tests to EPA's WebFIRE database through an electronic emissions test report structure called the ERT. This requirement to submit performance test data electronically to EPA does not require any additional performance testing, and applies only to those performance tests conducted using test methods that are supported by the ERT.

We are also finalizing a correction to an editorial error in 40 CFR 63.1257(e)(2)(iii)(A)(6)(ii). This section incorrectly provides that only one of the three listed criteria must be met for the inlet to the equalization tank to be considered the inlet to the biological treatment process. The final correction specifies that all of the criteria must be met.

These revisions to the Pharmaceutical Production MACT standards are not expected to result in substantial emissions reduction or economic impacts. We have determined that facilities in this source category can meet the applicable emissions standards at all times, including periods of startup and shutdown, are in compliance with the current MACT standard. No substantial changes in costs to industry are predicted. The correction to the editorial error may result in minimal costs to add or move equipment and may also result in some small amount of emission reductions for any facility that was meeting only one or two of the three listed criteria. However, as the intent of the current MACT standards at the time they were promulgated was to require facilities to meet all three criteria, the costs and emission reductions associated with this requirement were factored into the impacts of the MACT standards at the time the standards were promulgated in 1998. See 63 FR 50287.

D. What are the final rule amendments for the Printing and Publishing Industry source category?

Printing and publishing facilities are those facilities that use rotogravure, flexography, and other methods, such as lithography, letterpress, and screen

printing, to print on a variety of substrates, including paper, plastic film, metal foil, and vinyl. The Printing and Publishing Industry MACT standards include two subcategories: (1) Publication rotogravure printing and (2) product and packaging rotogravure and wide-web flexographic printing. Emissions occur from the evaporation of solvents in the inks and from cleaning solvents. The emission points include printing presses and associated dryers and ink and solvent storage.

For the reasons provided in the proposed rule and in the support documents in the docket, we have determined that the current MACT standards for Printing and Publishing facilities reduce risk to an acceptable level, provide an ample margin of safety to protect public health, and prevent adverse environmental effects. We are, therefore, re-adopting the existing MACT standards to satisfy section 112(f) of the CAA. We have also determined that the costs of the only significant development in practices, processes, or control technologies since promulgation of the MACT standards is disproportionate to the emission reduction that would be achieved, and, therefore, we are not adopting additional technology standards pursuant to CAA section 112(d)(6).

We are finalizing changes to the Printing and Publishing Industry MACT standards to eliminate the SSM exemption. These changes revise Table 1 in 40 CFR part 63, subpart KK 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 Printing and Publishing Industry 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 monitoring, 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.

We are also requiring the electronic submittal of performance test data to increase the ease and efficiency of data submittal and to improve data accessibility. Specifically, owners and operators of printing and publishing facilities are required to submit electronic copies of applicable reports of performance tests to EPA's WebFIRE

⁴ 46 CFR 153.282.

database through an electronic emissions test report structure called the Electronic ERT. This requirement to submit performance test data electronically to EPA does not require any additional performance testing, and applies only to those performance tests conducted using test methods that are supported by the ERT.

These revisions to the Printing and Publishing Industry MACT standards are not expected to result in substantial emissions reduction or economic impacts. We have determined that facilities in this source category can meet the applicable emissions standards at all times, including periods of startup and shutdown, are in compliance with the current MACT standards. No substantial changes in costs to industry are predicted.

E. 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 EPA's CAA section 112 regulations governing the emissions of HAP during periods of 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 is part of a regulation, commonly referred to as the "General Provisions Rule," that 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 emission standards during periods of SSM.

While the Court's ruling in *Sierra Club v. EPA*, 551 F.3d 1019 (DC Cir. 2008), did not directly affect all the NESHAP rules being addressed, the legality of source category-specific SSM provisions, such as those in all four NESHAP rules, are called into question based on the reasoning in that decision.

We have eliminated the SSM exemptions in these four NESHAP. Consistent with *Sierra Club v. EPA*, EPA's standards in these rules will apply at all times. We have eliminated or revised certain recordkeeping and reporting requirements that were related to the SSM exemption that no longer applies. EPA has attempted to ensure that we have not included in the regulatory language any provisions that are inappropriate, unnecessary, or redundant in light of the removal of the SSM exemption.

EPA has not established different standards for periods of startup and shutdown for three of the four NESHAP addressed in this rule because we believe compliance with the standards is achievable during these periods. In the case of MTVLO, loading of marine tank vessels occurs in "batches," and general practice is for the loading operators to test out the vapor control system before it is attached to the tank vessel. In the case of the Pharmaceuticals Production MACT standards, we expect the difference in emission levels during periods of startup and shutdown are insignificant and that facilities in this source category should be able to comply with the standards during these times. In the case of the Printing and Publishing MACT standards, we believe there are sufficiently long averaging times incorporated into the emissions limits that facilities should be able to comply during periods of startup and shutdown. In the case of Group I Polymers and Resins, one commenter stated that organic HAP emissions that are required to be sent to emissions control equipment (*i.e.*, flares) may not be able to comply with the MACT standards during periods of shutdown. The commenter stated that they may not always be able to route some of their process vents to a flare during periods of shutdown due to the low pressure or low heating value in the process vent. EPA agrees with the commenter that it is not possible to comply with the applicable standard during periods of shutdown, and has provided an alternative standard applicable during these times.

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 equipment, process equipment, or a process to operate in a normal or usual manner * * *" (40 CFR 60.2). 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 CAA section 112, emissions 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 CAA 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 EPA accounts for variability in setting emissions standards consistent with the CAA section 112 case law, nothing in that case law requires the Agency to consider malfunctions as part of that analysis. CAA Section 112 uses the concept of "best controlled" and "best performing" unit in defining the level of stringency that CAA 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. EPA's approach to malfunctions is consistent with CAA 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 standards as a result of a

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

Finally, EPA recognizes that even equipment that is properly designed and maintained can sometimes fail, and that such failure can sometimes cause an exceedance of the relevant emission standard. (See, e.g., *State Implementation Plans: Policy Regarding Excessive Emissions During Malfunctions, Startup, and Shutdown* (Sept. 20, 1999); *Policy on Excess Emissions During Startup, Shutdown, Maintenance, and Malfunctions* (Feb. 15, 1983)). EPA is, therefore, adding to the final rules an affirmative defense to civil penalties for exceedances of emission limits that are caused by malfunctions. See 40 CFR 63.482 (Group I Polymers and Resins), 63.561 (MTVLO), 63.822 (The Printing and Publishing Industry), 63.1251 (Pharmaceuticals Production). The regulations define "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. See 40 CFR 63.480 (Group I Polymers and Resins), 40 CFR 63.560 (MTVLO), 40 CFR 63.820 (The Printing and Publishing Industry), 40 CFR 63.1250 (Pharmaceuticals Production). The source must prove by a preponderance of evidence that it has met all of the elements set forth in affirmative defense. 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 40 CFR 63.6(e)(1)(i), 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 CAA (see also 40 CFR part 22.77).

F. What are the requirements for submission of emissions test results to EPA?

EPA must have performance test data to conduct effective reviews of CAA sections 112 and 129 standards, as well as for many other purposes, including compliance determinations, emission factor development, and annual emission rate determinations. In conducting these required reviews, EPA has found it ineffective and time consuming, not only for us, but also for regulatory agencies, and source owners and operators, to locate, collect, and submit performance test data because of varied locations for data storage and varied data storage methods. In recent years, though, performance test data in electronic format have become readily available, making it possible to move to an electronic data submittal system that would increase the ease and efficiency of data submittal and improve data accessibility.

In this action, as a step to increase the ease and efficiency of data submittal and improve data accessibility, EPA is requiring the electronic submittal of select performance test data. Specifically, EPA is requiring owners and operators of sources subject to these MACT standards to submit electronic copies of applicable reports of performance tests to EPA's WebFIRE database. The WebFIRE database was constructed to store performance test data for use in developing emission factors. A description of the WebFIRE

database is available at <http://cfpub.epa.gov/oarweb/index.cfm?action=fire.main>. Data entry will be through an electronic emissions test report structure called the ERT.

The ERT will be able to transmit the electronic report through EPA's Central Data Exchange (CDX) network for storage in the WebFIRE database. Although ERT is not the only electronic interface that can be used to submit performance test data to the CDX for entry into WebFIRE, it makes submittal of data very straightforward and easy. A description of the ERT can be found at http://www.epa.gov/ttn/chief/ert/ert_tool.html.

The requirement to submit performance test data electronically to EPA would not require any additional performance testing, and would apply to those performance tests conducted using test methods that are supported by the ERT. The ERT contains a specific electronic data entry form for most of the commonly used EPA reference methods. A listing of the pollutants and test methods supported by the ERT is available at http://www.epa.gov/ttn/chief/ert/ert_tool.html. When a facility submits performance test data to CDX, there will be no additional requirements for performance test data compilation. Moreover, we believe that industry will benefit from this new electronic data submittal requirement. Having these data, EPA will be able to develop improved emission factors, make fewer information requests, and promulgate better regulations. The information to be reported is already required for the existing test methods, and is necessary to evaluate the conformance to the test method.

One major advantage of submitting performance test data through the ERT is a standardized method to compile and store much of the documentation required to be reported by this rule that also clearly states what testing information would be required. Another important benefit of submitting these data to EPA at the time the source test is conducted is that it should substantially reduce the effort involved in data collection activities in the future. When EPA has performance test data in hand, there will likely be fewer or less substantial data collection requests in conjunction with prospective required residual risk assessments or technology reviews. This results in a reduced burden on both affected facilities (in terms of reduced manpower to respond to data collection requests) and EPA (in terms of preparing and distributing data collection requests and assessing the results).

State, local, and tribal agencies will benefit from electronic data submission as their review of the data will be more streamlined and accurate, because they would not have to re-enter the data to assess the calculations and verify the data entry. Finally, another benefit of submitting data to WebFIRE electronically is that these data will greatly improve the overall quality of the existing and new emission factors by supplementing the pool of emissions test data upon which the emission factor is based, and by ensuring that data are more representative of current industry operational procedures. A common complaint heard from industry and regulators is that emission factors are outdated or not representative of a particular source category. By receiving and incorporating data for most performance tests, EPA will be able to ensure that emission factors, when updated, represent the most current range of operational practices. In summary, in addition to supporting regulation development, control strategy development, and other air pollution control activities, having an electronic database populated with performance test data will save industry, State, local, and tribal agencies, and EPA significant time, money, and effort while improving the quality of emission inventories, and, as a result, air quality regulations.

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

The revisions to the MACT standards being promulgated in this action are effective on April 21, 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, April 21, 2011. The electronic reporting requirements for the four MACT standards being addressed in this action are effective on January 1, 2012. For the Group 1 Polymers and Resins MACT standards, the compliance date for existing sources for the new MACT standards applicable to front-end and back-end process operations is 1 year from the effective date of the standards, April 23, 2012. For the Marine Tank Vessel Loading Operations MACT standards, the compliance date for the new requirements for submerged fill is 1 year from the effective date of the standards, April 23, 2012. The compliance date for the corrected provision in the Pharmaceuticals Production MACT standards is the effective date of the standards, April 21, 2011. Beyond the revised SSM and electronic reporting requirements, there are no changes to The Printing and Publishing Industry MACT standards.

IV. Summary of Significant Changes Since Proposal

A. What changes did we make to the risk assessments for these source categories since proposal?

CAA section 112(f)(2) requires us to determine whether certain emissions standards reduce risk to an acceptable level, and once we have ensured that the risk is acceptable, whether the standards provide an ample margin of safety to protect public health and prevent an adverse environmental effect. First we determine whether there is an acceptable risk. EPA generally presumes that, if the maximum individual risk (MIR) is no higher than 100-in-1 million, that risk is acceptable. In addition to MIR, EPA also considers a series of other health measures and factors to complete an overall judgment on acceptability. In some cases, these health measures and factors taken together may provide a more realistic description of the magnitude of risk in the exposed population than MIR alone. If the risk is unacceptable, EPA must require additional controls, without consideration of cost, to ensure an acceptable level of risk. After determining that the level of risk is acceptable, EPA evaluates whether the standards provide an ample margin of safety by considering costs and economic impacts of controls, technological feasibility, and other relevant factors, in addition to those health measures and factors considered to determined acceptability. Considering all of these factors, EPA ensures that the standard is set at a level that provides an ample margin of safety to protect public health, as required by CAA section 112(f).

At proposal, we conducted risk assessments that provided estimates of the MIR posed by the allowable and actual HAP emissions from each source in a category, the distribution of cancer risks within the exposed populations, cancer incidence, hazard index (HI) for chronic exposures to HAP with non-cancer health effects, and hazard quotient (HQ) for acute exposures to HAP with non-cancer health effects. We found that the residual risks to public health from all source categories subject to these four MACT standards are acceptable, and, further, that the existing standards provide an ample margin of safety to protect public health and pose no adverse environmental effects. Thus, we proposed that no additional controls would be required to address such risks. Specifically, we found that the lifetime cancer risk to the individual most exposed to emissions from each of these seven source

categories⁵ was less than 100-in-1 million for both the actual emissions and the emissions that would occur if emissions from the source categories were at the maximum levels allowed by the standards. Additional analyses showed that the cancer incidence and number of people with cancer risk over 1-in-1 million were low. In addition, a review of the acute non-cancer exposures showed that none of these seven source categories posed an appreciable risk of acute non-cancer health effects. We also determined that HAP emissions from these source categories were not expected to result in adverse environmental effects.

To support our decisions regarding acceptability and ample margin of safety in the proposal, we also conducted risk assessments that accounted for HAP emissions from entire facilities at which a source covered by one of the standards under review was located. With the exception of two facilities with MTVLO on-site that had facility-wide risks greater than 100-in-1 million, based on the data we had at that time, we concluded, for purposes of the proposal, that the facility-wide risk for sources in the four source categories was also relatively low. As a result of data and information received from commenters on the proposal, we now project the highest facility-wide risk with MTVLO on-site is approximately 90-in-1 million.

Uncertainty and the potential for bias are inherent in all risk assessments, including those performed for the source categories addressed in these final rules. Although uncertainty exists, we believe that our approach, which used conservative tools and assumptions, ensures that our decisions are health-protective. A discussion of the uncertainties in the emissions datasets, dispersion modeling, inhalation exposure estimates, and dose-response relationships is provided in the preamble to the proposed rule. See 75 FR 65081–65083.

⁵ The seven source categories for which we conducted RTR are Epichlorohydrin Elastomers Production; Polybutadiene Rubber Production; Styrene Butadiene Rubber and Latex Production; and NBR Production; Marine Tank Vessel Loading Operations, Pharmaceuticals Production; and Printing and Publishing. We did not conduct RTR for four of the Group 1 Polymers and Resins source categories (Butyl Rubber Production; Ethylene Propylene Rubber Production; Polysulfide Rubber Production; and Neoprene), because we previously re-adopted the existing MACT standard to satisfy section 112(f) of the CAA. See 73 FR 76220, published December 16, 2008. In addition, we did not conduct RTR for Hypalon™ Production, because there are no longer any facilities operating in the United States.

B. What changes did we make to the Group I Polymers and Resins MACT since proposal?

We are eliminating the subcategories (*i.e.*, Butyl Rubber and Halobutyl Rubber) in the Butyl Rubber source category because we agree with commenters who stated that both facilities in the Butyl Rubber source category now produce halobutyl rubber as the primary product, and the technical differences that distinguished the subcategories no longer exist. The current MACT standards for facilities in this source category are not affected by the removal of the subcategory distinction because the existing standards are identical for each subcategory. In October 2010, we proposed the same standards for both subcategories for the front-end process operations. However, we proposed different standards for each subcategory for the back-end process operations. Considering that both facilities would now be identified as being part of one source category by primary product determination, it would not be appropriate to finalize the proposed requirements that were based on analyses of each facility in its own subcategory. To address the two facilities together in one Butyl Rubber source category, we re-evaluated the emissions reductions, costs, and other impacts of controls for both the back-end operations and the front-end process vents for these two facilities. For the front-end process vents, we had proposed beyond-the-floor standards for both the Butyl Rubber subcategory and the Halobutyl Rubber subcategory, along with the Ethylene Propylene Rubber source category. Based on our revised analyses, we are setting requirements for the combined Butyl Rubber source category at the MACT floor level of control. The requirements for the Ethylene Propylene Rubber source category are also being set at the MACT floor level of control. For the back-end process operations, we had proposed beyond-the-floor standards for the Butyl Rubber subcategory, and the MACT floor level of control for the Halobutyl Rubber subcategory. Based on our revised analyses, we are setting requirements for the combined Butyl Rubber source category at the MACT floor level of control.

We are finalizing our proposal to set standards at the MACT floor level of control for back-end process operations in the Epichlorohydrin Elastomers, NBR, and Neoprene source categories. However, based on information we received during the comment period, we have revised some of the MACT floor

limits for these source categories. Information received for the only facility in the Neoprene Rubber Production source category corrected the emissions rate of one HAP emissions source, and we have revised the MACT floor limit for that source category to reflect the corrected emissions rate. We also received information during the comment period for the one facility in the NBR source category, which showed that, due to the different grades of product produced, the rate of emissions per unit of production varies. Similarly, the one facility in the Epichlorohydrin Elastomers source category also expected to have variations in the rate of emissions per unit of production, based on its different grades of product produced. Considering this variation in emissions, we increased the limit of the MACT floor for these source categories to allow for the observed variability in emissions per unit of production. We also added factors to account for variation in emissions per unit of production for the Butyl Rubber and Ethylene Propylene Rubber source categories, based on information received for the facilities in this source category.

C. What changes did we make to the Marine Tank Vessel Loading Operations MACT since proposal?

We proposed the MACT floor as submerged fill for the two subcategories not previously regulated (facilities emitting less than 10/25 TPY of HAP from MTVLO, and those “offshore” facilities located more than 0.5 miles from shore). Additionally, under the CAA section 112(d)(6) technology review of the existing MTVLO MACT, and as setting the beyond-the-floor MACT standards for the two subcategories not previously regulated, we proposed that existing facilities loading 1 million barrels per year (bbl/yr) of gasoline install vapor controls, either meeting 97-percent control, or the equivalent emission limit of 10 milligrams per liter (mg/l).

We are finalizing the proposed MACT floor work practice to require submerged fill of liquids into marine tank vessels at those previously unregulated sources. However, as a result of information received during the comment period, we are not finalizing the requirements we proposed under the technology review requirements of CAA section 112(d)(6), the beyond the floor and technology review requirements for vapor control technology for facilities loading 1 million bbl/yr.

V. Summary of Significant Comments and Responses

In the proposed action, we requested public comments on our residual risk reviews, our technology reviews, proposed amendments to delete the startup and shutdown exemptions and the malfunction exemption, the control of unregulated HAP, and clarification of rule provisions. We received written comments from 104 commenters. Our responses to the public comments that changed the basis for our decisions or are otherwise significant are provided below.⁶

A. EPA's Authority Under CAA Section 112

Comment: We received comments both in favor of and objecting to EPA's consideration of various factors in determining acceptable risk. Some commenters argue that the two-step process developed to address residual risk and determine “ample margin of safety” in the Benzene NESHAP should be preserved. Commenters also request that EPA continue to use its discretion to determine that a maximum cancer risk of 100-in-1 million is acceptable. Another commenter supports EPA's commitment to avoid establishing inflexible decision points for acceptable risks or ample margin of safety. Commenters also debate whether EPA has the authority to evaluate, or should, as a matter of policy, evaluate facility-wide risk, demographic assessments, and risks based on actual or allowable emissions.

Response: For the four rules we are finalizing, our evaluation of facility-wide risk, demographics, and allowable emissions did not change our decisions about acceptability and ample margin of safety. Therefore, comments on how these factors were used by EPA in determining acceptable risks are not germane to these final rules. We note, however, that section 112(f)(2) of the CAA expressly preserves our use of the two-step process for developing standards to address residual risk and interpret “ample margin of safety” as developed in the Benzene NESHAP.⁷ In both the Benzene NESHAP and our

⁶ See *Summary of Public Comments and Responses for Group I Polymers and Resins, Marine Tank Vessel Loading Operations, Pharmaceutical Production, and The Printing and Publishing NESHAP* (March 2011), for summaries of other comments and our responses to them.

⁷ See National Emission Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants (Benzene NESHAP) (54 FR 38044, September 14, 1989).

Residual Risk Report⁸ to Congress, we explain that we do not define “rigid line(s) of acceptability” and that we will consider a series of other health measures and factors in determining if risk is acceptable. Our authority to use the two-step process laid out in the Benzene NESHAP, and to consider a variety of measures of risk to public health is discussed more thoroughly in the preamble to the proposal. See 75 FR 65071–65073.

Comment: Some commenters state that our review under CAA section 112(d)(6) should be limited to only advances in work practices and control technologies, and should not include emission points not regulated by the existing MACT standard. Expanding rule applicability should not be considered, as it has nothing to do with developments in practices, processes, or control technologies and is not indicated in the CAA as a basis for the technology review. The commenter states that EPA already made applicability determinations in the original MACT rules by evaluating the floor and beyond-the-floor options, and nothing in the CAA warrants review of these determinations. The commenters also state these changes should only be considered in the CAA section 112(f) risk review to reduce risks.

Some commenters stated that a review under CAA section 112(d)(6) is not required if the post-MACT emissions levels result in risks that are deemed to be protective of public health with an ample margin of safety. Furthermore, they stated that EPA should exempt source categories from CAA section 112(d)(6) review once this level has been achieved. They add that the review under CAA section 112(d)(6) should be considered an extension of the main purpose of CAA section 112, which is to reduce the public’s exposure to air toxics, and not to impose new technology just because it is available. One commenter states that it was the intent of Congress for the MACT standards to ultimately reduce risk from sources to a level considered acceptable, and there is no legislative history to suggest that Congress expected EPA to revise MACT standards after these levels had been achieved.

Another commenter states an opposing view, saying that, in keeping with the context of CAA section 112(d), which requires technology-based standards that reflect the maximum degree of emission reduction achievable, CAA section 112(d)(6) serves as an on-going ratchet to

continually require EPA to update standards to keep pace with new technology. The commenter states that the decision of the Court in the Hazardous Organic NESHAP (HON)⁹ ruling, while not requiring recalculation of the floor for that standard, did so only for that MACT because there were no new developments in practices, processes, or control technologies, and expressly declined to decide whether EPA was required to recalculate the floors for other instances where there were such developments.

Response: We note that we do not consider unregulated emission points under CAA section 112(d)(6). To the extent there are unregulated emission points, we set standards under CAA sections 112(d)(2) and (3). We are not revising any of the four MACT rules in this notice pursuant to the CAA section 112(d)(6) review. Instead, for the newly regulated emissions points in the Group I Polymers and Resins source categories and in the Marine Tank Vessel Loading Operations source category we are promulgating MACT standards under CAA sections 112(d)(2)–(3).

In our CAA section 112(d)(6) review of pre-existing standards, we consider both improvements in practices, processes, or control technologies that we may have previously considered, as well as practices, processes, or control technologies that are new, or were unknown to us when the original MACT rule was developed. Because incremental changes in the practices, processes, or control technologies can have a significant impact on emissions, these changes are considered in our analysis of whether to revise the MACT standards under CAA section 112(d)(6). In considering both existing and new practices, processes, and control technologies, we consider costs and other factors in determining whether it is “necessary” to revise the existing standard.

We disagree with the view that a determination under CAA section 112(f) of an ample margin of safety and no adverse environmental effects alone will, in all cases, cause us to determine that a revision is not necessary under CAA section 112(d)(6). In some cases, even if risk factors remain the same from one round of CAA section 112(d)(6) review to another, changes in costs or availability of control technology may be sufficient to alter a previous conclusion about whether to impose further controls. We also disagree with the assertion that the HON Court’s ruling that CAA section

112(d)(6) does not require re-calculation of MACT floors was limited to instances in which there have not been developments in practices, processes, or control technologies. In fact, the Court was quite clear on this point, and declined to rule only on whether it was appropriate for EPA to consider costs and risks in conducting CAA section 112(d)(6) reviews, as the issue was rendered moot by the litigants’ failure to preserve it. See *NRDC v. EPA*, 529 F.3d at 1084 (“It has been argued that EPA was obliged to completely recalculate the maximum achievable control technology—in other words, to start from scratch. We do not think the words ‘review, and revise as necessary’ can be construed reasonably as imposing any such obligation. Even if the statute did impose such an obligation, petitioners have not identified any post-1994 technological innovations that EPA has overlooked.”).

Comment: Commenters state that EPA does not have the authority under CAA section 112(d)(2) or (3) to later review and possibly revise the MACT determination once a MACT determination has been made for a source category. Several commenters state that EPA only has the authority to revisit the rulemaking if a timely legal challenge to the standard is lodged. The commenters further note they are not aware of any instance where EPA has revisited a beyond-the-floor analysis in the absence of a Court decision, rule vacatur, or settlement agreement. Commenters also state that reassessing MACT standards and imposing more stringent requirements would also be inconsistent with Congress’s desire for finality evident in the judicial review provisions of CAA section 307(b), which provides that challenges to MACT standards must be raised within 60 days of their promulgation, assuring that regulated entities, EPA, and the public know what emissions limitations will apply to a source rather than having those limitations be subject to flux.

In contrast, one commenter states that it is appropriate and essential that EPA establish control for all emissions sources, including sources that previously had “no control” floors, under CAA section 112(d)(6). The commenter states that EPA should continue to do this for all MACT standards.

Response: Under CAA section 112(d)(2), the EPA must promulgate technology-based standards that reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). Nothing in the

⁸ See *Residual Risk Report to Congress*, EPA-453/R-99-001 (March 1999).

⁹ *NRDC and LEAN v. EPA*, 529 F.3d 1077 (D.C. Cir. 2008).

CAA or its legislative history suggests that EPA is prohibited from reviewing and revising MACT standards, except as part of the CAA section 112(d)(6) or CAA section 112(f) reviews. Where we identify emission points that were erroneously not previously regulated under a MACT rule, we may identify MACT floor and beyond-the-floor control options for existing and new sources. An agency generally remains free to revise improperly promulgated or otherwise unsupportable rules, even in the absence of a remand from a Court. *United Gas Improvement Co. v. Callery Props., Inc.*, 382 U.S. 223, 229 (1966) (“An agency, like a court, can undo what is wrongfully done by virtue of its order.”); *Macktal v. Chao*, 286 F.3d 822, 825–26 (5th Cir. 2002) (“[I]t is generally accepted that in the absence of a specific statutory limitation, an administrative agency has the inherent authority to reconsider its decisions.”). Agencies have particularly broad authority to revise their regulations to correct their errors. *Last Best Beef, LLC v. Dudas*, 506 F.3d 333, 340 (4th Cir. 2007); *Friends of the Boundary Water Wilderness v. Bosworth*, 437 F.3d 815, 823 (8th Cir. 2006) (“It is widely accepted that an agency may, on its own initiative, reconsider its interim or even final decisions, regardless of whether the applicable statute and agency regulations expressly provide for such review.”) (citations omitted). Moreover, an agency may reconsider its methodologies and application of its statutory requirements and may even completely reverse course, regardless of whether a court has determined that its original regulation is flawed, so long as the agency explains its bases for doing so. *Motor Vehicle Mfrs. Ass’n v. State Farm Mutual Auto Ins. Co.*, 463 U.S. 29, 42 (1983); *FCC v. Fox Television Stations, Inc.*, 129 S. Ct. 1800, 1810 (2009); *Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 981–82 (2005) (internal citations omitted); (“An initial agency interpretation is not instantly carved in stone. On the contrary, the agency * * * must consider varying interpretations and the wisdom of its policy on a continuing basis,” *Chevron, supra* at 863–864[]), for example, in response to changed factual circumstances, or a change in administration. That is, no doubt, why in *Chevron* itself, this Court deferred to an agency interpretation that was a recent reversal of agency policy.”)

Here, both the Polymers and Resins I and the Marine Tank Vessel Loading Operations NESHAP, as originally promulgated, did not contain MACT

standards for certain significant HAP emissions points, and, we are, therefore, appropriately promulgating standards for those emissions points under CAA sections 112(d)(2)–(3) for the first time. CAA section 112(d)(6) and CAA section 112(f)(2) do not govern the initial establishment of the MACT standards. This approach is consistent with other recent actions that establish MACT standards for the first time for significant emissions points that had not been previously addressed by CAA section 112 (d) standards. See, e.g., National Emission Standards for Hazardous Air Pollutants from Petroleum Refineries; Final Rule, 74 FR 55670, 556773–74 (October 28, 2009).

B. Group 1 Polymers and Resins

Comment: One commenter states that, due to changes made at a facility since MACT promulgation, the facility would no longer fall into the Butyl Rubber subcategory, based on the primary product made, and would be in the Halobutyl Rubber subcategory. (The Butyl Rubber and Halobutyl Rubber subcategories comprise the Butyl Rubber source category.) However, the unit at this facility that produces halobutyl rubber as the primary product is a flexible operations unit that produces three major products, one of which is still butyl rubber, and, therefore, emits significantly different emissions from the only other halobutyl rubber facility in the United States, which produces halobutyl rubber exclusively. Commenters recommend EPA revise the Butyl Rubber source category descriptions to distinguish between halobutyl rubber-only and flexible units, and to apply primary product determinations only at the category level, and not the subcategory level. The commenters further state that, if these facilities are not separated into different subcategories and are both included in the Halobutyl Rubber subcategory, the current proposal and supporting analyses will not be applicable, and new analyses and proposal will be needed.

Response: Currently there are only two facilities in the United States that produce either butyl or halobutyl rubber. Since one of these facilities can produce both butyl rubber and halobutyl rubber, and since halobutyl rubber is the primary product for both of these facilities, we have concluded that there is no longer a need to maintain the subcategory distinction in the Butyl Rubber source category in the current MACT standards. Therefore, we have removed the subcategories of Halobutyl Rubber and Butyl Rubber in the Butyl Rubber source category, and

both facilities that were in these subcategories will now be included in the Butyl Rubber source category. The Group I Polymers and Resins MACT standards create separate source categories or subcategories by requiring different standards for different types of primary products. In the final rule, we have removed the language that distinguishes halobutyl rubber as a separate product type, which has the effect of removing the subcategories from the Butyl Rubber source category. While the existing MACT standards have identical requirements for the Butyl and Halobutyl Rubber subcategories, we proposed different requirements for these subcategories for back-end process operations, and common requirements for the front-end process vents at proposal.

With the removal of the subcategory distinction, we have revised our analyses of the emissions reductions, costs, and other impacts of controls for both the front-end and back-end process operations for these two facilities. Based on these analyses, we determined that the beyond-the-floor standards for front-end process operations that were proposed separately for both the Butyl Rubber and Halobutyl Rubber subcategories, which are a 98-percent reduction in organic HAP, and a 99-percent reduction in hydrogen halides and halogens, are not cost-effective for the Butyl Rubber source category. We are setting requirements for the combined front-end process operations for the Butyl Rubber source category at the MACT floor level of control. For the back-end process operations, we proposed beyond-the-floor standards for the Butyl Rubber subcategory, and the MACT floor level of control for the Halobutyl Rubber subcategory. Based on our revised analyses, the beyond-the-floor level of control, which is a 98-percent reduction in organic HAP, is not cost-effective for the Butyl Rubber source category. We are setting requirements for the combined back-end process operations for the Butyl Rubber source category at the MACT floor level of control. The current MACT standards are not affected by the removal of the subcategory distinction because the existing standards are identical for each subcategory.

Comment: One commenter stated that, if a facility was subject to MACT standards limiting HCl emissions from its front-end process vents in the Butyl Rubber source category and the Ethylene Propylene Rubber source category, then it would be unacceptable business practice to route those emissions to the proposed shared control device. A shared control device

would limit operating flexibility, cause lost business due to shutdown of both units for expected maintenance of thermal oxidizers and halogen scrubbers, and the potential for lost business, excess emissions, and dual violations from both units from unplanned shutdowns. The commenter states that EPA, therefore, needs to consider separate controls for each unit, a spare thermal oxidizer and halogen scrubber, or the significant lost business and other costs and emission impacts of having a shared control device in the beyond-the-floor costs analysis for the proposed control. The commenter estimates that the costs for the units to be controlled separately are \$20,600/ton HCl emissions reduced for the unit in the Butyl Rubber source category (note that the commenter refers to this as the halobutyl rubber unit, since that is the product being produced), and \$51,000/ton HCl emissions reduced for the unit in the Ethylene Propylene Rubber source category. Commenters also stated that the proposed beyond-the-floor MACT standards to control front-end process vents in the Butyl Rubber and Ethylene Propylene Rubber source categories are not cost-effective and should not be finalized. One commenter provided data showing costs to range from \$16,900/ton of HAP emissions reduced to \$80,100/ton of HAP emissions reduced to meet the proposed front-end process vent MACT standards.

Response: We disagree with the claim that the CAA precludes our taking note of the co-location of these units in estimating the costs to control the HCl from these units. Nevertheless, based on information received during the comment period, we recalculated separate source category cost estimates for control of HCl from ethylene propylene rubber and butyl rubber units for the one facility where these units are co-located. The changes from the estimate at proposal primarily include using a recuperative thermal oxidizer rather than a direct flame incinerator, and including additional ductwork and pumps needed to convey emissions to the control devices. We estimate that, considered separately, the cost to control the ethylene propylene rubber front-end process vents would be approximately \$19,000/ton HCl emissions reduced, and the cost to control the butyl rubber front-end process vents would be approximately \$12,000/ton HCl emission reduced.

Comment: Commenters state that the proposed beyond-the-floor MACT standards to control the back-end process vents in the Butyl Rubber source category are not cost-effective, and should not be finalized. One

commenter provided data showing costs to range from \$72,300/ton of HAP emissions reduced to \$75,600/ton of HAP emissions reduced to meet the proposed back-end process vent MACT standards.

Response: With the removal of the subcategory distinction, we revised our analyses of the emissions reductions, costs, and other impacts of the beyond-the-floor option identified at proposal. This beyond-the-floor option would require the ducting of emissions from the uncontrolled back-end process operations to a control device for the two facilities now in the Butyl Rubber source category. In this revised analysis, we considered information provided during the comment period regarding the types of oxidizers and ducting equipment that would be needed for the facilities in this source category for the beyond-the-floor control option, as well as the provided information on process flow rates. From the revised analysis, we estimate that thermal oxidizers would achieve an emissions reduction of 98 percent, resulting in a decrease in hexane emissions of approximately 66 TPY. The capital costs of this option are estimated to be approximately \$3.5 million, total annual costs are estimated to be approximately \$1.5 million, and the cost-effectiveness values would be approximately \$23,000 per ton of HAP emissions reduced. We believe the costs of this beyond-the-floor option are not reasonable, given the level of emission reduction. Therefore, we are finalizing the MACT floor level of emissions. We have determined that the MACT floor level of control for the source category is a production-based limit reflecting each source's organic HAP emissions divided by its total elastomer product leaving the stripper in 2009, multiplied by a variability factor of 1.35. In establishing the floor-level limit, the variability factor was included to account for the historic variability in the amount of emissions per unit of production at these facilities.

Comment: Commenters noted that the emissions from back-end process operations for facilities in the Epichlorohydrin Elastomers, NBR, and Butyl Rubber source categories, and HCl emissions from front-end process operations in the Ethylene Propylene Rubber and Butyl Rubber source categories will vary only by the mass of polymer product produced, because there is only one facility in each source category. The commenters note that the proposed MACT standards were based on emissions data and associated production levels for certain years. These commenters state that it is not appropriate to set the standards in this

way, as it does not allow for variability in the manufacturing process, or the potential for the production of different product mixes and volumes in the future. One commenter suggests using 2008 emissions, and, perhaps, other recent years of data in setting the limits. Another commenter suggests that EPA look at the statistical variation over time, and, if EPA revisits the current subcategorization scheme within the Butyl Rubber source category, then EPA should also consider variability in source design and operation. The commenter also notes that, over the last 10 years, emissions from back-end process vents varied by up to 43 percent from their levels in 2006 due to factors such as weather conditions, grade slate changes (such as product grade or slight variations in product type), and process and control device reliability/service. Both commenters submitted additional emissions data for EPA's consideration.

Response: We have adjusted the emissions limits in the final rule to better account for process variability and other factors for the front-end process vent MACT limits in the Butyl Rubber and Ethylene Propylene Rubber source categories and the back-end MACT limits for the Butyl Rubber, Epichlorohydrin Elastomers, and NBR source categories.¹⁰ For the Butyl Rubber source category, up to 10 years of annual emissions and annual production data were submitted for the two facilities in the source category. These data showed that the emissions per unit production varied up to 74 percent higher for HCl from front-end process vents than that reported in 2010, and varied up to 35 percent higher for back-end process vents than that reported for 2009. To account for this variability, we included a variability factor of 74 percent over the HCl emissions per unit production in 2010 in the front-end process operations limit, and a variability factor of 35 percent over the emissions per unit production in 2009 in the back-end process operations limit for this source category. For the Ethylene Propylene Rubber source category, historical annual emissions and annual production data were submitted for the one affected facility in the source category. These data showed that the emissions per unit production varied up to 39 percent higher for HCl from front-end process vents than reported in 2010. To account for this variability, we included a variability factor of 39 percent over the HCl emissions per unit production in 2010 in the front-end

¹⁰ See *Regulatory Alternative Impacts for Group I Polymers and Resins* (March 2011) in the docket.

process operations limit. Similarly, for the NBR source category, historical annual emissions and production data were submitted after the comment period for the one facility in the source category. While this facility recently installed emissions control systems beyond those required to meet the current MACT requirements, after these control were in place, the data showed that emissions per unit production varied up to 42 percent higher than that reported for 2009. To account for this variability, we included a variability factor of 42 percent over the emissions per unit production in 2009 in the back-end process operations limit for this source category. For the Epichlorohydrin Elastomers source category, historical annual emissions indicative of the expected variation of emissions was unavailable. Due to the similarities between the NBR and Epichlorohydrin Elastomers facilities in the equipment used, and how they operate their back-end processes, however, the same 42-percent variability factor was applied to the emissions per unit production in 2009 in the back-end process operations limit.

Comment: Commenters stated that EPA should provide an allowance for maintenance of any thermal oxidizer required to be installed. One commenter notes that a regenerative thermal oxidizer (RTO) requires maintenance that sometimes necessitates that the RTO be bypassed. The commenter notes that back-end process vents at existing sources in the Butyl Rubber source category are currently permitted to allow bypass emissions during maintenance work on the control device up to the permitted limit with the use of purchased Emission Reduction Credits in Texas, and an allowance for bypass emissions is included in the unit operating permit in Louisiana. The commenter suggests that the MACT standards for the back-end process vents should recognize that bypassing currently occurs for RTO-controlled emissions, and allow for it in the MACT standards.

Response: We recognize that bypassing currently occurs. However, the Court has made clear that MACT standards must apply at all times. See *Sierra Club v. EPA*, 551 F.3d 1019 (D.C. Cir. 2008), cert. denied, 130 S. Ct. 1735 (U.S. 2010). The emission limits we are finalizing for the back-end process operations are in the format of a 12-month rolling average, and, therefore, facilities may bypass only provided that they are in continuous compliance with the standards.

Comment: Commenters requested that EPA clarify the definition of back-end processes specifically to exclude operations that have essentially no HAP emission potential, such as handling and storage of finished products. They stated that it would also be helpful for the Agency to clarify that surge control vessels, equipment leaks, storage vessels, and wastewater, which are regulated by the Group I Polymers and Resins MACT, are not included in the definition of back-end processes.

Response: We agree with the commenters that the proposed definition of back-end processes was unclear, and that surge control vessels, equipment leaks, storage vessels, and wastewater are regulated in the existing Group I Polymers and Resins MACT standards, and that handling and storage of finished products is not part of the back-end process operations. We have revised the language in the final rule accordingly.

Comment: Commenters request clarification that, in the absence of allowing 4 years for compliance, the first compliance demonstration would be 24 months after the publication date for emission limits, based on a 12-month rolling average. This would allow for data collection to begin in the first month after the compliance date (13th month after promulgation) and provide for 1 year of data to be used in the compliance demonstration. One commenter requested that compliance not be determined on less than a 12-month basis, because this would limit the variability allowed for in the rolling 12-month limit.

Response: We agree with the commenter that compliance should be determined on a 12-month basis. The first time 12 months of data will be available will be in the 13th month after the compliance date, which is the 25th month after the publication date. To demonstrate compliance, the 12-month rolling average information must be included in the first periodic report that occurs after 12 months of data have been collected. We have clarified the timing of the compliance demonstration in the final rule language.

C. Marine Tank Vessel Loading Operations

Comment: Commenters stated that there were errors in the 2005 National Emissions Inventory (NEI) data set, and that EPA significantly overestimated the MIR for the MTVLO source category for each of these facilities due to data errors.

Response: At proposal, we found that the current MACT-based standards both provide an ample margin of safety to

protect public health and prevent adverse environmental effects, and, therefore, did not make any changes to the existing standards due to the risk analysis. We found that three facilities had MIR greater than 1-in-1 million (values of 10-, 20-, and 20-in-1 million) for the MTVLO source category. We identified two facilities with facility-wide MIR greater than 100-in-1 million (each with values of 200). Using new data obtained since proposal, we corrected the errors noted by the commenters for both MTVLO emission sources and other emission sources at the facilities. We found incorrect latitudes and longitudes for some emission sources, incorrect emissions reported for some sources, or incorrectly identified HAP. We updated the 2005 NEI data sets for each facility with corrected data, and conducted a reanalysis of the risk using the corrected data set. The revised risk assessment results show no facilities with MTVLO have a facility-wide risk of greater than 100-in-1 million.¹¹ Based on 2005 emissions data, MTVLO source category emissions from one facility result in a MIR of 50-in-1 million (20 percent from benzene and 80 percent from butadiene), however, this facility reports in its public comments an 89-percent reduction in benzene emissions and a 97-percent reduction in butadiene emissions between years 2006 and 2009. Based on this information, the revised MIR associated with actual MTVLO emissions from this facility is less than 1-in-1 million.¹² No other facility has MTVLO emissions resulting in a MIR greater than 1-in-1 million. The corrections to the emission data files and risk results are included in memoranda in the docket.

Comment: One commenter noted that it is not clear whether offshore loading terminals at refineries would be exempt from proposed changes to MTVLO MACT. The commenter recommended rule text changes for 40 CFR 63.560(d)(6). The commenter noted that their facility may be one of the few (or only) offshore loading terminals in the United States, meaning the cost analysis and controls selected for this subcategory by the MTVLO MACT proposal are likely to set a precedent in the Refinery RTR rule process.

¹¹ Of the two facilities with MTVLO that previously showed facility-wide risks exceeding 100-in-1 million, the revised risk assessment results show one facility has facility-wide risks of 70-in-1 million, and the other has facility-wide risks of 40-in-1 million.

¹² For this facility, reported actual and allowable emission are the same; therefore, the MIR is the same for both.

Response: We have considered the comment and agree that the proposed rule was not clear. Therefore, this final rule clarifies applicability for petroleum refineries.

Comment: Three commenters supported submerged fill requirements. One commenter supported the requirement for submerged fill for previously-exempt subcategories, and stated that submerged fill is cost-effective. One commenter agreed with EPA's decision to establish submerged fill as the MACT floor. The Commenter noted that submerged fill, as defined by the Coast Guard, has been standard industry practice for some time, reduces HAP emissions, and eliminates static electricity from free-falling cargo, thereby enhancing operational safety. One commenter suggested that if additional control is needed, a work practice standard (submerged fill) should be adopted for the offshore loading subcategory instead of 99-percent efficient vapor control systems.

Response: The commenters agree with the proposal to require submerged fill as the floor level of control for the two subcategories not previously regulated (those facilities emitting less than 10/25 TPY of HAP from MTVLO, and those facilities located more than 0.5 miles from shore). We have included the submerged fill requirement in the final rule.

Comment: One commenter noted the discussion in the preamble is confusing concerning whether the proposed 1 million bbl/yr threshold is a MACT measure, or a reasonably available control technology (RACT) measure. The preamble states that the existing MACT standards require vapor recovery control for at least 10 million bbl/yr of gasoline, however, this provision is in the RACT provisions of the existing rule. Furthermore, the commenter asserts that the proposal preamble justifies the proposed new 1 million bbl/yr threshold on a volatile organic compounds (VOC) RACT basis rather than a HAP (MACT) basis, and describes the lower threshold as a beyond-the-floor MACT measure for the two previously-exempt subcategories. In addition, the commenter noted that the throughput threshold for a major source is 5 million bbl/yr, and asked how a facility only loading 1 million bbl/yr could be considered a major source, and subject to MACT. The commenter stated that the preamble discussion should be consistent with both the basis presented for justification of this measure, and the language of the rule.

Response: The proposed and final rules only pertain to the MACT requirements in the rule that address

major sources of HAP; no changes were proposed for the RACT requirements.¹³ While the commenter noted that a particular throughput would be required to define a major source of HAP, the throughput levels for MTVLO were not defined with the intent of identifying a major source. Applicability for the current rule is two-fold: (1) Is the facility, as a whole, a major source of HAP; and (2) does the facility conduct MTVLO.

We agree that the discussion in the proposed preamble regarding the gasoline throughput thresholds used to analyze the proposed 1 million bbl/yr gasoline threshold was not clear (75 FR 65115). As discussed below, we have not included a requirement for MTVLO facilities with a throughput of 1 million bbl/yr of gasoline to install and operate vapor recovery controls in the final rule.

Comment: Two commenters stated that EPA's cost-effectiveness determination for the beyond-the-floor MACT is flawed/not accurate, and noted concerns that the cost analysis is based on information from one vendor, for one control technology, for a single facility, and assumed installation costs. One commenter stated that EPA's cost information was limited. One commenter indicated that beyond-the-floor MACT options must be cost-effective in reducing HAP, and since EPA's estimated cost was \$74,000/ton HAP emissions reduced, it is not cost-effective, and, thus, illegal to promulgate this requirement as a MACT measure. The commenter stated that the real cost, based on corrected values of HAP content, would be \$180,000/ton HAP emissions reduced. The commenter requested that EPA rescind the proposed action.

Commenters stated that the EPA does not have the authority to consider non-HAP emission reductions in conducting a review of existing MACT standards under CAA section 112(d). The commenters noted that, in setting MACT standards, the CAA expressly forbids EPA from considering the co-benefits of non-HAP emissions reductions, and the MACT floor must be based on the HAP emission reductions achieved; any beyond-the-floor standard may be based only on consideration of the cost of achieving HAP emission reductions, and any non-air quality health and environmental impacts and energy requirements.

Response: As discussed earlier, we established and proposed the MACT

floor as submerged fill for the two subcategories not previously regulated (facilities emitting less than 10/25 TPY of HAP from MTVLO, and those "offshore" facilities located more than 0.5 miles from shore). Additionally, under the CAA section 112(d)(6) technology review of the existing MTVLO MACT, and as setting the beyond-the-floor MACT standards for the two subcategories not previously regulated, we proposed that existing facilities loading 1 million bbl/yr of gasoline, install vapor controls either meeting 97-percent control, or the equivalent emission limit of 10 mg/l (10 milligrams of total organic compound emissions per liter of gasoline loaded). At proposal, we estimated the cost and emissions reductions for installing vapor controls for facilities loading 1 million bbl/yr of gasoline, and we estimated a cost of \$74,000/ton HAP emissions reduction (190 TPY HAP emissions reduction) and \$5,500/ton VOC emissions reduction (2,600 TPY VOC emissions reduction).

As discussed in the cost section of the response to comment and the cost memoranda in the docket, we received and considered the comments on the control costs, emission rate differences for ships and barges, additional costs for offshore facilities, and the HAP content in gasoline. All those factors change the cost-effectiveness calculations. Based on information received as part of the comments, we reevaluated the costs used at proposal. The revised costs and emissions for the proposed threshold of 1 million bbl/yr gasoline are as high as \$500,000 per ton of HAP emissions reduced (1.9 tons of HAP reduced annually per facility) for loading ships offshore. Looking at a less stringent threshold for the final rule of 7 million bbl/yr of gasoline loaded would likely achieve little or no HAP or VOC emission reductions, since many facilities near that threshold were required to install controls under the current rule. We agree with commenters that these costs are unreasonable. Therefore, we are not including the proposed vapor controls for loading 1 million bbl/yr of gasoline requirement in the final rule. We disagree with the commenter that we cannot consider VOC benefits, but, given that we are not requiring these additional vapor controls for HAP, the issue is now moot.

Comment: One commenter stated that VOC and HAP emission rates from ships and barges at their facility are lower than EPA uses in its cost-effectiveness determinations. EPA used the uncontrolled gasoline loading emissions factor for barges (3.4 pounds (lb) VOC/1,000 gallons (gal) loaded), but should

¹³ RACT and MACT requirements are both included in 40 CFR part 63, subpart Y—National Emission Standards of Marine Tank Vessel Loading Operations.

use the emissions factor for ocean-going ships and barges (1.8 lb VOC/1,000 gal loaded); AP-42 notes in Chapter 5 that vapor saturation is much lower in ship and barge loading.

Response: We agree with the commenter that the emission factors for ships and barges, as applicable to the type of marine vessel being loaded, should be considered for estimating VOC and HAP emissions. We have revised the emission estimates using the barge and ship emission factors from AP-42.

Comment: One commenter noted that HAP content in the vapor phase is 3.0 percent, and not the 7.3 percent determined by EPA in the proposal. The commenter provided the analysis showing the calculations, based on conventional gasoline, where the commenter assumed no methyl tertiary butyl ether (MTBE) in the gasoline; no change to the total partial pressure; and benzene concentration of 1.8 percent. Another commenter stated the HAP emissions factor is approximately 50 percent of the EPA factor.

Response: In the proposal, we determined that the HAP content in the vapor phase of gasoline of 7.3 percent (based on 2006 gasoline composition) was appropriate, and used 7.3 percent in our emissions estimates for gasoline loading at MTVLO. We reviewed and considered the data provided by the commenter, and reviewed HAP content information from several other sources that have more recent gasoline composition data. We conducted a reanalysis of the HAP content, looking at both conventional and reformulated gasoline, considering the phase-out of MTBE and the requirements for reduced benzene content. Based on the revised analysis, we concluded that a good typical value for HAP content in the vapor is 5.0 percent. The revised analysis of HAP content in gasoline is in a memorandum in the docket.

Comment: Commenters argued that lean oil absorption technology is not capable of meeting the rule efficiency, is not in common use for MTVLO, and must be demonstrated as an effective technology for MTVLO. One commenter cited an instance where lean oil absorption installed on MTVLO was unable to meet control requirements in their permit. The commenter stated that lean oil absorption is typically used in smaller applications. Commenters stated that EPA must provide actual performance data for lean oil absorption technology in the MTVLO source category.

Response: Lean oil absorption systems are not new control technologies for MTVLO. Lean oil absorption was

discussed as a vapor recovery device, in addition to refrigeration (condenser) systems and carbon adsorption systems, for marine vessel loading in the 1987 *National Research Council, Committee on Control and Recovery of Hydrocarbons Vapors from Ships and Barges* report, *Controlling Hydrocarbon Emissions from Tank Vessel Loading*. Lean oil absorption also was discussed in the 1992 proposal, *Technical Support Document for MTVLO* (EPA-450/3-92-001a), and has been installed as vapor recovery devices for MTVLO. While we have not selected a beyond-the-floor option as MACT, we would like to clarify that lean oil absorption systems were included in the cost analysis for the beyond-the-floor option, because lean oil absorption systems achieving an emission reduction efficiency of 97 percent are used by at least one MTVLO facility, and because the units are a relatively less expensive control technology option that has the added benefit of recovered product.

D. Startup, Shutdown, and Malfunction (SSM) Requirements

Comment: Two commenters state that EPA offers little support for the assertion that it is reasonable to interpret CAA section 112 as not requiring EPA to account for malfunctions in setting emissions standards, or that malfunctions are not a distinct operating mode. The commenters state that it does not make sense for EPA to assert that malfunctions are part of normal operations, but then exclude emissions from these parts of normal operations in the determination of the emissions limits. The commenters state that, due to the unplanned nature and variety of potential malfunctions, it would be difficult, if not impossible, for EPA to gather data and set an emissions standard for periods of malfunction. Due to these difficulties, the commenters suggest that, under the authority of CAA section 112(h), EPA prescribe alternative design, equipment, work practice, or operational standards where it is not feasible to set or enforce a numerical emissions limit. The commenters add that there are work practices that can be identified as being the best to minimize emissions during a malfunction, and EPA must acknowledge the fact that even the best-performing sources experience malfunction events.

Response: 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 CAA section 112,

emissions 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 CAA 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 EPA accounts for variability in setting emissions standards consistent with the CAA section 112 case law, nothing in that case law requires the Agency to consider malfunctions as part of that analysis.

CAA section 112 uses the concept of “best controlled” and “best performing” unit in defining the level of stringency that CAA 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. 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 (D.C. 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 (D.C. Cir. 1978) (“In the nature of things, no general limit, individual permit, or even any upset provision can anticipate all upset situations. After a certain point, the transgression of regulatory limits caused by ‘uncontrollable acts of third parties,’ such as strikes, sabotage, operator intoxication or insanity, and a variety of other eventualities, must be a matter for the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation.”). 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. EPA's approach to malfunctions is consistent with CAA section 112, and is a reasonable interpretation of the statute.

Comment: Several commenters argued that emissions limits should not apply during SSM events, while other commenters stated that SSM emissions should be included in calculations of emissions and standards. Commenters suggested that requiring continuous compliance during periods of SSM constitutes beyond-the-floor requirements, and the Agency should have to justify this more stringent level of control, because facilities would need to install redundant control systems and bypass systems. They further stated that, in order to assure that SSM are appropriately accommodated, EPA must either assure that the data on which the standard is based include representative data from such periods, or, alternatively, set a separate work practice standard to properly accommodate SSM, and they cited case law supporting establishment of special SSM provisions. Further, several commenters stated that compliance with emissions standards during malfunction events will be difficult to gauge since emissions testing during such events is nearly impossible, given the sporadic and unpredictable nature of malfunctions. The commenters contended that the rules could have the effect of forcing units to choose between safety and compliance with emissions requirements. The commenters stated that, for some affected units, malfunctions, by their very nature, create unsafe conditions which can lead to excessive combustible mixtures that can result in explosions, equipment damage, and personnel hazards. Commenters also noted that some of the MACT standards included in this action did not rely exclusively upon the General Provisions, and, thus, were not immediately affected by the Court's vacatur of the SSM exemptions in the General Provisions. The commenters pointed out that, given that these categories were not immediately affected, EPA is not compelled to remove the exemptions that are established within these individual category-specific MACT standards.

Other commenters expressed support for requiring continuous compliance with the MACT standards, including periods of SSM. They noted that malfunctions are also preventable, and, thus, there should be no relief from the standards during these events.

Response: At this time, we are not promulgating separate emission

standards for periods of startup and shutdown for three of the four categories addressed in this rule, because we believe compliance with the standards is achievable during these periods. In the case of the Pharmaceuticals Production MACT standards, we expect the difference in emission levels during periods of startup and shutdown are insignificant, and that facilities in this source category should be able to comply with the standards during these times. In the case of the Printing and Publishing MACT standards, we believe there are sufficiently long averaging times incorporated into the emissions limits that facilities should be able to comply during periods of startup and shutdown. In the case of MTVLO, loading of marine tank vessels occurs in "batches," and general practice is for the loading operators to test out the vapor control system before it is attached to the tank vessel. In the case of Group I Polymers and Resins, one commenter stated that organic HAP emissions that are required to be sent to emissions control equipment (*i.e.*, flares) may not be able to comply with the MACT standards during periods of shutdown. The commenter stated that they may not always be able to route some of their process vents to a flare during periods of shutdown due to low pressure or low heat content in the process vent. EPA agrees with the commenter that it is not possible to comply with the applicable standard during periods of shutdown, and is establishing alternative emissions standards that apply during these periods.

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 equipment, process equipment, or a process to operate in a normal or usual manner * * *" (40 CFR 60.2). EPA has determined that malfunctions should not be viewed as a distinct operating mode, and, therefore, any emissions that occur at such times do not need to be factored into development of CAA section 112 standards, which, once promulgated, apply at all times. Also refer to section III.E of this preamble, and the response to comments document available in the docket for this action for additional discussion of this issue.

Comment: Commenters on the Group I Polymers and Resins MACT disagreed with EPA's statement that the proposed rules will reduce the reporting burden associated with having to prepare and submit an SSM report. The commenters also state that the claims EPA makes

that EPA is not proposing any new paperwork requirements is false if a facility wants to claim an affirmative defense. The affirmative defense provision contains much more onerous reporting and implied recordkeeping requirements than the existing rules. The commenters state that EPA needs to account for the information collection burden associated with affirmative defense in the Information Collection Request (ICR) for the SSM portion of the Group I Polymers and Resins MACT, and otherwise comply with the Paperwork Reduction Act.

Response: As discussed in section VII.B of this preamble, EPA is providing 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, and is providing administrative adjustments to the ICR for the MACT standards subject to these final rules that show what the notification, recordkeeping, and reporting requirements associated with the assertion of the affirmative defense might entail.

Comment: Two commenters note that, in making changes to the rules to exclude the SSM exemption and add the general duty clause to the MACT standards, three of the six MACT standards in the proposal include the statement that "the general duty to minimize emissions does not require the owner or operator to make any further efforts to reduce emissions if levels required by this standard have been achieved," but the other three do not (*i.e.*, Group I Polymers and Resins, MTLVO, and Printing and Publishing Industry MACT standards). The commenters state that this clarifying language should be included in all six standards.

Response: We agree that this language should be included in each of the six MACT standards, and we have added this clarifying language to 40 CFR 63.823(b) in the Printing and Publishing Industry MACT standards and 40 CFR 63.562(e) in the MTVLO MACT standards. However, we find that 40 CFR 63.483 in the Group 1 Polymers and Resins MACT standards already includes this language, and we have not revised the proposed language.

VI. Impacts of the Final Rules

The final changes to the Group I Polymers and Resins, MTVLO, Pharmaceuticals Production, and the Printing and Publishing Industry MACT standards are not estimated to have any significant emission reductions, costs, or other impacts.

VII. Statutory and Executive Order Reviews

A. Executive Orders 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, 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 information collection requirements in the final rules have been submitted for approval to OMB under the *Paperwork Reduction Act*, 44 U.S.C. 3501, *et seq.* The information collection requirements are not enforceable until OMB approves them.

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 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.

These final rules would require maintenance inspections of the control devices, but would not require any notifications or reports beyond those required by the General Provisions. The recordkeeping requirements require only the specific information needed to determine compliance.

When a malfunction occurs, sources must report them according to the applicable reporting requirements of 40 CFR part 63, subparts U, Y, KK, and GGG. 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 reasonable 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.

For two of the rules promulgated, National Emissions Standards for Group I Polymers and Resins (Butyl Rubber Production, Epichlorohydrin Elastomers Production, Ethylene Propylene Rubber Production, Hypalon™ Production, Neoprene Production, NBR Production, Polybutadiene Rubber Production, Polysulfide Rubber Production, and Styrene Butadiene Rubber and Latex Production); and Pharmaceuticals Production, 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, EPA has provided administrative adjustments to these two ICR that show what the notification, recordkeeping, and reporting requirements associated with the assertion of the affirmative defense might entail. 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 EPA. 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 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, subparts U and GGG 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.

With respect to MTVLO and Printing and Publishing source categories, operations would not proceed or continue if there is a malfunction of a control device, and, thus, it is unlikely that a control device malfunction would cause an exceedance of any emission limit. The existing MTVLO rule requires the vapor displaced during loading of the vessel be sent to vapor processors that meet specified efficiency standards. In discussions with industry, and at plant visits, the industry reports that marine vessels are not allowed to start loading until the vapor collection and processor system has been thoroughly checked for proper operation. If the loading equipment, and the vapor collection and processor system are not properly operating, the vessel is not allowed to load. In addition, if processor system settings are not maintained during vessel loading, loading is automatically stopped. Therefore, we believe there is no burden to the industry for the affirmative defense provisions added to the final rule. Additionally, an ICR document (number 1679.08) was prepared and submitted for the October 21, 2010, proposed rule that included burdens associated with testing, reporting, and recordkeeping for the proposed lowering of the threshold for when additional vapor collection and processor systems are required. In this action we are not requiring the lower threshold for additional vapor collection and processor systems. However, submerged fill requirements are added in the final rule, and are already being met under Coast Guard rules; thus, there is no additional ICR burden associated with the final rule for MTVLO.

For Printing and Publishing, we do not believe that printing and publishing

facilities have excess emissions caused by malfunctions. Printing presses and control devices are interlocked. If the control device is not operating, the press cannot start printing. If the control device stops operating, the press stops printing. Also, given the characteristics of the affected units at printing and publishing sources, EPA does not believe that any other type of malfunction could conceivably cause excess emissions.

Therefore, sources within these two source categories are not expected to have any need or use for the affirmative defense. Thus, for these source categories, EPA is not assigning any burden associated with affirmative defense.

For the Group I Polymers and Resins MACT standards, an ICR document prepared by EPA for the amendments to the standards has been assigned EPA ICR number 2410.02, which has been revised since the proposed estimate assigned EPA ICR number 2410.01. Burden changes associated with these amendments result from the reporting and recordkeeping requirements of the affirmative defense provisions added to the rule; the reporting and recordkeeping requirements associated with the new back-end process operation emission limits for Epichlorohydrin Elastomers, Neoprene Rubber, NBR, and Butyl Rubber Production source categories; and the reporting and recordkeeping requirements associated with the new HCl emission limits for the front-end process vents for the Ethylene Propylene Rubber and Butyl Rubber Production source categories. The respondents' annual reporting and recordkeeping burden for this collection (averaged over the first 3 years after the effective date of the standards) for these amendments is estimated to be 251 labor hours at a cost of \$12,222 per year. The annual burden for the Federal government (averaged over the first 3 years after the effective date of the standard) for these amendments is estimated to be 9 labor hours at a cost of \$408 per year.

For the Pharmaceuticals Production MACT standards ICR document prepared by EPA, which has been revised to include the amendments to the standards, has been assigned EPA ICR number 1781.06. 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 20 labor hours at a cost of \$2,094 per year. There is no estimated change in annual burden to the Federal government for these amendments.

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. When these ICR are approved by OMB, the Agency will publish a technical amendment to 40 CFR part 9 in the **Federal Register** to display the OMB control numbers for the approved information collection requirements contained in the final rules.

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. These final rules will not change the level of any emission standard, or impose emission measurements or reporting requirements on small entities beyond those specified in existing regulations.

D. Unfunded Mandates Reform Act

These rules do not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. Thus, these rules are not subject to the

requirements of sections 202 or 205 of 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, and because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action will not relax the control measures on existing regulated sources, and EPA's risk assessments (included in the docket for the proposed rules) demonstrate that the existing regulations are health protective.

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 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 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, 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.

EPA has determined that these final rules will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations, because they do not affect the level of protection provided to human health or the environment. To examine the potential for any environmental justice issues that might be associated with each source category, we evaluated the distributions of HAP-related cancer and non-cancer risks across different social, demographic, and economic groups within the populations living near the facilities where these source categories are located. Our analyses also show that, for all the source categories evaluated, there is no potential for an adverse

environmental effect or human health multipathway effects, and that acute and chronic non-cancer health impacts are unlikely. Our additional analysis of facility-wide risks showed that the maximum facility-wide cancer risks for all source categories are within the range of acceptable risks, and that the maximum chronic non-cancer risks are unlikely to cause health impacts. Our additional analysis of the demographics of the exposed population may show disparities in risks between demographic groups for all three categories, but EPA has determined that, although there may be a disparity in risks between demographic groups, no group is exposed to unacceptable level of risk.

The rules will not relax the control measures on emissions sources regulated by the rules, and, therefore, will not increase risks to any populations exposed to these emissions 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. EPA will submit a report containing these final rules 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 rules 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 April 21, 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: March 31, 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 U—[Amended]

■ 2. Section 63.480 is amended by revising paragraph (j) to read as follows:

§ 63.480 Applicability and designation of affected sources.

* * * * *

(j) *Applicability of this subpart.*

Paragraphs (j)(1) through (4) of this section shall be followed during periods of non-operation of the affected source or any part thereof.

(1) The emission limitations set forth in this subpart and the emission limitations referred to in this subpart shall apply at all times except during periods of non-operation of the affected source (or specific portion thereof) resulting in cessation of the emissions to which this subpart applies. However, if a period of non-operation of one portion of an affected source does not affect the ability of a particular emission point to comply with the emission limitations to which it is subject, then that emission point shall still be required to comply with the applicable emission limitations of this subpart during the period of non-operation. For example, if there is an overpressure in the reactor area, a storage vessel that is part of the affected source would still be required to be controlled in accordance with the emission limitations in § 63.484.

(2) The emission limitations set forth in subpart H of this part, as referred to in § 63.502, shall apply at all times, except during periods of non-operation of the affected source (or specific portion thereof) in which the lines are drained and depressurized, resulting in cessation of the emissions to which § 63.502 applies.

(3) The owner or operator shall not shut down items of equipment that are required or utilized for compliance with this subpart during times when emissions (or, where applicable, wastewater streams or residuals) are being routed to such items of equipment if the shutdown would contravene requirements of this subpart applicable to such items of equipment.

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

(i) To establish the affirmative defense in any action to enforce such a limit, the owners or operators of a facility must timely meet the notification requirements of paragraph (j)(4)(ii) of this section, and must prove by a preponderance of evidence that:

(A) The excess emissions were caused by a sudden, infrequent, and unavoidable failure of air pollution control and monitoring equipment, or a process to operate in a normal and usual manner; and could not have been prevented through careful planning, proper design, or better operation and maintenance practices; did not stem from any activity or event that could have been foreseen and avoided, or planned for; and were not part of a recurring pattern indicative of inadequate design, operation, or maintenance;

(B) 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;

(C) The frequency, amount, and duration of the excess emissions (including any bypass) were minimized to the maximum extent practicable during periods of such emissions;

(D) 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;

(E) All possible steps were taken to minimize the impact of the excess emissions on ambient air quality, the environment, and human health;

(F) All emissions monitoring and control systems were kept in operation, if at all possible, consistent with safety and good air pollution control practices;

(G) All of the actions in response to the excess emissions were documented by properly signed, contemporaneous operating logs;

(H) At all times, the facility was operated in a manner consistent with good practices for minimizing emissions; and

(I) The owner or operator has prepared a written root cause analysis, 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 the best monitoring methods and engineering judgment, the amount of excess emissions that were the result of the malfunction.

(ii) *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 2 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 standard in this subpart to demonstrate, with all necessary supporting documentation, that it has met the requirements set forth in paragraph (j)(4)(i) 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.

■ 3. Section 63.481 is amended by revising paragraph (c) to read as follows:

§ 63.481 Compliance dates and relationship of this subpart to existing applicable rules.

* * * * *

(c) With the exceptions provided in paragraphs (c)(1) through (3) of this section, existing affected sources shall be in compliance with this subpart no later than June 19, 2001, as provided in § 63.6(c), unless an extension has been granted as specified in paragraph (e) of this section.

(1) Existing affected sources producing epichlorohydrin elastomer, butyl rubber, neoprene rubber, and nitrile butadiene rubber shall be in compliance with the applicable emission limitation in § 63.494(a)(4) no later than April 23, 2012.

(2) Existing affected sources producing butyl rubber and ethylene propylene rubber shall be in compliance with § 63.485(q)(1) no later than April 23, 2012.

(3) Compliance with § 63.502 is covered by paragraph (d) of this section.

* * * * *

■ 4. Section 63.482 is amended by removing the definition of “halobutyl rubber,” adding in alphabetical order a definition for “affirmative defense,” revising the definitions of “back-end,” “butyl rubber,” “elastomer product,” “initial start-up,” and “product” in paragraph (b) to read as follows:

§ 63.482 Definitions.

* * * * *

(b) * * * * *
Affirmative defense means, in the context of an enforcement proceeding, a response or a 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.

* * * * *

Back-end refers to the unit operations in an EPPU following the stripping operations. Back-end process operations include, but are not limited to, filtering, coagulation, blending, concentration, drying, separating, and other finishing operations, as well as latex and crumb storage. Back-end does not include storage and loading of finished product or emission points that are regulated under §§ 63.484, 63.501, or 63.502 of this subpart.

* * * * *

Butyl rubber means a copolymer of isobutylene and other monomers. Typical other monomers include isoprene and methylstyrene. A typical composition of butyl rubber is approximately 85- to 99-percent isobutylene, and 1- to 15-percent other monomers. Most butyl rubber is produced by precipitation polymerization, although other methods may be used. Halobutyl rubber is a type of butyl rubber elastomer produced using halogenated copolymers.

* * * * *

Elastomer product means one of the following types of products, as they are defined in this section:

- (1) Butyl Rubber;
- (2) Epichlorohydrin Elastomer;
- (3) Ethylene Propylene Rubber;
- (4) Hypalon™;
- (5) Neoprene;
- (6) Nitrile Butadiene Rubber;
- (7) Nitrile Butadiene Latex;
- (8) Polybutadiene Rubber/Styrene Butadiene Rubber by Solution;
- (9) Polysulfide Rubber;
- (10) Styrene Butadiene Rubber by Emulsion; and
- (11) Styrene Butadiene Latex.

* * * * *

Initial start-up means the first time a new or reconstructed affected source begins production of an elastomer product, or, for equipment added or changed as described in § 63.480(i), the first time the equipment is put into operation to produce an elastomer product. Initial start-up does not include operation solely for testing equipment. Initial start-up does not include subsequent start-ups of an affected source or portion thereof

following shutdowns, or following changes in product for flexible operation units, or following recharging of equipment in batch operation.

* * * * *

Product means a polymer produced using the same monomers, and varying in additives (e.g., initiators, terminators, etc.); catalysts; or in the relative proportions of monomers, that is manufactured by a process unit. With respect to polymers, more than one recipe may be used to produce the same product, and there can be more than one grade of a product. As an example, styrene butadiene latex and butyl rubber each represent a different product. Product also means a chemical that is not a polymer, is manufactured by a process unit. By-products, isolated intermediates, impurities, wastes, and trace contaminants are not considered products.

* * * * *

■ 5. Section 63.483 is amended by revising paragraph (a) to read as follows:

§ 63.483 Emission standards.

(a) At all times, each owner or operator must operate and maintain any affected source subject to the requirements of this subpart, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require the owner or operator to make any further efforts to reduce emissions if levels required by this standard have been achieved. 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. Except as allowed under paragraphs (b) through (d) of this section, the owner or operator of an existing or new affected source shall comply with the provisions in:

- (1) Section 63.484 for storage vessels;
- (2) Section 63.485 for continuous front-end process vents;
- (3) Sections 63.486 through 63.492 for batch front-end process vents;
- (4) Sections 63.493 through 63.500 for back-end process operations;
- (5) Section 63.501 for wastewater;
- (6) Section 63.502 for equipment leaks;
- (7) Section 63.504 for additional test methods and procedures;
- (8) Section 63.505 for monitoring levels and excursions; and

(9) Section 63.506 for general reporting and recordkeeping requirements.

* * * * *

■ 6. Section 63.484 is amended by revising paragraph (b)(4) to read as follows:

§ 63.484 Storage vessel provisions.

* * * * *

(b) * * *

(4) Storage vessels located downstream of the stripping operations at affected sources subject to the back-end residual organic HAP limitation located in § 63.494(a)(1) through (3), that are complying through the use of stripping technology, as specified in § 63.495;

* * * * *

■ 7. Section 63.485 is amended by:

- a. Revising paragraphs (q) introductory text, and (q)(1) introductory text;
- b. Adding paragraphs (q)(1)(iii) through (q)(1)(vi); and
- c. Adding paragraph (w) to read as follows:

§ 63.485 Continuous front-end process vent provisions.

* * * * *

(q) Group 1 halogenated continuous front-end process vents must comply with the provisions of § 63.113(a)(1)(ii) and § 63.113(c), with the exceptions noted in paragraphs (q)(1) and (2) of this section.

(1) Group I halogenated continuous front-end process vents at existing affected sources producing butyl rubber or ethylene propylene rubber using a solution process are exempt from the provisions of § 63.113(a)(1)(ii) and § 63.113(c) if the conditions in paragraphs (q)(1)(i) and (ii) of this section are met, and shall comply with the requirements in paragraphs (q)(1)(iii) through (vi) of this section. Group I halogenated continuous front-end process vents at new affected sources producing butyl rubber or ethylene propylene rubber using a solution process are not exempt from § 63.113(a)(1)(ii) and § 63.113(c).

* * * * *

(iii) The average HCl emissions from all front-end process operations at affected sources producing butyl rubber and ethylene propylene rubber using a solution process shall not exceed the limits determined in accordance with paragraphs (q)(1)(iii)(A) and (B) of this section for any consecutive 12-month period. The specific limitation for each elastomer type shall be determined based on the calculation or the emissions level provided in paragraphs

(q)(1)(iii)(A) and (B) of this section divided by the base year elastomer product that leaves the stripping operation (or the reactor(s), if the plant has no stripper(s)). The limitation shall be calculated and submitted in accordance with paragraph (q)(1)(iv) of this section.

(A) For butyl rubber, the HCl emission limitation shall be calculated using the following equation:

$$BRHClEL = \frac{HCl_{2010}}{P_{2010}} * 1.74$$

Where:

HCl₂₀₁₀ = HCl emissions in 2010, megagrams per year (Mg/yr)

BRHClEL = Butyl rubber HCl emission limit, Mg HCl emissions/Mg butyl rubber produced

P₂₀₁₀ = Total elastomer product leaving the stripper in 2010, Mg/yr

1.74 = variability factor, unitless

(B) For ethylene propylene rubber using a solution process, the HCl emission limitation, in units of Mg HCl emissions per Mg of ethylene propylene rubber produced, shall be calculated by dividing 27 Mg/yr by the mass of ethylene propylene rubber produced in 2010, in Mg.

(iv) If the front-end process operation is subject to a HCl emission limitation in paragraph (q)(1)(iii) of this section, the owner and operator must submit the information specified in paragraphs (q)(1)(iv)(A) and (B) of this section.

(A) The applicable HCl emission limitation determined in accordance with paragraphs (q)(1)(iii)(A) and (B) of this section shall be submitted no later than 180 days from the date of publication of the final rule amendments in the **Federal Register**.

(B) Beginning with the first periodic report required to be submitted by § 63.506(e)(6) that is at least 13 months after the compliance date, the total mass of HCl emitted for each of the rolling 12-month periods in the reporting period divided by the total mass of elastomer produced during the corresponding 12-month period, determined in accordance with paragraph (q)(1)(v) of this section.

(v) Compliance with the HCl emission limitations determined in accordance with paragraph (q)(1)(iii) of this section shall be demonstrated in accordance with paragraphs (q)(1)(v)(A) through (E) of this section.

(A) Calculate your HCl emission limitation in accordance with paragraphs (q)(1)(iii)(A) and (B) of this section, as applicable, record it, and submit it in accordance with paragraph (q)(1)(iv) of this section.

(B) Each month, calculate and record the HCl emissions from all front-end process operations using engineering assessment. Engineering assessment includes, but is not limited to, the following:

- (1) Use of material balances;
- (2) Estimation of flow rate based on physical equipment design, such as pump or blower capacities;
- (3) Estimation of HCl concentrations based on saturation conditions; and
- (4) Estimation of HCl concentrations based on grab samples of the liquid or vapor.

(C) Each month, record the mass of elastomer product produced.

(D) Each month, calculate and record the sum of the HCl emissions and the mass of elastomer produced for the previous calendar 12-month period.

(E) Each month, divide the total mass of HCl emitted for the previous calendar 12-month period by the total mass of elastomer produced during this 12-month period. This value must be recorded in accordance with paragraph (q)(1)(vi) of this section and reported in accordance with paragraph (q)(1)(iv) of this section.

(vi) If the front-end process operation is subject to an HCl emission limitation in paragraph (q)(1)(iii) of this section, the owner or operator shall maintain the records specified in paragraphs (q)(1)(vi)(A) through (D) of this section.

(A) The applicable HCl emission limitation determined in accordance with paragraphs (q)(1)(iii)(A) and (B) of this section.

(B) The HCl emissions from all front-end process operations for each month, along with documentation of all calculations, and other information used in the engineering assessment to estimate these emissions.

(C) The mass of elastomer product produced each month.

(D) The total mass of HCl emitted for each 12-month period divided by the total mass of elastomer produced during the 12-month period, determined in accordance with paragraph (q)(1)(v) of this section.

* * * * *

(w) *Shutdown.* (1) During periods of shutdown, a Group 1 continuous front-end process vent at an existing affected source producing butyl rubber or ethylene propylene rubber using a solution process must be routed to a flare until either the organic HAP concentration in the vent is less than 50 ppmv, or the vent pressure is below 103.421 kPa.

■ 8. Section 63.489 is amended by revising paragraph (b)(4)(ii)(C) to read as follows:

§ 63.489 Batch front-end process vents—monitoring equipment.

* * * * *

(b) * * *

(4) * * *

(ii) * * *

(C) The owner or operator may prepare and implement a gas stream flow determination plan that documents an appropriate method which will be used to determine the gas stream flow. The plan shall require determination of gas stream flow by a method which will at least provide a value for either a representative or the highest gas stream flow anticipated in the scrubber during representative operating conditions. The plan shall include a description of the methodology to be followed and an explanation of how the selected methodology will reliably determine the gas stream flow, and a description of the records that will be maintained to document the determination of gas stream flow. The owner or operator shall maintain the plan as specified in § 63.506(a).

* * * * *

■ 9. Section 63.491 is amended by revising paragraph (e)(2)(ii) to read as follows:

§ 63.491 Batch front-end process vents—recordkeeping requirements.

* * * * *

(e) * * *

(2) * * *

(ii) Monitoring data recorded during periods of monitoring system breakdowns, repairs, calibration checks, and zero (low-level) and high-level adjustments shall not be included in computing the batch cycle daily averages. In addition, monitoring data recorded during periods of non-operation of the EPPU (or specific portion thereof) resulting in cessation of organic HAP emissions shall not be included in computing the batch cycle daily averages.

* * * * *

■ 10. Section 63.493 is revised to read as follows:

§ 63.493 Back-end process provisions.

Owners and operators of new and existing affected sources shall comply with the requirements in §§ 63.494 through 63.500. Owners and operators of affected sources whose only elastomer products are latex products, liquid rubber products, or products produced in a gas-phased reaction process, are not subject to the provisions of §§ 63.494 through 63.500. If latex or liquid rubber products are produced in an affected source that also produces another elastomer product, the

provisions of §§ 63.494 through 63.500 do not apply to the back-end operations dedicated to the production of one or more latex products, or to the back-end operations during the production of a latex product. Table 8 to this subpart contains a summary of compliance alternative requirements for the emission limits in § 63.494(a)(1)–(3) and associated requirements.

- 11. Section 63.494 is amended by:
 - a. Revising the section heading;
 - b. Revising paragraph (a) introductory text;
 - c. Revising paragraph (a)(4);
 - d. Revising paragraph (a)(5) introductory text;
 - e. Adding paragraph (a)(6);
 - f. Revising paragraph (b);
 - g. Revising paragraph (c); and
 - h. Revising paragraph (d) to read as follows:

§ 63.494 Back-end process provisions—residual organic HAP and emission limitations.

(a) The monthly weighted average residual organic HAP content of all grades of styrene butadiene rubber produced by the emulsion process, polybutadiene rubber and styrene butadiene rubber produced by the solution process, and ethylene-propylene rubber produced by the solution process that is processed, shall be measured after the stripping operation (or the reactor(s), if the plant has no stripper(s)), as specified in § 63.495(d), and shall not exceed the limits provided in paragraphs (a)(1) through (3) of this section, as applicable. Owners or operators of these affected sources shall comply with the requirements of paragraphs (a)(1) through (3) of this section using either stripping technology, or control or recovery devices. The organic HAP emissions from all back-end process operations at affected sources producing butyl rubber, epichlorohydrin elastomer, neoprene, and nitrile butadiene rubber shall not exceed the limits determined in accordance with paragraph (a)(4) of this section, as applicable.

* * * * *

(4) The organic HAP emissions from back-end processes at affected sources producing butyl rubber, epichlorohydrin elastomer, neoprene, and nitrile butadiene rubber shall not exceed the limits determined in accordance with paragraphs (a)(4)(i) through (iv) of this section for any consecutive 12-month period. The specific limitation for each elastomer type shall be determined based on the calculation or the emissions level provided in paragraphs (a)(4)(i) through

(iv) of this section divided by the base year elastomer product that leaves the stripping operation (or the reactor(s), if the plant has no stripper(s)). The

limitation shall be calculated and submitted in accordance with § 63.499(f)(1).

(i) For butyl rubber, the organic HAP emission limitation shall be calculated using the following equation:

$$BREL = \frac{Ce_{2009} + Be_{2009} + UCe_{2009}}{P_{2009}} * 1.35$$

Where:

- Be₂₀₀₉ = Bypass emissions in 2009, Mg/yr
- BREL = Butyl rubber emission limit, Mg organic HAP emissions/Mg butyl rubber produced
- Ce₂₀₀₉ = Controlled emissions in 2009, Mg/yr
- P₂₀₀₉ = Total elastomer product leaving the stripper in 2009, Mg/yr
- UCe₂₀₀₉ = Uncontrolled emissions in 2009, Mg/yr
- 1.35 = variability factor, unitless

(ii) For epichlorohydrin elastomer, the organic HAP emission limitation, in units of Mg organic HAP emissions per Mg of epichlorohydrin elastomer produced, shall be calculated by dividing 51 Mg/yr by the mass of epichlorohydrin elastomer produced in 2009, in Mg.

(iii) For neoprene, the organic HAP emission limitation, in units of Mg organic HAP emissions per Mg of neoprene produced, shall be calculated by dividing 30 Mg/yr by the mass of neoprene produced in 2007, in Mg.

(iv) For nitrile butadiene rubber, the organic HAP emission limitation, in units of Mg organic HAP emissions per Mg of nitrile butadiene rubber produced, shall be calculated by dividing 2.4 Mg/yr by the mass of nitrile butadiene rubber produced in 2009, in Mg.

(5) For EPPU that produce both an elastomer product with a residual organic HAP limitation listed in paragraphs (a)(1) through (3) of this section, and a product listed in paragraphs (a)(5)(i) through (iv) of this section, only the residual HAP content of the elastomer product with a residual organic HAP limitation shall be used in determining the monthly average residual organic HAP content.

* * * * *

(6) There are no back-end process operation residual organic HAP or emission limitations for Hypalon™ and polysulfide rubber production. There are also no back-end process operation residual organic HAP limitations for latex products, liquid rubber products, products produced in a gas-phased reaction process, styrene butadiene rubber produced by any process other than a solution or emulsion process, polybutadiene rubber produced by any

process other than a solution process, or ethylene-propylene rubber produced by any process other than a solution process.

(b) If an owner or operator complies with the residual organic HAP limitations in paragraph (a)(1) through (3) of this section using stripping technology, compliance shall be demonstrated in accordance with § 63.495. The owner or operator shall also comply with the recordkeeping provisions in § 63.498, and the reporting provisions in § 63.499.

(c) If an owner or operator complies with the residual organic HAP limitations in paragraph (a)(1) through (3) of this section using control or recovery devices, compliance shall be demonstrated using the procedures in § 63.496. The owner or operator shall also comply with the monitoring provisions in § 63.497, the recordkeeping provisions in § 63.498, and the reporting provisions in § 63.499.

(d) If the owner or operator complies with the residual organic HAP limitations in paragraph (a)(1) through (3) of this section using a flare, the owner or operator of an affected source shall comply with the requirements in § 63.504(c).

- 12. Section 63.495 is amended by:
- a. Revising the section heading;
- b. Revising paragraph (a);
- c. Revising paragraph (b)(5); and
- d. Adding paragraph (g) to read as follows:

§ 63.495 Back-end process provisions—procedures to determine compliance with residual organic HAP limitations using stripping technology and organic HAP emissions limitations.

(a) If an owner or operator complies with the residual organic HAP limitations in § 63.494(a)(1) through (3) using stripping technology, compliance shall be demonstrated using the periodic sampling procedures in paragraph (b) of this section, or using the stripper parameter monitoring procedures in paragraph (c) of this section. The owner or operator shall determine the monthly weighted average residual organic HAP content for each month in which any portion of the back-end of an elastomer production

process is in operation. A single monthly weighted average shall be determined for all back-end process operations at the affected source.

(b) * * *

(5) The monthly weighted average shall be determined using the equation in paragraph (f) of this section. All representative samples taken and analyzed during the month shall be used in the determination of the monthly weighted average.

* * * * *

(g) Compliance with the organic HAP emission limitations determined in accordance with § 63.494(a)(4) shall be demonstrated in accordance with paragraphs (g)(1) through (5) of this section.

(1) Calculate your organic HAP emission limitation in accordance with § 63.494(a)(4)(i) through (iv), as applicable, record it, and submit it in accordance with § 63.499(f)(1).

(2) Each month, calculate and record the organic HAP emissions from all back-end process operations using engineering assessment. Engineering assessment includes, but is not limited to, the following:

(i) Previous test results, provided the test was representative of current operating practices.

(ii) Bench-scale or pilot-scale test data obtained under conditions representative of current process operating conditions.

(iii) Design analysis based on accepted chemical engineering principles, measurable process parameters, or physical or chemical laws or properties. Examples of analytical methods include, but are not limited to:

- (A) Use of material balances;
- (B) Estimation of flow rate based on physical equipment design, such as pump or blower capacities;
- (C) Estimation of organic HAP concentrations based on saturation conditions; and
- (D) Estimation of organic HAP concentrations based on grab samples of the liquid or vapor.

(3) Each month, record the mass of elastomer product produced.

(4) Each month, calculate and record the sums of the organic HAP emissions

and the mass of elastomer produced for the previous calendar 12-month period.

(5) Each month, divide the total mass of organic HAP emitted for the previous calendar 12-month period by the total mass of elastomer produced during this 12-month period. This value must be recorded in accordance with § 63.498(e) and reported in accordance with § 63.499(f)(2).

- 13. Section 63.496 is amended by:
 - a. Revising the section heading;
 - b. Revising paragraph (a);
 - c. Revising paragraph (c)(2); and
 - d. Revising paragraph (d) to read as follows:

§ 63.496 Back-end process provisions—procedures to determine compliance with residual organic HAP limitations using control or recovery devices.

(a) If an owner or operator complies with the residual organic HAP limitations in § 63.494(a)(1) through (3) using control or recovery devices, compliance shall be demonstrated using the procedures in paragraphs (b) and (c) of this section. Previous test results conducted in accordance with paragraphs (b)(1) through (6) of this section may be used to determine compliance in accordance with paragraph (c) of this section.

* * * * *

(c) * * *

(2) A facility is in compliance if the average of the organic HAP contents calculated for all three test runs is below the residual organic HAP limitations in § 63.494(a)(1) through (3).

(d) An owner or operator complying with the residual organic HAP limitations in § 63.494(a)(1) through (3) using a control or recovery device, shall redetermine the compliance status through the requirements described in paragraph (b) of this section whenever process changes are made. The owner or operator shall report the results of the redetermination in accordance with § 63.499(d). For the purposes of this section, a process change is any action that would reasonably be expected to impair the performance of the control or recovery device. For the purposes of this section, the production of an elastomer with a residual organic HAP content greater than the residual organic HAP content of the elastomer used in the compliance demonstration constitutes a process change, unless the overall effect of the change is to reduce organic HAP emissions from the source as a whole. Other examples of process changes may include changes in production capacity or production rate, or removal or addition of equipment. For the purposes of this paragraph, process changes do

not include: Process upsets; unintentional, temporary process changes; or changes that reduce the residual organic HAP content of the elastomer.

- 14. Section 63.497 is amended by:
 - a. Revising the section heading;
 - b. Revising paragraph (a) introductory text; and
 - c. Revising paragraph (d) introductory text to read as follows:

§ 63.497 Back-end process provisions—monitoring provisions for control and recovery devices used to comply with residual organic HAP limitations.

(a) An owner or operator complying with the residual organic HAP limitations in § 63.494(a)(1) through (3) using control or recovery devices, or a combination of stripping and control or recovery devices, shall install the monitoring equipment specified in paragraphs (a)(1) through (6) of this section, as appropriate.

* * * * *

(d) The owner or operator of an affected source with a controlled back-end process vent using a vent system that contains bypass lines that could divert a vent stream away from the control or recovery device used to comply with § 63.494(a)(1) through (3), shall comply with paragraph (d)(1) or (2) of this section. Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, and pressure relief valves needed for safety purposes are not subject to this paragraph.

* * * * *

- 15. Section 63.498 is amended by:
 - a. Revising paragraph (a) introductory text;
 - b. Revising paragraph (a)(3);
 - c. Adding paragraph (a)(4);
 - d. Revising paragraph (b) introductory text;
 - e. Revising paragraph (b)(3);
 - f. Revising paragraph (c) introductory text;
 - g. Revising paragraph (d) introductory text;
 - h. Revising paragraph (d)(5)(ii)(B);
 - i. Revising paragraph (d)(5)(ii)(E); and
 - j. Adding paragraph (e) to read as follows:

§ 63.498 Back-end process provisions—recordkeeping.

(a) Each owner or operator shall maintain the records specified in paragraphs (a)(1) through (4), and paragraphs (b) through (e) of this section, as appropriate.

* * * * *

(3) If the back-end process operation is subject to a residual organic HAP

limitation in § 63.494(a)(1) through (3), whether compliance will be achieved by stripping technology, or by control or recovery devices.

(4) If the back-end process operation is subject to an emission limitation in § 63.494(a)(4), the organic HAP emission limitation calculated in accordance with § 63.494(a)(4)(i) through (iv), as applicable.

(b) Each owner or operator of a back-end process operation using stripping technology to comply with a residual organic HAP limitation in § 63.494(a)(1) through (3), and demonstrating compliance using the periodic sampling procedures in § 63.495(b), shall maintain the records specified in paragraph (b)(1), and in paragraph (b)(2) or paragraph (b)(3) of this section, as appropriate.

* * * * *

(3) If the organic HAP contents for all samples analyzed during a month are below the appropriate level in § 63.494(a), the owner or operator may record that all samples were in accordance with the residual organic HAP limitations in § 63.494(a)(1) through (3), rather than calculating and recording a monthly weighted average.

(c) Each owner or operator of a back-end process operation using stripping technology to comply with a residual organic HAP limitation in § 63.494(a)(1) through (3), and demonstrating compliance using the stripper parameter monitoring procedures in § 63.495(c), shall maintain the records specified in paragraphs (c)(1) through (3) of this section.

* * * * *

(d) Each owner or operator of a back-end process operation using control or recovery devices to comply with a residual organic HAP limitation in § 63.494(a)(1) through (3), shall maintain the records specified in paragraphs (d)(1) through (5) of this section. The recordkeeping requirements contained in paragraphs (d)(1) through (4) pertain to the results of the testing required by § 63.496(b), for each of the three required test runs.

* * * * *

- (5) * * *
- (ii) * * *

(B) Monitoring data recorded during periods of monitoring system breakdowns, repairs, calibration checks, and zero (low-level) and high-level adjustments, shall not be included in computing the hourly or daily averages. In addition, monitoring data recorded during periods of non-operation of the EPPU (or specific portion thereof) resulting in cessation of organic HAP emissions, shall not be included in

computing the hourly or daily averages. Records shall be kept of the times and durations of all such periods and any other periods of process or control device operation when monitors are not operating.

* * * * *

(E) For flares, records of the times and duration of all periods during which the pilot flame is absent, shall be kept rather than daily averages. The records specified in this paragraph are not required during periods when emissions are not routed to the flare.

* * * * *

(e) If the back-end process operation is subject to an organic HAP emission limitation in § 63.494(a)(4), the records specified in paragraphs (e)(1) through (4) of this section.

(1) The applicable organic HAP emission limitation determined in accordance with § 63.494(a)(4)(i) through (iv).

(2) The organic HAP emissions from all back-end process operations for each month, along with documentation of all calculations and other information used in the engineering assessment to estimate these emissions.

(3) The mass of elastomer product produced each month.

(4) The total mass of organic HAP emitted for each 12-month period divided by the total mass of elastomer produced during the 12-month period, determined in accordance with § 63.495(g)(5).

■ 16. Section 63.499 is amended by:

- a. Revising paragraph (a)(3);
- b. Revising paragraph (b) introductory text;
- c. Revising paragraph (c) introductory text;
- d. Revising paragraph (d) introductory text; and
- e. Adding paragraph (f) to read as follows:

§ 63.499 Back-end process provisions—reporting.

(a) * * *

(3) If the back-end process operation is subject to a residual organic HAP limitation in § 63.494(a)(1) through (3), whether compliance will be achieved by stripping technology, or by control or recovery devices.

(b) Each owner or operator of a back-end process operation using stripping to comply with a residual organic HAP limitation in § 63.494(a)(1) through (3), and demonstrating compliance by stripper parameter monitoring, shall submit reports as specified in paragraphs (b)(1) and (2) of this section.

* * * * *

(c) Each owner or operator of an affected source with a back-end process

operation control or recovery device that shall comply with a residual organic HAP limitation in § 63.494(a)(1) through (3), shall submit the information specified in paragraphs (c)(1) through (3) of this section as part of the Notification of Compliance Status specified in § 63.506(e)(5).

* * * * *

(d) Whenever a process change, as defined in § 63.496(d), is made that causes the redetermination of the compliance status for the back-end process operations subject to a residual organic HAP limitation in § 63.494(a)(1) through (3), the owner or operator shall submit a report within 180 days after the process change, as specified in § 63.506(e)(7)(iii). The report shall include:

* * * * *

(f) If the back-end process operation is subject to an organic HAP emission limitation in § 63.494(a)(4), the owner and operator must submit the information specified in paragraphs (f)(1) and (2) of this section.

(1) The applicable organic HAP emission limitation determined in accordance with § 63.494(a)(4)(i) through (iv), shall be submitted no later than 180 days from the date of publication of the final rule amendments in the **Federal Register**.

(2) Beginning with the first periodic report required to be submitted by § 63.506(e)(6) that is at least 13 months after the compliance date, the total mass of organic HAP emitted for each of the rolling 12-month periods in the reporting period divided by the total mass of elastomer produced during the corresponding 12-month period, determined in accordance with § 63.495(g)(5).

■ 17. Section 63.501 is amended by revising paragraph (c)(2) to read as follows:

§ 63.501 Wastewater provisions.

* * * * *

(c) * * *

(2) Back-end streams at affected sources that are subject to a residual organic HAP limitation in § 63.494(a)(1) through (3) and that are complying with these limitations through the use of stripping technology.

■ 18. Section 63.502 is amended by revising paragraphs (a) and (b)(4) to read as follows:

§ 63.502 Equipment leak and heat exchange system provisions.

(a) *Equipment leak provisions.* The owner or operator of each affected source, shall comply with the requirements of subpart H of this part,

with the exceptions noted in paragraphs (b) through (m) of this section. Surge control vessels required to be controlled by subpart H may, alternatively, comply with the Group 1 storage vessel provisions specified in § 63.484.

(b) * * *

(4) Surge control vessels and bottoms receivers located downstream of the stripping operations at affected sources subject to the back-end residual organic HAP limitation located in § 63.494(a)(1) through (3) that are complying through the use of stripping technology, as specified in § 63.495;

* * * * *

§ 63.503—[Amended]

■ 19. Section 63.503 is amended by removing and reserving paragraph (f)(1).

■ 20. Section 63.504 is amended by revising paragraph (a)(1) introductory text to read as follows:

§ 63.504 Additional requirements for performance testing.

(a) * * *

(1) Performance tests shall be conducted at maximum representative operating conditions achievable during one of the time periods described in paragraph (a)(1)(i) of this section, without causing any of the situations described in paragraph (a)(1)(ii) of this section to occur. 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.

* * * * *

■ 21. Section 63.505 is amended by:

- a. Revising paragraph (e)(4);
- b. Revising paragraph (g)(1) introductory text;
- c. Revising paragraph (g)(1)(v)(A);
- d. Revising paragraph (g)(1)(v)(B);
- e. Removing paragraphs (g)(1)(v)(C) through (g)(1)(v)(E);
- f. Revising paragraph (g)(2)(ii)(B) introductory text; and
- g. Adding paragraph (j) to read as follows:

§ 63.505 Parameter monitoring levels and excursions.

* * * * *

(e) * * *

(4) An owner or operator complying with the residual organic HAP limitations in paragraphs (a)(1) through (3) of § 63.494 using stripping, and demonstrating compliance by stripper parameter monitoring, shall redetermine the residual organic HAP content for all affected grades whenever process changes are made. For the purposes of this section, a process change is any action that would reasonably be

expected to impair the performance of the stripping operation. For the purposes of this section, examples of process changes may include changes in production capacity or production rate, or removal or addition of equipment. For purposes of this paragraph, process changes do not include: Process upsets; unintentional, temporary process changes; or changes that reduce the residual organic HAP content of the elastomer.

* * * * *

(g) * * *
 (1) With respect to storage vessels (where the applicable monitoring plan specifies continuous monitoring), continuous front-end process vents, aggregate batch vent streams, back-end process operations complying with § 63.494(a)(1) through (3) through the use of control or recovery devices, and process wastewater streams, an excursion means any of the three cases listed in paragraphs (g)(1)(i) through (g)(1)(iii) of this section. * * *

(v) * * *
 (A) Monitoring system breakdowns, repairs, calibration checks, and zero (low-level) and high-level adjustments; or

(B) Periods of non-operation of the affected source (or portion thereof), resulting in cessation of the emissions to which the monitoring applies.

(2) * * *
 (ii) * * *

(B) Subtract the time during the periods of monitoring system breakdowns, repairs, calibration checks, and zero (low-level) and high-level adjustments from the total amount of time determined in paragraph (g)(2)(ii)(A) of this section, to obtain the operating time used to determine if monitoring data are insufficient.

* * * * *

(j) *Excursion definition for back-end operations subject to § 63.494(a)(4).* An excursion means when the total mass of organic HAP emitted for any consecutive 12-month period divided by the total mass of elastomer produced during the 12-month period, determined in accordance with § 63.495(g), is greater than the applicable emission limitation, determined in accordance with § 63.494(a)(4)(i) through (iv) and submitted in accordance with § 63.499(f)(1).

- 22. Section 63.506 is amended by:
- a. Revising paragraph (b)(1) introductory text;
- b. Revising paragraph (d)(7);
- c. Revising paragraph (e)(3) introductory text;
- d. Removing and reserving paragraph (e)(3)(viii);

- e. Revising paragraph (e)(3)(ix)(B);
- f. Revising paragraph (e)(6)(iii)(E);
- g. Revising paragraph (h)(1)(i);
- h. Revising paragraph (h)(1)(ii)(C);
- i. Revising paragraph (h)(1)(iii);
- j. Revising paragraph (h)(2)(iii);
- k. Removing and reserving paragraph (h)(2)(iv)(A); and
- l. Adding paragraph (i) to read as follows:

§ 63.506 General recordkeeping and reporting provisions.

* * * * *

(b) * * *
 (1) *Malfunction records.* Each owner or operator of an affected source subject to this subpart shall maintain records of the occurrence and duration of each malfunction of operation (*i.e.*, process equipment), air pollution control equipment, or monitoring equipment. Each owner or operator shall maintain records of actions taken during periods of malfunction to minimize emissions in accordance with § 63.483(a)(1), including corrective actions to restore malfunctioning process and air pollution control and monitoring equipment to its normal or usual manner of operation.

* * * * *

(d) * * *
 (7) Monitoring data recorded during periods identified in paragraphs (d)(7)(i) and (ii) of this section shall not be included in any average computed under this subpart. Records shall be kept of the times and durations of all such periods and any other periods during process or control device or recovery device operation when monitors are not operating.

(i) Monitoring system breakdowns, repairs, calibration checks, and zero (low-level) and high-level adjustments; or

(ii) Periods of non-operation of the affected source (or portion thereof), resulting in cessation of the emissions to which the monitoring applies.

* * * * *

(e) * * *
 (3) *Precompliance Report.* Owners or operators of affected sources requesting an extension for compliance; requesting approval to use alternative monitoring parameters, alternative continuous monitoring and recordkeeping, or alternative controls; requesting approval to use engineering assessment to estimate emissions from a batch emissions episode, as described in § 63.488(b)(6)(i); wishing to establish parameter monitoring levels according to the procedures contained in § 63.505(c) or (d); shall submit a Precompliance Report according to the schedule described in paragraph (e)(3)(i)

of this section. The Precompliance Report shall contain the information specified in paragraphs (e)(3)(ii) through (vii) of this section, as appropriate.

* * * * *
 (viii) [Reserved]
 (ix) * * *

(B) Supplements to the Precompliance Report may be submitted to request approval to use alternative monitoring parameters, as specified in paragraph (e)(3)(iii) of this section; to use alternative continuous monitoring and recordkeeping, as specified in paragraph (e)(3)(iv) of this section; to use alternative controls, as specified in paragraph (e)(3)(v) of this section; to use engineering assessment to estimate emissions from a batch emissions episode, as specified in paragraph (e)(3)(vi) of this section; or to establish parameter monitoring levels according to the procedures contained in § 63.505(c) or (d), as specified in paragraph (e)(3)(vii) of this section.

* * * * *
 (6) * * *
 (iii) * * *

(E) 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 § 63.483(a)(1), including actions taken to correct a malfunction.

* * * * *
 (h) * * *
 (1) * * *

(i) The monitoring system is capable of detecting unrealistic or impossible data during periods of normal operation (*e.g.*, a temperature reading of -200 °C on a boiler), and will alert the operator by alarm or other means. The owner or operator shall record the occurrence. All instances of the alarm or other alert in an operating day constitute a single occurrence.

(ii) * * *
 (C) The running average reflects a period of normal operation.
 (iii) The monitoring system is capable of detecting unchanging data during periods of normal operation, except in circumstances where the presence of unchanging data is the expected operating condition based on past experience (*e.g.*, pH in some scrubbers), and will alert the operator by alarm or other means. The owner or operator shall record the occurrence. All instances of the alarm or other alert in

an operating day constitute a single occurrence.

* * * * *

(2) * * *
 (iii) The owner or operator shall retain the records specified in paragraphs (h)(1)(i) through (iii) of this section, for the duration specified in paragraph (h) of this section. For any calendar week, if compliance with paragraphs (h)(1)(i) through (iii) of this section does not result in retention of a record of at least one occurrence or measured parameter value, the owner or operator shall record and retain at least one parameter value during a period of normal operation.

(iv) * * *

(A) [Reserved]

* * * * *

(i)(1) As of January 1, 2012, and within 60 days after the date of completing each performance test, as defined in § 63.2 and as required in this subpart, you must submit performance test data, except opacity data, electronically to EPA's Central Data Exchange by using the Electronic Reporting Tool (ERT) (see http://www.epa.gov/ttn/chief/ert/ert_tool.html/) or other compatible electronic spreadsheet. Only data collected using test methods compatible with ERT are subject to this requirement to be submitted electronically into EPA's WebFIRE database.

(2) All reports required by this subpart not subject to the requirements in paragraphs (i)(1) of this section must be sent to the Administrator at the

appropriate address listed in § 63.13. If acceptable to both the Administrator and the owner or operator of a source, these reports may be submitted on electronic media. The Administrator retains the right to require submittal of reports subject to paragraph (i)(1) of this section in paper format.

- 23. Table 1 to Subpart U of part 63 is amended by:
- a. Removing entry 63.6(e);
- b. Revising entries 63.6(e)(1)(i) and 63.6(e)(1)(ii);
- c. Revising entry 63.6(e)(2);
- d. Adding entry 63.6(e)(3);
- e. Removing entries 63.6(e)(3)(i) through 63.6(e)(3)(ix);
- f. Revising entry 63.6(f)(1); and
- g. Revising entries 63.7(e)(1) and 63.10(d)(5)(i) to read as follows:

TABLE 1 TO SUBPART U OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART U AFFECTED SOURCES

Reference	Applies to subpart U	Explanation
§ 63.6(e)(1)(i)	No	See § 63.483(a)(1) for general duty requirement. Any cross reference to § 63.6(e)(1)(i) in any other general provision incorporated by reference shall be treated as a cross reference to § 63.483(a)(1).
§ 63.6(e)(1)(ii)	No.	
§ 63.6(e)(2)	No	[Reserved.]
§ 63.6(e)(3)	No.	
§ 63.6(f)(1)	No.	
§ 63.7(e)(1)	No	See § 63.504(a)(1). Any cross-reference to § 63.7(e)(1) in any other general provision incorporated by reference shall be treated as a cross-reference to § 63.504(a)(1).
63.10(d)(5)(i)	No.	

■ 24. Table 5 to Subpart U of part 63 is revised to read as follows:

TABLE 5 TO SUBPART U OF PART 63—KNOWN ORGANIC HAP EMITTED FROM THE PRODUCTION OF ELASTOMER PRODUCTS

[Known organic HAP emitted from the production of elastomer products]

Organic HAP/Chemical name (CAS No.)	Elastomer product/subcategory										
	BR	EPI	EPR	HYP	NEO	NBL	NBR	PBR/SBRS	PSR	SBL	SBRE
Acrylonitrile (107131)						X	X				
1,3 Butadiene (106990)						X	X	X		X	X
Carbon Disulfide						X	X	X		X	X
Carbon Tetrachloride (56235)				X							
Chlorobenzene (108907)				X							
Chloroform (67663)				X							
Chloroprene (126998)					X						
Epichlorohydrin (106898)		X									
Ethylbenzene (100414)	X									X	
Ethylene Dichloride (107062)									X		
Ethylene Oxide (75218)		X							X		
Formaldehyde (50000)		X							X		

TABLE 5 TO SUBPART U OF PART 63—KNOWN ORGANIC HAP EMITTED FROM THE PRODUCTION OF ELASTOMER PRODUCTS—Continued

[Known organic HAP emitted from the production of elastomer products]

Organic HAP/Chemical name (CAS No.)	Elastomer product/subcategory										
	BR	EPI	EPR	HYP	NEO	NBL	NBR	PBR/SBRS	PSR	SBL	SBRE
Hexane (110543)	X		X					X			
Methanol (67561)	X							X			
Methyl Chloride (74873)	X			X							
Propylene Oxide (75569)		X									
Styrene (100425)								X		X	X
Toluene (108883)		X	X		X			X			
Xylenes (1330207)	X										
Xylene (m-) (108383)	X										
Xylene (o-) (95476)	X										
Xylene (p-) (106423)	X										

CAS No. = Chemical Abstract Service Number.
 BR = Butyl Rubber.
 EPI = Epichlorohydrin Rubber.
 EPR = Ethylene Propylene Rubber.
 HYP = Hypalon™.
 NEO = Neoprene.
 NBL = Nitrile Butadiene Latex.
 NBR = Nitrile Butadiene Rubber.
 PBR/SBRS = Polybutadiene and Styrene Butadiene Rubber by Solution.
 PSR = Polysulfide Rubber.
 SBL = Styrene Butadiene Latex.
 SBRE = Styrene Butadiene Rubber by Emulsion.

Subpart Y—[Amended]

- 25–26. Section 63.560 is amended by:
- a. Adding paragraph (a)(4);
- b. Revising paragraph (d)(6); and
- c. Adding paragraph (e)(1)(iv) to read as follows:
- d. Table 1 to subpart Y of part 63 is amended by:
- 1. Revising entry 63.6(f)(1);
- 2. Removing entry 63.7(e);
- 3. Adding entries 63.7(e)(1) and 63.7(e)(2)–(4);
- 4. Removing entries 63.8(c)(1)(i), 63.8(c)(1)(ii), and 63.8(c)(1)(iii);
- 5. Adding entry 63.8(c)(1);
- 6. Removing entry 63.10(b)(2)(i);
- 7. Adding entry 63.10(b)(2)(i)–(ii);
- 8. Removing entry 63.10(b)(2)(ii)–(iii);

- 9. Adding entry 63.10(b)(2)(iii);
 - 10. Removing entry 63.10(c)(10)–(13); and
 - 11. Adding entries 63.10(c)(10)–(11) and 63.10(c)(12)–(13).
- The additions and revisions read as follows:

§ 63.560 Applicability and designation of affected source.

- (a) * * *
- (4) Existing sources with emissions less than 10 and 25 tons must meet the submerged fill standards of 46 CFR 153.282. This submerged fill requirement does not apply to petroleum refineries.
- * * * * *
- (d) * * *

(6) The provisions of this subpart do not apply to marine tank vessel loading operations at existing offshore loading terminals, as that term is defined in § 63.561, however existing offshore loading terminals must meet the submerged fill standards of 46 CFR 153.282.

* * * * *

(e) * * *

(1) * * *

(iv) Existing sources with emissions less than 10 and 25 tons, and existing offshore loading terminals, shall comply with the submerged fill requirements in paragraph (a)(4) and (d)(6) of this section by April 23, 2012.

* * * * *

TABLE 1 OF § 63.560—GENERAL PROVISIONS APPLICABILITY TO SUBPART Y

Reference	Applies to affected sources in subpart Y	Comment
63.6(f)(1)	No.	
63.7(e)(1)	No	See 63.563(b)(1). Any cross reference to 63.7(e)(1) in any other general provision incorporated by reference shall be treated as a cross-reference to 63.563(b)(1).
63.7(e)(2)–(4)	Yes.	
63.8(c)(1)	No.	
63.10(b)(2)(i)–(ii)	No	See 63.567(m).

TABLE 1 OF § 63.560—GENERAL PROVISIONS APPLICABILITY TO SUBPART Y—Continued

Reference	Applies to affected sources in subpart Y	Comment
63.10(b)(2)(iii)	Yes.	
63.10(c)(10)–(11)	No	See 63.567(m) for reporting malfunctions. Any cross-reference to 63.10(c)(10) or 63.10(c)(11) in any other general provision incorporated by reference shall be treated as a cross-reference to 63.567(m).
63.10(c)(12)–(13)	Yes.	

■ 27. Section 63.561 is amended by adding in alphabetical order a definition for “affirmative defense” to read as follows:

§ 63.561 Definitions.

* * * * *

Affirmative defense means, in the context of an enforcement proceeding, a response or a 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.

* * * * *

■ 28. Section 63.562 is amended by:
 ■ a. Revising paragraph (e) introductory text; and
 ■ b. Adding paragraph (e)(7) to read as follows:

§ 63.562 Standards.

* * * * *

(e) Operation and maintenance requirements for air pollution control equipment and monitoring equipment for affected sources. At all times, owners or operators of affected sources shall operate and maintain a source, including associated air pollution control equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. Determination of whether acceptable 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.

* * * * *

(7) 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 a malfunction, as defined in § 63.2. Appropriate penalties may be assessed, however, if the respondent fails to meet its burden of proving all the requirements in the affirmative defense. The affirmative defense shall not be available for claims for injunctive relief.

(i) To establish the affirmative defense in any action to enforce such a limit, the owners or operators of a facility must timely meet the notification requirements of paragraph (e)(7)(ii) of this section, and must prove by a preponderance of evidence that:

(A) The excess emissions were caused by a sudden, infrequent, and unavoidable failure of air pollution control and monitoring equipment, or a process to operate in a normal and usual manner; and could not have been prevented through careful planning, proper design or better operation and maintenance practices; and did not stem from any activity or event that could have been foreseen and avoided, or planned for; and were not part of a recurring pattern indicative of inadequate design, operation, or maintenance;

(B) 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;

(C) The frequency, amount and duration of the excess emissions (including any bypass) were minimized to the maximum extent practicable during periods of such emissions;

(D) 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;

(E) All possible steps were taken to minimize the impact of the excess

emissions on ambient air quality, the environment, and human health;

(F) All emissions monitoring and control systems were kept in operation if at all possible, consistent with safety and good air pollution control practices;

(G) All of the actions in response to the excess emissions were documented by properly signed, contemporaneous operating logs;

(H) At all times, the affected facility was operated in a manner consistent with good practices for minimizing emissions; and

(I) The owner or operator has prepared a written root cause analysis, 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 the best monitoring methods and engineering judgment, the amount of excess emissions that were the result of the malfunction.

(ii) *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 2 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 standard in this subpart to demonstrate, with all necessary supporting documentation, that it has met the requirements set forth in paragraph (e)(7)(i) 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.

■ 29. Section 63.563 is amended by revising paragraph (b)(1) to read as follows:

§ 63.563 Compliance and performance testing.

* * * * *

(b) * * *

(1) *Initial performance test.* An initial performance test shall be conducted using the procedures listed in § 63.7 of subpart A of this part according to the applicability in Table 1 of § 63.560, the procedures listed in this section, and the test methods listed in § 63.565. The initial performance test shall be conducted within 180 days after the compliance date for the specific affected source. During this performance test, sources subject to MACT standards under § 63.562(b)(2), (3), (4), and (5), and (d)(2) shall determine the reduction of HAP emissions, as VOC, for all combustion or recovery devices other than flares. 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. Sources subject to RACT standards under § 63.562(c)(3), (4), and (5), and (d)(2) shall determine the reduction of VOC emissions for all combustion or recovery devices other than flares.

* * * * *

■ 30. Section 63.567 is amended by adding paragraphs (m) and (n) to read as follows:

§ 63.567 Recordkeeping and reporting requirements.

* * * * *

(m) 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 shall be stated in a semiannual report. 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 § 63.562(e), including actions taken to correct a malfunction. The report, to be

certified by the owner or operator or other responsible official, shall be submitted semiannually and delivered or postmarked by the 30th day following the end of each calendar half.

(n)(1) As of January 1, 2012 and within 60 days after the date of completing each performance test, as defined in § 63.2, and as required in this subpart, you must submit performance test data, except opacity data, electronically to EPA's Central Data Exchange by using the ERT (see <http://www.epa.gov/ttn/chief/ert/tool.html>) or other compatible electronic spreadsheet. Only data collected using test methods compatible with ERT are subject to this requirement to be submitted electronically into EPA's WebFIRE database.

(2) All reports required by this subpart not subject to the requirements in paragraph (n)(1) of this section must be sent to the Administrator at the appropriate address listed in § 63.13. If acceptable to both the Administrator and the owner or operator of a source, these reports may be submitted on electronic media. The Administrator retains the right to require submittal of reports subject to paragraph (n)(1) of this section in paper format.

Subpart KK—[Amended]

■ 31. Section 63.820 is amended by adding paragraph (c) to read as follows:

§ 63.820 Applicability.

* * * * *

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

(1) To establish the affirmative defense in any action to enforce such a limit, the owners or operators of a facility must timely meet the notification requirements of paragraph (c)(2) of this section, and must prove by a preponderance of evidence that:

(i) The excess emissions were caused by a sudden, infrequent, and unavoidable failure of air pollution control and monitoring equipment, or a process to operate in a normal or usual manner; and could not have been prevented through careful planning, proper design or better operation and maintenance practices; and did not stem

from any activity or event that could have been foreseen and avoided, or planned for; and were not part of a recurring pattern indicative of inadequate design, operation, or maintenance;

(ii) 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;

(iii) The frequency, amount, and duration of the excess emissions (including any bypass) were minimized to the maximum extent practicable during periods of such emissions;

(iv) 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;

(v) All possible steps were taken to minimize the impact of the excess emissions on ambient air quality, the environment, and human health;

(vi) All emissions monitoring and control systems were kept in operation, if at all possible, consistent with safety and good air pollution control practices;

(vii) All of the actions in response to the excess emissions were documented by properly signed, contemporaneous operating logs;

(viii) At all times, the facility was operated in a manner consistent with good practices for minimizing emissions; and

(ix) The owner or operator has prepared a written root cause analysis, 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 the best monitoring methods and engineering judgment, the amount of excess emissions that were the result of the malfunction.

(2) *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 2 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 standard in this subpart to demonstrate, with all necessary supporting documentation,

that it has met the requirements set forth in paragraph (c)(1) 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.

■ 32. Section 63.822 is amended by adding in alphabetical order a definition for “affirmative defense” to paragraph (a) to read as follows:

§ 63.822 Definitions.

(a) * * *

Affirmative defense means, in the context of an enforcement proceeding, a response or a 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.

* * * * *

■ 33. Section 63.823 is revised to read as follows:

§ 63.823 Standards: General.

(a) Table 1 to this subpart provides cross references to the 40 CFR part 63, subpart A, general provisions, indicating the applicability of the general provisions requirements to this subpart KK.

(b) Each owner or operator of an affected source subject to this subpart must at all times operate and maintain that 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.

■ 34. Section 63.827 is amended by adding introductory text to read as follows:

§ 63.827 Performance test methods.

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.

* * * * *

■ 35. Section 63.829 is amended by adding paragraphs (g) and (h) to read as follows:

§ 63.829 Recordkeeping requirements.

* * * * *

(g) Each owner or operator of an affected source subject to this subpart shall maintain records of the occurrence and duration of each malfunction of operation (*i.e.*, process equipment), air pollution control equipment, or monitoring equipment.

(h) Each owner or operator of an affected source subject to this subpart shall maintain records of actions taken during periods of malfunction to minimize emissions in accordance with § 63.823(b), including corrective actions to restore malfunctioning process and air pollution control and monitoring equipment to its normal or usual manner of operation.

■ 36. Section 63.830 is amended by:

- a. Removing and reserving paragraph (b)(5);
- b. Adding paragraph (b)(6)(v); and
- c. Adding paragraph (c) to read as follows:

§ 63.830 Reporting requirements.

* * * * *

(b) * * *

(6) * * *

(v) 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 § 63.823(b), including actions taken to correct a malfunction.

(c)(1) As of January 1, 2012, and within 60 days after the date of completing each performance test, as defined in § 63.2 and as required in this subpart, you must submit performance test data, except opacity data, electronically to EPA’s Central Data Exchange by using the ERT (see <http://www.epa.gov/ttn/chief/ert/tool.html/>) or other compatible electronic spreadsheet. Only data collected using test methods compatible with ERT are subject to this requirement to be submitted electronically into EPA’s WebFIRE database.

(2) All reports required by this subpart not subject to the requirements in paragraph (c)(1) of this section must be sent to the Administrator at the appropriate address listed in § 63.13. If acceptable to both the Administrator and the owner or operator of a source, these reports may be submitted on electronic media. The Administrator retains the right to require submittal of reports subject to paragraph (c)(1) of this section in paper format.

■ 37. Table 1 to Subpart KK of part 63 is amended by:

- a. Removing entry 63.6(e);
- b. Adding entries 63.6(e)(1)(i), 63.6(e)(1)(ii); 63.6(e)(1)(iii), 63.6(e)(2), and 63.6(e)(3);
- c. Removing entry 63.6(f);
- d. Adding entries 63.6(f)(1) and 63.6(f)(2)–(f)(3);
- e. Removing entry 63.7;
- f. Adding entries 63.7(a)–(d), 63.7(e)(1), and 63.7(e)(2)–(e)(4);
- g. Removing entry 63.8(d)–(f);
- h. Adding entries 63.8(d)(1)–(2), 63.8(d)(3), and 63.8(e)–(f);
- i. Removing entries 63.10(b)(1)–(b)(3), 63.10(c)(10)–(c)(15), and 63.10(d)(4)–(d)(5);
- j. Adding entries 63.10(b)(1), 63.10(b)(2)(i), 63.10(b)(2)(ii), 63.10(b)(2)(iii), 63.10(b)(2)(iv)–(b)(2)(v), 63.10(b)(2)(vi)–(b)(2)(xiv), 63.10(b)(3), 63.10(c)(10), 63.10(c)(11), 63.10(c)(12)–(c)(14), 63.10(c)(15), 63.10(d)(4), and 63.10(d)(5) to read as follows:

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

General provisions reference	Applicable to subpart KK	Comment
* * * * *	* * * * *	* * * * *
§ 63.6(e)(1)(i)	No	See 63.823(b) for general duty requirement. Any cross-reference to 63.6(e)(1)(i) in any other general provision incorporated by reference shall be treated as a cross-reference to 63.823(b).

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

General provisions reference	Applicable to subpart KK	Comment
§ 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(f)(2)–(f)(3)	Yes.	
* * *	* * *	* * *
§ 63.7(a)–(d)	Yes.	
§ 63.7(e)(1)	No	See 63.827 introductory text. Any cross-reference to 63.7(e)(1) in any other general provision incorporated by reference shall be treated as a cross-reference to 63.827 introductory text.
§ 63.7(e)(2)–(e)(4)	Yes.	
* * *	* * *	* * *
§ 63.8(d)(1)–(2)	Yes.	
§ 63.8(d)(3)	Yes, except for last sentence.	
§ 63.8(e)–(f)	Yes.	
* * *	* * *	* * *
§ 63.10(b)(1)	Yes.	
§ 63.10(b)(2)(i)	No.	
§ 63.10(b)(2)(ii)	No	See 63.829(g) for recordkeeping of occurrence and duration of malfunctions. See 63.829(h) for recordkeeping of actions taken during malfunction. Any cross-reference to 63.10(b)(2)(ii) in any other general provision incorporated by reference shall be treated as a cross-reference to 63.829(g).
§ 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)(10)	No	See 63.830(b)(6)(v) for reporting malfunctions. Any cross-reference to 63.10(c)(10) in any other general provision incorporated by reference shall be treated as a cross-reference to 63.830(b)(6)(v).
§ 63.10(c)(11)	No	See 63.830(b)(6)(v) for reporting malfunctions. Any cross-reference to 63.10(c)(11) in any other general provision incorporated by reference shall be treated as a cross-reference to 63.830(b)(6)(v).
§ 63.10(c)(12)–(c)(14)	Yes.	
§ 63.10(c)(15)	No.	
* * *	* * *	* * *
§ 63.10(d)(4)	Yes.	
§ 63.10(d)(5)	No.	
* * *	* * *	* * *

Subpart GGG—[Amended]

■ 38. Section 63.1250 is amended by revising paragraph (g) to read as follows:

§ 63.1250 Applicability.

* * * * *

(g) *Applicability of this subpart.* (1) Each provision set forth in this subpart shall apply at all times, except that the provisions set forth in § 63.1255 of this subpart shall not apply during periods of nonoperation of the PMPU (or specific portion thereof) in which the lines are drained and depressurized resulting in the cessation of the emissions to which § 63.1255 of this subpart applies.

(2) The owner or operator shall not shut down items of equipment that are required or utilized for compliance with the emissions limitations of this subpart during times when emissions (or, where applicable, wastewater streams or residuals) are being routed to such items of equipment, if the shutdown would contravene emissions limitations of this subpart applicable to such items of equipment. This paragraph does not apply if the owner or operator must shut down the equipment to avoid damage to a PMPU or portion thereof.

(3) At all times, each owner or operator must operate and maintain any affected source subject to the requirements of this subpart, including associated air pollution control

equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require the owner or operator to make any further efforts to reduce emissions if levels required by this standard have been achieved. 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.

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

(i) To establish the affirmative defense in any action to enforce such a limit, the owners or operators of a facility must timely meet the notification requirements of paragraph (g)(4)(ii) of this section, and must prove by a preponderance of evidence that:

(A) The excess emissions were caused by a sudden, infrequent, and unavoidable failure of air pollution control and monitoring equipment, or a process to operate in a normal and usual manner; and could not have been prevented through careful planning, proper design, or better operation and maintenance practices; and did not stem from any activity or event that could have been foreseen and avoided, or planned for; and were not part of a recurring pattern indicative of inadequate design, operation, or maintenance;

(B) 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;

(C) The frequency, amount, and duration of the excess emissions (including any bypass) were minimized to the maximum extent practicable during periods of such emissions;

(D) 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;

(E) All possible steps were taken to minimize the impact of the excess emissions on ambient air quality, the environment, and human health;

(F) All emissions monitoring and control systems were kept in operation if at all possible, consistent with safety and good air pollution control practices;

(G) All of the actions in response to the excess emissions were documented by properly signed, contemporaneous operating logs;

(H) At all times, the facility was operated in a manner consistent with good practices for minimizing emissions; and

(I) The owner or operator has prepared a written root cause analysis, 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 the best monitoring methods and engineering judgment, the amount of excess emissions that were the result of the malfunction.

(ii) *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 2 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 standard in this subpart to demonstrate, with all necessary supporting documentation, that it has met the requirements set forth in paragraph (g)(4)(i) 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.

* * * * *

■ 39. Section 63.1251 is amended by adding in alphabetical order a definition for “affirmative defense” to read as follows:

§ 63.1251 Definitions.

* * * * *

Affirmative defense means, in the context of an enforcement proceeding, a response or a 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.

* * * * *

■ 40. Section 63.1255 is amended by revising paragraph (g)(4)(v)(A) to read as follows:

§ 63.1255 Standards: Equipment leaks.

* * * * *

- (g) * * *
- (4) * * *

(v) * * *

(A) The owner or operator may develop a written procedure that identifies the conditions that justify a delay of repair. The written procedures shall be included in a document that is maintained at the plant site. Reasons for delay of repair may be documented by citing the relevant sections of the written procedure.

* * * * *

■ 41. Section 63.1256 is amended by revising paragraph (a)(4)(i) introductory text, and removing paragraphs (a)(4)(iii) and (iv) to read as follows:

§ 63.1256 Standards: Wastewater.

(a) * * *

(4) * * *

(i) The owner or operator shall prepare a description of maintenance procedures for management of wastewater generated from the emptying and purging of equipment in the process during temporary shutdowns for inspections, maintenance, and repair (*i.e.*, a maintenance turnaround) and during periods which are not shutdowns (*i.e.*, routine maintenance). The descriptions shall be included in a document that is maintained at the plant site and shall:

* * * * *

■ 42. Section 63.1257 is amended by revising paragraph (a) introductory text and the first sentence of paragraph (e)(2)(iii)(A)(*θ*)(*ii*) to read as follows:

§ 63.1257 Test methods and compliance procedures.

(a) *General.* Except as specified in paragraph (a)(5) of this section, the procedures specified in paragraphs (c), (d), (e), and (f) of this section are required to demonstrate initial compliance with §§ 63.1253, 63.1254, 63.1256, and 63.1252(e), respectively. The provisions in paragraphs (a)(2) and (3) apply to performance tests that are specified in paragraphs (c), (d), and (e) of this section. The provisions in paragraph (a)(5) of this section are used to demonstrate initial compliance with the alternative standards specified in §§ 63.1253(d) and 63.1254(c). The provisions in paragraph (a)(6) of this section are used to comply with the outlet concentration requirements specified in §§ 63.1253(c), 63.1254(a)(2)(i), and (a)(3)(ii)(B), 63.1254(b)(i), and 63.1256(h)(2). Performance tests shall be conducted under such conditions representative of 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.

- * * * * *
- (e) * * *
- (2) * * *
- (iii) * * *
- (A) * * *
- (6) * * *

(ii) The owner or operator may consider the inlet to the equalization tank as the inlet to the biological treatment process if the wastewater is conveyed by hard-piping from either the last previous treatment process or the point of determination to the equalization tank; and the wastewater is conveyed from the equalization tank exclusively by hard-piping to the biological treatment process and no treatment processes or other waste management units are used to store, handle, or convey the wastewater between the equalization tank and the biological treatment process; and the equalization tank is equipped with a fixed roof and a closed-vent system that routes emissions to a control device that meets the requirements of § 63.1256(b)(1)(i) through (iv) and § 63.1256(b)(2)(i). * * *

§ 63.1258 [Amended]

- 43. Section 63.1258 is amended by removing paragraph (b)(8)(iv).
- 44. Section 63.1259 is amended by revising paragraph (a)(3) to read as follows:

§ 63.1259 Recordkeeping requirements.

(a) * * *

(3) *Malfunction records.* Each owner or operator of an affected source subject to this subpart shall maintain records of the occurrence and duration of each malfunction of operation (*i.e.*, process equipment), air pollution control

equipment, or monitoring equipment. Each owner or operator shall maintain records of actions taken during periods of malfunction to minimize emissions in accordance with § 63.1250(g)(3), including corrective actions to restore malfunctioning process and air pollution control and monitoring equipment to its normal or usual manner of operation.

- * * * * *
- 45. Section 63.1260 is amended by:
 - a. Revising paragraph (a);
 - b. Revising paragraph (i); and
 - c. Adding paragraph (n) to read as follows:

§ 63.1260 Reporting requirements.

(a) The owner or operator of an affected source shall comply with the reporting requirements of paragraphs (b) through (n) of this section. Applicable reporting requirements of §§ 63.9 and 63.10 are also summarized in Table 1 of this subpart.

(i) The owner or operator shall submit a report of 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 § 63.1250(g)(3), including actions taken to correct a malfunction. The report shall be submitted on the same schedule as the periodic reports required under paragraph (g) of this section.

(n)(1) As of January 1, 2012, and within 60 days after the date of completing each performance test, as

defined in § 63.2 and as required in this subpart, you must submit performance test data, except opacity data, electronically to EPA's Central Data Exchange by using the ERT (see http://www.epa.gov/ttn/chief/ert/ert_tool.html/) or other compatible electronic spreadsheet. Only data collected using test methods compatible with ERT are subject to this requirement to be submitted electronically into EPA's WebFIRE database.

(2) All reports required by this subpart not subject to the requirements in paragraphs (n)(1) of this section must be sent to the Administrator at the appropriate address listed in § 63.13. If acceptable to both the Administrator and the owner or operator of a source, these reports may be submitted on electronic media. The Administrator retains the right to require submittal of reports subject to paragraph (n)(1) of this section in paper format.

- 46. Table 1 to Subpart GGG is amended by:
 - a. Removing entry 63.6(e);
 - b. Adding entries 63.6(e)(1)(i), 63.6(e)(1)(ii), 63.6(e)(1)(iii), 63.6(e)(2), and 63.6(e)(3);
 - c. Removing entry 63.6(f)–(g);
 - d. Adding entries 63.6(f)(1), 63.6(f)(2)–(3), 63.6(g);
 - e. Removing entry 63.7(e);
 - f. Adding entries 63.7(e)(1) and 63.7(e)(2)–(4);
 - g. Removing entry 63.8(d);
 - h. Adding entries 63.8(d)(1)–(2) and 63.8(d)(3).
 - i. Removing entry 63.10(c)–(d)(2);
 - j. Adding entries 63.10(c)(1)–(9), 63.10(c)(10), 63.10(c)(11), 63.10(c)(12)–(14), 63.10(c)(15), and 63.10(d)(1)–(2);
 - k. Removing entry 63.10(d)(4–5); and
 - l. Adding entries 63.10(d)(4) and 63.10(d)(5) to read as follows:

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

General provisions reference	Summary of requirements	Applies to subpart GGG	Comments
§ 63.6(e)(1)(i)	Requirements during periods of startup, shutdown, and malfunction.	No	See 63.1250(g)(3) for general duty requirement. Any cross-reference to 63.6(e)(1)(i) in any other general provision incorporated by reference shall be treated as a cross-reference to 63.1250(g)(3).
§ 63.6(e)(1)(ii)	Malfunction correction requirements.	No.	
§ 63.6(e)(1)(iii)	Enforceability of operation and maintenance requirements.	Yes.	
§ 63.6(e)(2)	Reserved	No	Section reserved.
§ 63.6(e)(3)	Startup, shutdown, and malfunction plan requirements.	No.	

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

General provisions reference	Summary of requirements	Applies to subpart GGG	Comments
63.6(f)(1)	Applicability of non-opacity emission standards.	No.	
63.6(f)(2)–(3)	Methods of determining compliance and findings compliance.	Yes.	
63.6(g)	Use of an alternative nonopacity emission standard.	Yes.	
63.7(e)(1)	Conduct of performance tests.	No	See 63.1257(a) text. Any cross-reference to 63.7(e)(1) in any other general provision incorporated by reference shall be treated as a cross-reference to 63.1257(a).
63.7(e)(2)–(4)	Performance tests requirements.	Yes.	
63.8(d)(1)–(2)	CMS quality control program requirements.	Yes.	
63.8(d)(3)	CMS quality control program recordkeeping requirements.	Yes, except for last sentence.	
63.10(c)(1)–(9)	Additional recordkeeping requirements for sources with continuous monitoring systems.	Yes.	
63.10(c)(10)	Malfunction recordkeeping requirement.	No	Subpart GGG specifies recordkeeping requirements.
63.10(c)(11)	Malfunction corrective action recordkeeping requirement.	No	Subpart GGG specifies recordkeeping requirements.
63.10(c)(12)–(14)	Additional recordkeeping requirements for sources with continuous monitoring systems.	Yes.	
63.10(c)(15)	Additional SSM recordkeeping requirements.	No.	
63.10(d)(1)–(2)	General reporting requirements.	Yes.	
63.10(d)(4)	Progress report requirements.	Yes.	
63.10(d)(5)	Startup, shutdown, and malfunction report requirements.	No	Subpart GGG specifies reporting requirements.