

The EPA Administrator, Andrew R. Wheeler, signed the following notice on 01/05/2021, and EPA is submitting it for publication in the *Federal Register* (FR). While we have taken steps to ensure the accuracy of this Internet version of the rule, it is not the official version of the rule for purposes of compliance. Please refer to the official version in a forthcoming FR publication, which will appear on the Government Printing Office's govinfo website (<https://www.govinfo.gov/app/collection/fr>) and on Regulations.gov (<https://www.regulations.gov>) in Docket No. EPA-HQ-OAR-2020-0572. Once the official version of this document is published in the FR, this version will be removed from the Internet and replaced with a link to the official version.

6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 63**

**[EPA-HQ-OAR-2020-0572; FRL-10017-90-OAR]**

**RIN 2060-AU57**

### **National Emission Standards for Hazardous Air Pollutants: Flexible Polyurethane Foam Fabrication Operations Residual Risk and Technology Review and Flexible Polyurethane Foam Production and Fabrication Area Source Technology Review**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** This action presents the proposed results of the U.S. Environmental Protection Agency's (EPA's) residual risk and technology review (RTR) required under the Clean Air Act (CAA) for the National Emission Standards for Hazardous Air Pollutants (NESHAP) for major source Flexible Polyurethane Foam Fabrication Operations, initially promulgated in 2003.

Pursuant to the CAA, this action also presents the proposed results of the technology review for the NESHAP for two area source categories, Flexible Polyurethane Foam Production and Flexible Polyurethane Foam Fabrication, which are combined in one subpart initially promulgated in 2007. In this action, the EPA is proposing to establish a numeric emission limit for one major source subcategory; remove exemptions for periods of startup, shutdown, and malfunction (SSM) and specify that the emissions standards apply at all times; require periodic performance tests; and require electronic reporting of performance test results and compliance

reports. Implementation of these proposed rules is not expected to result in significant changes to the hazardous air pollutant (HAP) emissions from affected facilities in these three source categories or to human health impacts or environmental impacts associated with those emissions. However, this action, if finalized, would result in improved monitoring, compliance, and implementation of the existing standards and codify existing industry practices to prevent backsliding.

**DATES: Comments.** Comments must be received on or before **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

*Public hearing:* If anyone contacts us requesting a public hearing on or before **[INSERT DATE 5 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, we will hold a virtual public hearing. See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

**ADDRESSES:** You may send comments, identified by Docket ID No. EPA-HQ-OAR-2020-0572 by any of the following methods:

- Federal eRulemaking Portal: <https://www.regulations.gov/> (our preferred method).  
Follow the online instructions for submitting comments.
- Email: [a-and-r-docket@epa.gov](mailto:a-and-r-docket@epa.gov). Include Docket ID No. EPA-HQ-OAR-2020-0572- in the subject line of the message.
- Fax: (202) 566-9744. Attention Docket ID No. EPA-HQ-OAR-2020-0572.

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- Mail: U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA-HQ-OAR-2020-0572 EPA Mail Code 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.
- Hand/Courier Delivery: EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m. – 4:30 p.m., Monday – Friday (except federal holidays).

*Instructions:* All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to <https://www.regulations.gov/>, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via <https://www.regulations.gov/> or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** For questions about this proposed action, contact Dr. Tina Ndoh, Sector Policies and Programs Division (D243-04), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-1516; fax number: (919) 541-4991; and email address: [ndoh.tina@epa.gov](mailto:ndoh.tina@epa.gov). For specific information regarding the risk modeling methodology,

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contact Mr. Chris Sarsony, Health and Environmental Impacts Division (C539-02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-4843; fax number: (919) 541-0840; and email address: *sarsony.chris@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

*Participation in virtual public hearing.* Please note that the EPA is deviating from its typical approach for public hearings because the President has declared a national emergency. Due to the current Centers for Disease Control and Prevention (CDC) recommendations, as well as state and local orders for social distancing to limit the spread of COVID-19, the EPA cannot hold in-person public meetings at this time.

To request a virtual public hearing, contact the public hearing team at (888) 372-8699 or by email at *SPPDpublichearing@epa.gov*. If requested, the virtual hearing will be held on

**[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. The hearing will convene at 9:00 a.m. Eastern Time (ET) and will conclude at 3:00 p.m. ET. The EPA may close a session 15 minutes after the last pre-registered speaker has testified if there are no additional speakers. The EPA will announce further details at <https://www.epa.gov/stationary-sources-air-pollution/flexible-polyurethane-foam-fabrication-operations-national-emission>.

Upon publication of this document in the *Federal Register*, the EPA will begin pre-registering speakers for the hearing, if a hearing is requested. To register to speak at the virtual hearing, please use the online registration form available at <https://www.epa.gov/stationary-sources-air-pollution/flexible-polyurethane-foam-fabrication-operations-national-emission> or contact the public hearing team at (888) 372-8699 or by email at *SPPDpublichearing@epa.gov*.

The last day to pre-register to speak at the hearing will be **[INSERT DATE 12 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Prior to the hearing, the EPA

will post a general agenda that will list pre-registered speakers in approximate order at:

*<https://www.epa.gov/stationary-sources-air-pollution/flexible-polyurethane-foam-fabrication-operations-national-emission>*.

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearings to run either ahead of schedule or behind schedule.

Each commenter will have 5 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) by emailing it to *[ndoh.tina@epa.gov](mailto:ndoh.tina@epa.gov)*. The EPA also recommends submitting the text of your oral testimony as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *<https://www.epa.gov/stationary-sources-air-pollution/flexible-polyurethane-foam-fabrication-operations-national-emission>*. While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact the public hearing team at (888) 372-8699 or by email at *[SPPDpublichearing@epa.gov](mailto:SPPDpublichearing@epa.gov)* to determine if there are any updates. The EPA does not intend to publish a document in the *Federal Register* announcing updates.

If you require the services of a translator or a special accommodation such as audio description, please pre-register for the hearing with the public hearing team and describe your needs by **[INSERT DATE 7 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. The EPA may not be able to arrange accommodations without advanced notice.

*Docket.* The EPA has established a docket for this rulemaking under Docket ID No. EPA-HQ-OAR-2020-0572. All documents in the docket are listed in <https://www.regulations.gov/>. Although listed, 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. With the exception of such material, publicly available docket materials are available electronically in Regulations.gov.

*Instructions.* Direct your comments to Docket ID No. EPA-HQ-OAR-2020-0572. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <https://www.regulations.gov/>, including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted by mail as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional

submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit

*<https://www.epa.gov/dockets/commenting-epa-dockets>.*

The *<https://www.regulations.gov/>* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *<https://www.regulations.gov/>*, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *<https://www.epa.gov/dockets>*.

The EPA is temporarily suspending its Docket Center and Reading Room for public visitors, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *<https://www.regulations.gov/>* as there may be a delay in processing mail and faxes. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at *<https://www.epa.gov/dockets>*.

The EPA continues to carefully and continuously monitor information from the CDC, local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID-19.

*Submitting CBI.* Do not submit information containing CBI to the EPA through <https://www.regulations.gov/> or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404-02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA-HQ-OAR-2020-0572. Note that written comments containing CBI and submitted by mail may be delayed and no hand deliveries will be accepted.

*Preamble acronyms and abbreviations.* We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

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AEGL	acute exposure guideline level
AERMOD	air dispersion model used by the HEM-3 model
ATSDR	Agency for Toxic Substances and Disease Registry
CAA	Clean Air Act
CalEPA	California EPA
CBI	Confidential Business Information
CDC	Centers for Disease Control and Prevention
CDX	Central Data Exchange
CEDRI	Compliance and Emissions Data Reporting
CFR	Code of Federal Regulations
EPA	Environmental Protection Agency
ERPG	emergency response planning guideline
ERT	Electronic Reporting Tool
GACT	generally available control technology
HAP	hazardous air pollutant(s)
HCl	hydrochloric acid
HEM-3	Human Exposure Model, Version 1.5.5
HF	hydrogen fluoride
HI	hazard index
HQ	hazard quotient
IRIS	Integrated Risk Information System
km	kilometer
MACT	maximum achievable control technology
mg/m <sup>3</sup>	milligrams per cubic meter
MIR	maximum individual risk
NAICS	North American Industry Classification System
NATA	National Air Toxics Assessment
NEI	National Emissions Inventory
NESHAP	national emission standards for hazardous air pollutants
NSR	New Source Review
OAQPS	Office of Air Quality Planning and Standards
OMB	Office of Management and Budget
PB-HAP	hazardous air pollutants known to be persistent and bio-accumulative in the environment
PDF	portable document format
POM	polycyclic organic matter
ppm	parts per million

RBLC	Reasonably Available Control Technology, Best Available Control Technology, and Lowest Achievable Emission Rate Clearinghouse
REL	reference exposure level
RfC	reference concentration
RfD	reference dose
RTR	residual risk and technology review
SAB	Science Advisory Board
SDS	safety data sheets
SSM	startup, shutdown, and malfunction
TDI	toluene diisocyanate
TOSHI	target organ-specific hazard index
tpy	tons per year
TRI	Toxics Release Inventory
TRIM.FaTE	Total Risk Integrated Methodology.Fate, Transport, and Ecological Exposure model
UF	uncertainty factor
URE	unit risk estimate

*Organization of this document.* The information in this preamble is organized as follows:

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- B. What are the source categories and how do the current NESHAP regulate their HAP emissions?
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#### III. Analytical Procedures and Decision-Making

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- B. How do we perform the technology review?
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- A. What actions are we taking pursuant to CAA sections 112(d)(2) and 112(d)(3) for the Flexible Polyurethane Foam Fabrication Operations source category?
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- C. What are our proposed decisions regarding risk acceptability, ample margin of safety, and adverse environmental effect?

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- E. What other actions are we proposing?
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  - B. What are the air quality impacts?
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- VII. Submitting Data Corrections
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  - B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs
  - C. Paperwork Reduction Act (PRA)
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  - E. Unfunded Mandates Reform Act (UMRA)
  - F. Executive Order 13132: Federalism
  - G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
  - H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
  - I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
  - J. National Technology Transfer and Advancement Act (NTTAA)
  - K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

## **I. General Information**

### *A. Does this action apply to me?*

The source categories that are the subject of this proposal are Flexible Polyurethane Foam Fabrication Operations Major Sources regulated under 40 CFR part 63, subpart MMMMM, and Flexible Polyurethane Foam Production and Flexible Polyurethane Foam Fabrication Area Sources, regulated under 40 CFR part 63, subpart OOOOOO. The North American Industry Classification System (NAICS) code for fabricators of flexible polyurethane foam industry is 326150. This list of categories and NAICS codes is not intended to be

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exhaustive, but rather provides a guide for readers regarding the entities that this proposed action is likely to affect. The proposed standards, once promulgated, will be directly applicable to the affected sources. Federal, state, local, and tribal government entities would not be affected by this proposed action.

The Flexible Polyurethane Foam Fabrication Operations major source category was added to the EPA's HAP source category list in 1996. (61 FR 28197, June 4, 1996.) The NESHAP for that major source category, 40 CFR part 63, subpart M, was promulgated in 2003. (68 FR 18062, April 14, 2003.) The Flexible Polyurethane Foam Fabrication area source category was added to the EPA's HAP source category list in 1999. (64 FR 38706, July 19, 1999.) The Flexible Polyurethane Foam Production area source category was added to the EPA's HAP source category list in 2002. (67 FR 70427, November 22, 2002.) The Flexible Polyurethane Foam Production major source category, Part 63, subpart III, was included on the EPA's initial HAP source category list. (57 FR 31576, July 16, 1992.) The maximum achievable control technology (MACT) standards for subpart III were initially promulgated in 1998. (63 FR 53980, October 7, 1998.) The EPA established one area source NESHAP at 40 CFR part 63, subpart O, that applies to the two area source categories due to similarity of their operations and because they are often collocated. (72 FR 38864, July 16, 2007.)

The Flexible Polyurethane Foam Fabrication Operations major source category and the Flexible Polyurethane Foam Fabrication area source category include facilities engaged in cutting, gluing, and/or laminating pieces of flexible polyurethane foam. Those source categories include fabrication operations that are collocated with foam production plants as well as those located offsite from foam production plants. Emissions from foam fabrication primarily result from the lamination of polyurethane foam to adhere foam to other substrates and from the use of

HAP-based adhesives in the gluing process. The Flexible Polyurethane Foam Production area source category includes facilities that manufacture foam made from a polymer containing a plurality of carbamate linkages in the chain backbone (polyurethane). Polyurethane is commonly made by reacting a polyisocyanate with an organic polyhydroxyl material in the presence of water. Application of blowing agents, catalysts, surfactants, and fillers transform the polyurethane into a foam with specialized properties.

This proposed action addresses the major source NESHAP that applies to the Flexible Polyurethane Foam Fabrication Operations major source category and also addresses the area source NESHAP that applies to the Flexible Polyurethane Foam Production area source category and the Flexible Polyurethane Foam Fabrication area source category.

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

In addition to being available in the docket, an electronic copy of this action is available on the Internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at <https://www.epa.gov/stationary-sources-air-pollution/flexible-polyurethane-foam-fabrication-operations-national-emission>. Following publication in the *Federal Register*, the EPA will post the *Federal Register* version of the proposal and key technical documents at this same website. Information on the overall RTR program is available at <https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html>.

The proposed changes to the CFR that would be necessary to incorporate the changes proposed in this action are set out in an attachment to the memorandum titled *Proposed Regulation Edits for 40 CFR Part 63, Subparts M M M M M and O O O O O O*, available in the docket for this action (Docket ID No. EPA-HQ-OAR-2020-0572). This document includes the specific proposed amendatory language for revising the CFR and, for the convenience of

interested parties, a redline version of the regulations. Following signature by the EPA Administrator, the EPA will also post a copy of this memorandum and the attachment to <https://www.epa.gov/stationary-sources-air-pollution/flexible-polyurethane-foam-fabrication-operations-national-emission>.

## **II. Background**

### *A. What is the statutory authority for this action?*

The statutory authority for this action is provided by sections 112 and 301 of the CAA, as amended (42 U.S.C. 7401 *et seq.*). Section 112 of the CAA establishes a two-stage regulatory process to develop standards for emissions of HAP from stationary sources. Generally, the first stage involves establishing technology-based standards and the second stage involves evaluating those standards that are based on MACT to determine whether additional standards are needed to address any remaining risk associated with HAP emissions. This second stage is commonly referred to as the “residual risk review.” In addition to the residual risk review, the CAA also requires the EPA to review standards set under CAA section 112 every 8 years and revise the standards as necessary taking into account any “developments in practices, processes, or control technologies.” This review is commonly referred to as the “technology review.” When the two reviews are combined into a single rulemaking, it is commonly referred to as the “risk and technology review.” The discussion that follows identifies the most relevant statutory sections and briefly explains the contours of the methodology used to implement these statutory requirements. A more comprehensive discussion appears in the document titled *CAA Section 112 Risk and Technology Reviews: Statutory Authority and Methodology*, in the docket for this proposed rule (Docket ID No. EPA-HQ-OAR-2020-0572).

In the first stage of the CAA section 112 standard setting process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as

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emitting one or more of the HAP listed in CAA section 112(b). Sources of HAP emissions are either major sources or area sources, and CAA section 112 establishes different requirements for major source standards and area source standards. “Major sources” are those that emit or have the potential to emit 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any combination of HAP. All other sources are “area sources.” For major sources, CAA section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). These standards are commonly referred to as MACT standards. CAA section 112(d)(3) also establishes a minimum control level for MACT standards, known as the MACT “floor.” In certain instances, as provided in CAA section 112(h), the EPA may set work practice standards in lieu of numerical emission standards. The EPA must also consider control options that are more stringent than the floor. Standards more stringent than the floor are commonly referred to as beyond-the-floor standards. For area sources, CAA section 112(d)(5) gives the EPA discretion to set standards based on generally available control technologies or management practices (GACT standards) in lieu of MACT standards.

The second stage in standard-setting focuses on identifying and addressing any remaining (*i.e.*, “residual”) risk pursuant to CAA section 112(f). For source categories subject to MACT standards, section 112(f)(2) of the CAA requires the EPA to determine whether promulgation of additional standards is needed to provide an ample margin of safety to protect public health or to prevent an adverse environmental effect. Section 112(d)(5) of the CAA provides that this residual risk review is not required for categories of area sources subject to GACT standards. Section 112(f)(2)(B) of the CAA further expressly preserves the EPA’s use of the two-step approach for developing standards to address any residual risk and the Agency’s interpretation of

“ample margin of safety” developed in the National Emissions Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants (Benzene NESHAP) (54 FR 38044, September 14, 1989). The EPA notified Congress in the Residual Risk Report that the Agency intended to use the Benzene NESHAP approach in making CAA section 112(f) residual risk determinations (EPA-453/R-99-001, p. ES-11). The EPA subsequently adopted this approach in its residual risk determinations and the United States Court of Appeals for the District of Columbia Circuit (the court) upheld the EPA’s interpretation that CAA section 112(f)(2) incorporates the approach established in the Benzene NESHAP. See *NRDC v. EPA*, 529 F.3d 1077, 1083 (D.C. Cir. 2008).

The approach incorporated into the CAA and used by the EPA to evaluate residual risk and to develop standards under CAA section 112(f)(2) is a two-step approach. In the first step, the EPA determines whether risks are acceptable. This determination “considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual lifetime [cancer] risk (MIR)<sup>1</sup> of approximately 1 in 10 thousand.” (54 FR at 38045). If risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level without considering costs. In the second step of the approach, the EPA considers whether the emissions standards provide an ample margin of safety to protect public health “in consideration of all health information, including the number of persons at risk levels higher than approximately 1 in 1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular

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<sup>1</sup> Although defined as “maximum individual risk,” MIR refers only to cancer risk. MIR, one metric for assessing cancer risk, is the estimated risk if an individual were exposed to the maximum level of a pollutant for a lifetime.



decision.” *Id.* The EPA must promulgate emission standards necessary to provide an ample margin of safety to protect public health or determine that the standards being reviewed provide an ample margin of safety without any revisions. After conducting the ample margin of safety analysis, we consider whether a more stringent standard is necessary to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

CAA section 112(d)(6) separately requires the EPA to review standards promulgated under CAA section 112 and revise them “as necessary (taking into account developments in practices, processes, and control technologies)” no less often than every 8 years. In conducting this review, which we call the “technology review,” the EPA is not required to recalculate the MACT floor. *Natural Resources Defense Council (NRDC) v. EPA*, 529 F.3d 1077, 1084 (D.C. Cir. 2008). *Association of Battery Recyclers, Inc. v. EPA*, 716 F.3d 667 (D.C. Cir. 2013). The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6). The EPA is required to address regulatory gaps, such as missing standards for listed air toxics known to be emitted from the source category. *Louisiana Environmental Action Network (LEAN) v. EPA*, 955 F.3d 1088 (D.C. Cir. 2020). Section 112(k)(3)(B) of the CAA required the EPA to identify at least 30 HAP that pose the greatest potential health threat in urban areas, and CAA section 112(c)(3) requires the EPA to regulate the area source categories that represent 90 percent of the emissions of the 30 “listed” HAP (“urban HAP”).

*B. What are the source categories and how do the current NESHAP regulate their HAP emissions?*

For both the Flexible Polyurethane Foam Fabrication Operations major source category and the Flexible Polyurethane Foam Fabrication area source category, operations involve cutting, bonding, and/or laminating pieces of flexible polyurethane foam together or to other substrates.

Typical bonding techniques include gluing, taping, and flame lamination. In years preceding the This document is a prepublication version, signed by EPA Administrator, Andrew R. Wheeler on 01/05/2021. We have taken steps to ensure the accuracy of this version, but it is not the official version.

listing of the flexible polyurethane foam fabrication major and area source categories, some foam fabrication operations may have used methylene chloride-based adhesives to adhere pieces of foam together; however, the industry no longer uses any methylene chloride-based adhesives. Most foam fabrication adhesives are applied by workers using spray guns. Application of adhesives is typically performed in large open rooms, with workstations spaced along a conveyor that moves the pieces of foam to be glued together. Loop slitter adhesive use is a specialized type of foam fabrication adhesive use. Loop slitters are equipment used at slabstock foam production and/or fabrication facilities to slice large foam “buns” into thin sheets. Adhesive is used to attach the ends of the foam buns to one another before they are mounted on the loop slitter. The amount of adhesive used for loop slitters is relatively low because the adhesive is not applied continuously, just once or twice per shift when the foam buns are loaded onto the loop slitter. Flame lamination refers to the bonding of foam to any substrate (*e.g.*, fabric, foam, plastic) where the bonding agent is scorched or melted foam. Thin sheets of foam are passed under a flame which scorches the foam surface and makes it sticky. The tacky foam sheet is then applied and adhered to a substrate.

The Flexible Polyurethane Foam Production area source category includes facilities that manufacture foam made from polyurethanes, which are in the class of compounds called “reaction polymers.” Application of blowing agents, catalysts, surfactants, and fillers transforms the polyurethane into a foam with specialized properties. There are three types of polyurethane foam production facilities: slabstock flexible polyurethane foam (slabstock foam), molded flexible polyurethane foam (molded foam), and rebond foam. Slabstock foam is produced in large continuous buns that are then cut into the desired size and shape. Slabstock foam is used in a wide variety of applications, including furniture and mattresses. Molded foam is produced by

“shooting” the foam mixture into a mold of the desired shape and size. Molded foam is used in office furniture, automobile seats, novelties, and many other applications. Rebond foam is made from scrap foam that is converted into a material primarily used for carpet underlay.

The EPA estimates that there are 32 facilities currently subject to the area source standards, of which approximately 20 are believed to be owned by small businesses.

The EPA promulgated MACT standards for major source Flexible Polyurethane Foam Fabrication Operations facilities in 2003 under 40 CFR part 63, subpart M. The standards apply to major sources of HAP at existing and new flexible polyurethane foam fabrication facilities. Because of their potential to generate HAP emissions, the processing units of interest at foam fabrication facilities are loop slitters and flame lamination units. The MACT standards for Flexible Polyurethane Foam Fabrication Operations require HAP emissions reductions and control for new flame lamination units and prohibit use of HAP-based adhesives in new and existing loop slitting operations. For new flame lamination units, a 90-percent reduction in HAP emissions is required. For existing flame lamination units, there are currently no MACT emission limits. For new and existing loop slitters, the MACT standards prohibit use of any adhesive containing 5 percent or more (by weight) of total HAP. The EPA estimates that there are currently three facilities subject to subpart M—two in Indiana, and one in New Mexico.

Both the Flexible Polyurethane Foam Production and Flexible Polyurethane Fabrication Operations area source categories were listed for regulation due to emissions of the urban HAP methylene chloride. At the time of the initial area source standards promulgation, methylene chloride was the only urban HAP used at foam production and foam fabrication facilities. Now, however, there are no known urban HAP used at foam production and foam fabrication facilities.

In the past, slabstock foam production facilities sometimes used methylene chloride as an auxiliary blowing agent to control the density and other properties of the foam as it expanded during the pouring process.<sup>2</sup> Methylene chloride was also sometimes used as an equipment cleaner, in particular for mix heads. A small number of molded and rebond foam facilities used methylene chloride in mold release agents, and some molded foam facilities used it as a mixhead cleaner. Foam fabricators used methylene chloride-based adhesives to adhere pieces of foam to one another. Flame laminators have never used methylene chloride and, as such, are not regulated by the area source standards.

In 2007, the EPA promulgated GACT standards for the Flexible Polyurethane Foam Production area source category and the Flexible Polyurethane Foam Fabrication area source category together under 40 CFR part 63, subpart OOOOOO. The GACT standards required that methylene chloride be significantly reduced or eliminated from slabstock foam production, molded foam release agents, equipment cleaning, rebond foam mold release agents, and from foam fabrication adhesive use. Although both area source categories were listed for regulation due to emissions of the urban HAP methylene chloride, the EPA finds that methylene chloride is no longer used within either source category.

*C. What data collection activities were conducted to support this action?*

For the Flexible Foam Fabrication Operations NESHAP RTR, the EPA used emissions and supporting data from the 2017 and 2014 National Emissions Inventory (NEI), 2018 and 2019 Toxics Release Inventory (TRI) data, and 2014 stack test data from one facility to develop the

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<sup>2</sup> Other regulations address methylene chloride. For example, the EPA listed methylene chloride as an unacceptable (prohibited) blowing agent for use in flexible polyurethane under section 612 of the CAA (81 FR 86778, December 1, 2016).

model input files for the residual risk assessments for major source flexible foam fabrication facilities.

The NEI is a database that contains information about sources that emit criteria air pollutants, their precursors, and HAP. The database includes estimates of annual air pollutant emissions from point, nonpoint, and mobile sources in the 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. The EPA collects this information and releases an updated version of the NEI database every 3 years. The NEI includes data necessary for conducting risk modeling, including annual HAP emissions estimates from individual emission sources at facilities and the related emissions release parameters. In certain cases, we contacted state inventory compilers and facility owners or operators to confirm and clarify the sources of emissions, emissions estimates, and release parameters that were reported in the NEI.

The TRI is a resource for learning about toxic chemical releases and pollution prevention activities reported by industrial and federal facilities. The TRI tracks the management of certain toxic chemicals that may pose a threat to human health and the environment. U.S. facilities in different industry sectors must report annually how much of each chemical is released to the environment and/or managed through recycling, energy recovery, and treatment.<sup>3</sup>

Additional information on the development of the modeling file can be found in Appendix 1 to the *Residual Risk Assessment for the Flexible Polyurethane Foam Fabrication Operations Source Category in Support of the 2020 Risk and Technology Review Proposed Rule*, which is available in the docket for this proposed rule (Docket ID No. EPA-HQ-OAR-2020-0572).

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<sup>3</sup> Available at <https://www.epa.gov/toxics-release-inventory-tri-program>.

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For the Flexible Foam Production and Fabrication area source standards, we relied on information provided by industry to determine whether any urban HAP were emitted from the regulated facilities. Through industry meetings and email and telephone conversations, the EPA found that there are no additional urban HAP emitted from flexible foam production and fabrication facilities subject to area source standards. Detailed information of the technology review can be found in the memorandum titled *Technology Review for the Flexible Polyurethane Foam Production and Fabrication Area Source Categories*, which is available in the docket for this proposed rule (Docket ID No. EPA-HQ-OAR-2020-0572).

The Flexible Polyurethane Foam Production and Flexible Polyurethane Foam Fabrication MACT standards were promulgated in 1998 and 2003 respectively. Since that time, the EPA has developed air toxics regulations for a number of additional source categories that emit HAP from the same types of emission sources that are present in the Flexible Polyurethane Foam Production and Fabrication source categories. In air toxic regulatory actions carried out subsequent to the initial MACT standard development for these source categories, the EPA has consistently evaluated any new practices, processes, and control technologies. A review of these initial and subsequent air toxics regulations, including supporting documentation used in the rulemakings, was conducted to determine whether any practices, processes, or control technologies could be applied to the Flexible Foam Fabrication source category.

One potential development in practices, processes, and control technologies was identified through the review of other air toxics regulations, which is discussed further in section IV.D of this document.

*D. What other relevant background information and data are available?*

For the risk review portion of the RTR, we reviewed facility permits for the three major sources subjected to the Flexible Polyurethane Foam Fabrication Operations NESHAP. Facility permits provide data on maximum allowable emissions and other relevant production and emission factors.

For the technology review portion of the RTR, we collected information from the Reasonably Available Control Technology, Best Available Control Technology, and Lowest Achievable Emission Rate Clearinghouse (RBLC) to identify developments in practices, processes, and control technologies since the MACT standards were developed. The RBLC is a database that contains case-specific information on air pollution technologies that have been required to reduce the emissions of air pollutants from stationary sources. Under the EPA's New Source Review (NSR) program, if a facility is planning new construction or a modification that will increase the air emissions above certain defined thresholds, an NSR permit must be obtained. The RBLC promotes the sharing of information among permitting agencies and aids in case-by-case determinations for NSR permits. We examined information contained in the RBLC to determine what technologies are currently used for these source categories to reduce air emissions. Additional information about these data collection activities for the technology reviews is contained in the technology review memorandum titled *Technology Review for the Flexible Polyurethane Foam Fabrication Operations Source Category*, which is available in the docket for this proposed rule (Docket ID No. EPA-HQ-OAR-2020-0572).

The RBLC provides several options for searching the permit database on-line to locate applicable control technologies. Our initial search of the RBLC specified processes in polyurethane foam products manufacturing, with permits dating back to 2001. This search did not provide any results for foam fabrication operations. Further searches of the database were

conducted based on relevant keywords. The search included all available data fields, which among others, included the following:

- RBLC ID;
- Facility Name and State;
- Permit Date;
- Process name;
- Throughput;
- Pollutant;
- Control technology;
- Percent efficiency of control; and
- Pollutants/Compliance Notes.

The results of this search are presented in Appendix 1 of the *Technology Review for the Flexible Polyurethane Foam Manufacturing Source Category*. As shown in Appendix 1, no control technologies more stringent than the Flexible Polyurethane Foam NESHAP were identified through this search.

Two of the three facilities subject to major source standards have loop slitter operations and use adhesives. Both facilities provided the EPA with safety data sheets (SDS) for the adhesives in use. Those SDS were used to determine chemical composition and potential HAP emissions from the adhesives. Additional background information on adhesive use and regulation was collected through review of other NESHAP in similar industrial sectors. Specifically, we searched for other NESHAP regulating HAP emissions from coatings and adhesives and compared the stringency of those standards to the existing requirements for HAP adhesives for loop slitters. Data from the SDS provided and the NESHAP for similar source



categories were also used in the technology evaluation for the Flexible Polyurethane Foam Fabrication Operations NESHAP. The findings for the technology review are discussed further in section IV.D of this preamble.

### **III. Analytical Procedures and Decision-Making**

In this section, we describe the analyses performed to support the proposed decisions for the RTR and other issues addressed in this proposal.

In this proposed action, pursuant to CAA section 112(f), the EPA is conducting a risk review for the major source NESHAP (40 CFR part 63, subpart M) MACT standards for Flexible Polyurethane Foam Fabrication Operations. Consistent with the provision regarding alternative standards for area sources in CAA section 112(d)(5), the risk review does not cover the NESHAP for area sources. Therefore, the discussions of risk assessment methods and modeling analyses described in the following paragraphs only apply to the major source category.

However, pursuant to CAA section 112(d)(6), the EPA is proposing the technology review for both the major source NESHAP and the area source NESHAP (40 CFR part 63, subpart O). Therefore, the discussions in the paragraphs below regarding how the EPA conducted the technology reviews apply to both major sources and area sources.

#### *A. How do we consider risk in our decision-making?*

As discussed in section II.A of this preamble and in the Benzene NESHAP, in evaluating and developing standards under CAA section 112(f)(2), we apply a two-step approach to determine whether or not risks are acceptable and to determine if the standards provide an ample margin of safety to protect public health. As explained in the Benzene NESHAP, “the first step judgment on acceptability cannot be reduced to any single factor” and, thus, “[t]he Administrator believes that the acceptability of risk under section 112 is best judged on the basis of a broad set of factors.” This document is a prepublication version, signed by EPA Administrator, Andrew R. Wheeler on 01/05/2021. We have taken steps to ensure the accuracy of this version, but it is not the official version.

of health risk measures and information.” (54 FR at 38046). Similarly, with regard to the ample margin of safety determination, “the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including cost and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors.” *Id.*

The Benzene NESHAP approach provides flexibility regarding factors the EPA may consider in making determinations and how the EPA may weigh those factors for each source category. The EPA conducts a risk assessment that provides estimates of the MIR posed by emissions of HAP that are carcinogens from each source in the source category, the hazard index (HI) for chronic exposures to HAP with the potential to cause noncancer health effects, and the hazard quotient (HQ) for acute exposures to HAP with the potential to cause noncancer health effects.<sup>4</sup> The assessment also provides estimates of the distribution of cancer risk within the exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The scope of the EPA’s risk analysis is consistent with the explanation in the EPA’s response to comments on our policy under the Benzene NESHAP:

The policy chosen by the Administrator permits consideration of multiple measures of health risk. Not only can the MIR figure be considered, but also incidence, the presence of non-cancer health effects, and the uncertainties of the risk estimates. In this way, the effect on the most exposed individuals can be reviewed as well as the impact on the general public. These factors can then be weighed in each individual case. This approach complies with the *Vinyl Chloride* mandate that the Administrator ascertain an acceptable level of risk to the public by employing his expertise to assess available data. It also complies with the Congressional intent behind the CAA, which did not exclude the use of any particular measure of public health risk from the EPA's consideration with respect to CAA section 112 regulations, and thereby implicitly permits consideration of any and all

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<sup>4</sup> The MIR is defined as the cancer risk associated with a lifetime of exposure at the highest concentration of HAP where people are likely to live. The HQ is the ratio of the potential HAP exposure concentration to the noncancer dose-response value; the HI is the sum of HQs for HAP that affect the same target organ or organ system.

measures of health risk which the Administrator, in his judgment, believes are appropriate to determining what will “protect the public health”.

(54 FR at 38057). Thus, the level of the MIR is only one factor to be weighed in determining acceptability of risk. The Benzene NESHAP explained that “an MIR of approximately one in 10 thousand should ordinarily be the upper end of the range of acceptability. As risks increase above this benchmark, they become presumptively less acceptable under CAA section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability. Or, the Agency may find, in a particular case, that a risk that includes an MIR less than the presumptively acceptable level is unacceptable in the light of other health risk factors.” *Id.* at 38045. In other words, risks that include an MIR above 100-in-1 million may be determined to be acceptable, and risks with an MIR below that level may be determined to be unacceptable, depending on all of the available health information. Similarly, with regard to the ample margin of safety analysis, the EPA stated in the Benzene NESHAP that: “EPA believes the relative weight of the many factors that can be considered in selecting an ample margin of safety can only be determined for each specific source category. This occurs mainly because technological and economic factors (along with the health-related factors) vary from source category to source category.” *Id.* at 38061. We also consider the uncertainties associated with the various risk analyses, as discussed earlier in this preamble, in our determinations of acceptability and ample margin of safety.

The EPA notes that it has not considered certain health information to date in making residual risk determinations. At this time, we do not attempt to quantify the HAP risk that may be associated with emissions from other facilities that do not include the source category under review, mobile source emissions, natural source emissions, persistent environmental pollution, or atmospheric transformation in the vicinity of the sources in the category.

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The EPA understands the potential importance of considering an individual's total exposure to HAP in addition to considering exposure to HAP emissions from the source category and facility. We recognize that such consideration may be particularly important when assessing noncancer risk, where pollutant-specific exposure health reference levels (*e.g.*, reference concentrations (RfCs)) are based on the assumption that thresholds exist for adverse health effects. For example, the EPA recognizes that, although exposures attributable to emissions from a source category or facility alone may not indicate the potential for increased risk of adverse noncancer health effects in a population, the exposures resulting from emissions from the facility in combination with emissions from all of the other sources (*e.g.*, other facilities) to which an individual is exposed may be sufficient to result in an increased risk of adverse noncancer health effects. In May 2010, the Science Advisory Board (SAB) advised the EPA "that RTR assessments will be most useful to decision makers and communities if results are presented in the broader context of aggregate and cumulative risks, including background concentrations and contributions from other sources in the area."<sup>5</sup>

In response to the SAB recommendations, the EPA incorporates cumulative risk analyses into its RTR risk assessments. The Agency (1) conducts facility-wide assessments, which include source category emission points, as well as other emission points within the facilities; (2) combines exposures from multiple sources in the same category that could affect the same individuals; and (3) for some persistent and bioaccumulative pollutants, analyzes the ingestion route of exposure. In addition, the RTR risk assessments consider aggregate cancer risk from all

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<sup>5</sup> Recommendations of the SAB Risk and Technology Review Methods Panel are provided in their report, which is available at:  
[https://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/\\$File/EP A-SAB-10-007-unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/$File/EP A-SAB-10-007-unsigned.pdf).

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carcinogens and aggregated noncancer HQs for all noncarcinogens affecting the same target organ or target organ system.

Although we are interested in placing source category and facility-wide HAP risk in the context of total HAP risk from all sources combined in the vicinity of each source, we are concerned about the uncertainties of doing so. Estimates of total HAP risk from emission sources other than those that we have studied in depth during this RTR review would have significantly greater associated uncertainties than the source category or facility-wide estimates. Such aggregate or cumulative assessments would compound those uncertainties, making the assessments too unreliable.

*B. How do we perform the technology review?*

Our technology review primarily focuses on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the MACT standards were promulgated. Where we identify such developments, we analyze their technical feasibility, estimated costs, energy implications, and non-air environmental impacts. We also consider the emission reductions associated with applying each development. This analysis informs our decision of whether it is “necessary” to revise the emissions standards. In addition, we consider the appropriateness of applying controls to new sources versus retrofitting existing sources. For this exercise, we consider any of the following to be a “development”:

- Any add-on control technology or other equipment that was not identified and considered during development of the original MACT standards;
- Any improvements in add-on control technology or other equipment (that were identified and considered during development of the original MACT standards) that could result in additional emissions reduction;

- Any work practice or operational procedure that was not identified or considered during development of the original MACT standards;
- Any process change or pollution prevention alternative that could be broadly applied to the industry and that was not identified or considered during development of the original MACT standards; and
- Any significant changes in the cost (including cost effectiveness) of applying controls (including controls the EPA considered during the development of the original MACT standards).

In addition to reviewing the practices, processes, and control technologies that were considered at the time we originally developed the NESHAP, we review a variety of data sources in our investigation of potential practices, processes, or controls to consider. We also review the NESHAP and the available data to determine if there are any unregulated emissions of HAP within the source category and evaluate this data for use in developing new emission standards. See sections II.C and II.D of this preamble for information on the specific data sources that were reviewed as part of the technology review.

*C. How do we estimate post-MACT risk posed by the source category?*

In this section, we provide a complete description of the types of analyses that we generally perform during the risk assessment process. In some cases, we do not perform a specific analysis because it is not relevant. For example, in the absence of emissions of HAP known to be persistent and bioaccumulative in the environment (PB-HAP), we would not perform a multipathway exposure assessment. Where we do not perform an analysis, we state that we do not and provide the reason. While we present all of our risk assessment methods, we

only present risk assessment results for the analyses actually conducted (see section IV.B of this preamble).

The EPA conducts a risk assessment that provides estimates of the MIR for cancer posed by the HAP emissions from each source in the source category, the HI for chronic exposures to HAP with the potential to cause noncancer health effects, and the HQ for acute exposures to HAP with the potential to cause noncancer health effects. The assessment also provides estimates of the distribution of cancer risk within the exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The seven sections that follow this paragraph describe how we estimated emissions and conducted the risk assessment. The docket for this proposed rule contains the following document that provides more information on the risk assessment inputs and models: *Residual Risk Assessment for the Flexible Polyurethane Foam Fabrication Operations Source Category in Support of the 2020 Risk and Technology Review Proposed Rule*. The methods used to assess risk (as described in the seven primary steps below) are consistent with those described by the EPA in the document reviewed by a panel of the EPA's SAB in 2009;<sup>6</sup> and described in the SAB review report issued in 2010. They are also consistent with the key recommendations contained in that report.

1. How did we estimate actual emissions and identify the emissions release characteristics?

The actual emissions and the emission release characteristics for each facility were obtained primarily from either the 2014 NEI or the 2017 NEI; most data were obtained from the 2017 NEI, unless a facility was not included in that base year file, in which case the 2014 NEI

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<sup>6</sup> U.S. EPA. *Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing*, June 2009. EPA-452/R-09-006. Available at: <https://www3.epa.gov/airtoxics/rrisk/rtrpg.html>.

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data were used. In one instance, a facility was contacted to confirm emissions that appeared to be outliers because they were inconsistent with our understanding of the industry. That facility provided a test report containing data that were more consistent with our understanding of emissions from the industry and were ultimately used as actual emissions for the risk modeling file. Additional information on the development of the modeling file for the Flexible Polyurethane Foam Fabrication Operations source category, including the development of the actual emissions and emissions release characteristics, can be found in the memorandum, *Emissions Data for the National Emission Standards for Hazardous Air Pollutants for Flexible Polyurethane Foam Fabrication Operations*, which is available in the respective docket for this action.

## 2. How did we estimate MACT-allowable emissions?

The available emissions data in the RTR emissions dataset include estimates of the mass of HAP emitted during a specified annual time period. These “actual” emission levels are often lower than the emission levels allowed under the requirements of the current MACT standards. The emissions allowed under the MACT standards are referred to as the “MACT-allowable” emissions. We discussed the consideration of both MACT-allowable and actual emissions in the final Coke Oven Batteries RTR (70 FR 19992, 19998 and 19999, April 15, 2005) and in the proposed and final Hazardous Organic NESHAP RTR (71 FR 34421, 34428, June 14, 2006, and 71 FR 76603, 76609, December 21, 2006, respectively). In those actions, we noted that assessing the risk at the MACT-allowable level is inherently reasonable since that risk reflects the maximum level facilities could emit and still comply with national emission standards. We also explained that it is reasonable to consider actual emissions, where such data are available, in both steps of the risk analysis, in accordance with the Benzene NESHAP approach (54 FR 38044).



For the Flexible Polyurethane Foam Fabrication Operations source category, allowable emissions were assumed to be equal to actual emissions. For the subcategory of flame laminators, there currently are no emissions limits for existing sources, and there have been no new sources since the promulgation of the standards. Therefore, we conclude that the emissions that are allowed under the existing standards are equal to actual emissions. For the loop slitter subcategory, there were no HAP emissions from the adhesive, and we are not aware of any HAP-based substitutes that could be used in place of current industry practice; therefore, we again conclude that allowable emissions would be equal to actual emissions, which in this case are zero.

3. How do we conduct dispersion modeling, determine inhalation exposures, and estimate individual and population inhalation risk?

Both long-term and short-term inhalation exposure concentrations and health risk from the major source category addressed in this proposal were estimated using the Human Exposure Model (HEM-3).<sup>7</sup> The HEM-3 performs three primary risk assessment activities: (1) conducting dispersion modeling to estimate the concentrations of HAP in ambient air, (2) estimating long-term and short-term inhalation exposures to individuals residing within 50 kilometers (km) of the modeled sources, and (3) estimating individual and population-level inhalation risk using the exposure estimates and quantitative dose-response information.

#### a. Dispersion Modeling

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<sup>7</sup> For more information about HEM-3, go to <https://www.epa.gov/fera/risk-assessment-and-modeling-human-exposure-model-hem>.

The air dispersion model AERMOD, used by the HEM-3 model, is one of the EPA's preferred models for assessing air pollutant concentrations from industrial facilities.<sup>8</sup> To perform the dispersion modeling and to develop the preliminary risk estimates, HEM-3 draws on three data libraries. The first is a library of meteorological data, which is used for dispersion calculations. This library includes 1 year (2016) of hourly surface and upper air observations from 824 meteorological stations selected to provide coverage of the United States and Puerto Rico. A second library of United States Census Bureau census block<sup>9</sup> internal point locations and populations provides the basis of human exposure calculations (U.S. Census, 2010). In addition, for each census block, the census library includes the elevation and controlling hill height, which are also used in dispersion calculations. A third library of pollutant-specific dose-response values is used to estimate health risk. These are discussed below.

#### b. Risk from Chronic Exposure to HAP

In developing the risk assessment for chronic exposures, we use the estimated annual average ambient air concentrations of each HAP emitted by each source in the major source category. The HAP air concentrations at each nearby census block centroid located within 50 km of the facility are a surrogate for the chronic inhalation exposure concentration for all the people who reside in that census block. A distance of 50 km is consistent with both the analysis supporting the 1989 Benzene NESHAP (54 FR 38044, September 14, 1989) and the limitations of Gaussian dispersion models, including AERMOD.

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<sup>8</sup> U.S. EPA. Revision to the *Guideline on Air Quality Models: Adoption of a Preferred General Purpose (Flat and Complex Terrain) Dispersion Model and Other Revisions* (70 FR 68218, November 9, 2005).

<sup>9</sup> A census block is the smallest geographic area for which census statistics are tabulated.

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For each facility, we calculate the MIR as the cancer risk associated with a continuous lifetime (24 hours per day, 7 days per week, 52 weeks per year, 70 years) exposure to the maximum concentration at the centroid of each inhabited census block. We calculate individual cancer risk by multiplying the estimated lifetime exposure to the ambient concentration of each HAP (in micrograms per cubic meter) by its unit risk estimate (URE). The URE is an upper-bound estimate of an individual's incremental risk of contracting cancer over a lifetime of exposure to a concentration of 1 microgram of the pollutant per cubic meter of air. For residual risk assessments, we generally use UREs from the EPA's Integrated Risk Information System (IRIS). For carcinogenic pollutants without IRIS values, we look to other reputable sources of cancer dose-response values, often using California EPA (CalEPA) UREs, where available. In cases where new, scientifically credible dose-response values have been developed in a manner consistent with the EPA guidelines and have undergone a peer review process similar to that used by the EPA, we may use such dose-response values in place of, or in addition to, other values, if appropriate. The pollutant-specific dose-response values used to estimate health risk are available at <https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants>.

To estimate individual lifetime cancer risks associated with exposure to HAP emissions from each facility in the source category, we sum the risks for each of the carcinogenic HAP<sup>10</sup> emitted by the modeled facility. We estimate cancer risk at every census block within 50 km of every facility in the source category. The MIR is the highest individual lifetime cancer risk estimated for any of those census blocks. In addition to calculating the MIR, we estimate the distribution of individual cancer risks for the source category by summing the number of individuals within 50 km of the sources whose estimated risk falls within a specified risk range. We also estimate annual cancer incidence by multiplying the estimated lifetime cancer risk at each census block by the number of people residing in that block, summing results for all of the census blocks, and then dividing this result by a 70-year lifetime.

To assess the risk of noncancer health effects from chronic exposure to HAP, we calculate either an HQ or a target organ-specific hazard index (TOSHI). We calculate an HQ when a single noncancer HAP is emitted. Where more than one noncancer HAP is emitted, we sum the HQ for each of the HAP that affects a common target organ or target organ system to obtain a TOSHI. The HQ is the estimated exposure divided by the chronic noncancer dose-

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<sup>10</sup> The EPA's 2005 *Guidelines for Carcinogen Risk Assessment* classifies carcinogens as: "carcinogenic to humans," "likely to be carcinogenic to humans," and "suggestive evidence of carcinogenic potential." These classifications also coincide with the terms "known carcinogen, probable carcinogen, and possible carcinogen," respectively, which are the terms advocated in the EPA's *Guidelines for Carcinogen Risk Assessment*, published in 1986 (51 FR 33992, September 24, 1986). In August 2000, the document, *Supplemental Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (EPA/630/R-00/002), was published as a supplement to the 1986 document. Copies of both documents can be obtained from <https://cfpub.epa.gov/ncea/risk/recorddisplay.cfm?deid=20533&CFID=70315376&CFTOKEN=71597944>. Summing the risk of these individual compounds to obtain the cumulative cancer risk is an approach that was recommended by the EPA's SAB in their 2002 peer review of the EPA's National Air Toxics Assessment (NATA) titled *NATA - Evaluating the National-scale Air Toxics Assessment 1996 Data -- an SAB Advisory*, available at [https://yosemite.epa.gov/sab/sabproduct.nsf/214C6E915BB04E14852570CA007A682C/\\$File/ecadv02001.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/214C6E915BB04E14852570CA007A682C/$File/ecadv02001.pdf).

response value, which is a value selected from one of several sources. The preferred chronic noncancer dose-response value is the EPA RfC, defined as “an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime”

([https://iaspub.epa.gov/sor\\_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=IRIS%20Glossary](https://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=IRIS%20Glossary)). In cases where an RfC from the EPA’s IRIS is not available or where the EPA determines that using a value other than the RfC is appropriate, the chronic noncancer dose-response value can be a value from the following prioritized sources, which define their dose-response values similarly to the EPA: (1) the Agency for Toxic Substances and Disease Registry (ATSDR) Minimum Risk Level (<https://www.atsdr.cdc.gov/mrls/index.asp>); (2) the CalEPA Chronic Reference Exposure Level (REL) (<https://oehha.ca.gov/air/crnrr/notice-adoption-air-toxics-hot-spots-program-guidance-manual-preparation-health-risk-0>); or (3) as noted above, a scientifically credible dose-response value that has been developed in a manner consistent with the EPA guidelines and has undergone a peer review process similar to that used by the EPA. The pollutant-specific dose-response values used to estimate health risks are available at <https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants>.

#### c. Risk from Acute Exposure to HAP that May Cause Health Effects Other Than Cancer

For each HAP for which appropriate acute inhalation dose-response values are available, the EPA also assesses the potential health risks due to acute exposure. For these assessments, the EPA makes conservative assumptions about emission rates, meteorology, and exposure location. As part of our efforts to continually improve our methodologies to evaluate the risks that HAP

emitted from categories of industrial sources pose to human health and the environment,<sup>11</sup> we revised our treatment of meteorological data to use reasonable worst-case air dispersion conditions in our acute risk screening assessments instead of worst-case air dispersion conditions. This revised treatment of meteorological data and the supporting rationale are described in more detail in *Residual Risk Assessment for Flexible Polyurethane Foam Fabrication Operations Source Category in Support of the 2020 Risk and Technology Review Proposed Rule* and in Appendix 5 of the report: *Technical Support Document for Acute Risk Screening Assessment*. This revised approach has been used in this proposed rule and in all other RTR rulemakings proposed on or after June 3, 2019.

To assess the potential acute risk to the maximally exposed individual, we use the peak hourly emission rate for each emission point,<sup>12</sup> reasonable worst-case air dispersion conditions (*i.e.*, 99<sup>th</sup> percentile), and the point of highest off-site exposure. Specifically, we assume that peak emissions from the source category and reasonable worst-case air dispersion conditions co-occur and that a person is present at the point of maximum exposure.

To characterize the potential health risks associated with estimated acute inhalation exposures to a HAP, we generally use multiple acute dose-response values, including acute RELs, acute exposure guideline levels (AEGLs), and emergency response planning guidelines (ERPG) for 1-hour exposure durations, if available, to calculate acute HQs. The acute HQ is

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<sup>11</sup> See, *e.g.*, U.S. EPA, *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis* (Draft Report, May 2017). <https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html>.

<sup>12</sup> In the absence of hourly emission data, we develop estimates of maximum hourly emission rates by multiplying the average actual annual emissions rates by a factor (either a category-specific factor or a default factor of 10) to account for variability. This is documented in *Residual Risk Assessment for Flexible Polyurethane Foam Fabrication Operations Source Category in Support of the 2020 Risk and Technology Review Proposed Rule* and in Appendix 5 of the report: *Technical Support Document for Acute Risk Screening Assessment*. Both are available in the docket for this rulemaking.

calculated by dividing the estimated acute exposure concentration by the acute dose-response value. For each HAP for which acute dose-response values are available, the EPA calculates acute HQs.

An acute REL is defined as “the concentration level at or below which no adverse health effects are anticipated for a specified exposure duration.”<sup>13</sup> Acute RELs are based on the most sensitive, relevant, adverse health effect reported in the peer-reviewed medical and toxicological literature. They are designed to protect the most sensitive individuals in the population through the inclusion of margins of safety. Because margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact. AEGLs represent threshold exposure limits for the general public and are applicable to emergency exposures ranging from 10 minutes to 8 hours.<sup>14</sup> They are guideline levels for “once-in-a-lifetime, short-term exposures to airborne concentrations of acutely toxic, high-priority chemicals.” *Id.* at 21. The AEGL–1 is specifically defined as “the airborne concentration (expressed as ppm (parts per million) or mg/m<sup>3</sup> (milligrams per cubic meter)) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However,

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<sup>13</sup> CalEPA issues acute RELs as part of its Air Toxics Hot Spots Program, and the 1-hour and 8-hour values are documented in *Air Toxics Hot Spots Program Risk Assessment Guidelines, Part I, The Determination of Acute Reference Exposure Levels for Airborne Toxicants*, which is available at <https://oehha.ca.gov/air/general-info/oehha-acute-8-hour-and-chronic-reference-exposure-level-rel-summary>.

<sup>14</sup> National Academy of Sciences, 2001. *Standing Operating Procedures for Developing Acute Exposure Levels for Hazardous Chemicals*, page 2. Available at [https://www.epa.gov/sites/production/files/2015-09/documents/sop\\_final\\_standing\\_operating\\_procedures\\_2001.pdf](https://www.epa.gov/sites/production/files/2015-09/documents/sop_final_standing_operating_procedures_2001.pdf). Note that the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances ended in October 2011, but the AEGL program continues to operate at the EPA and works with the National Academies to publish final AEGLs (<https://www.epa.gov/aegl>). This document is a prepublication version, signed by EPA Administrator, Andrew R. Wheeler on 01/05/2021. We have taken steps to ensure the accuracy of this version, but it is not the official version.

the effects are not disabling and are transient and reversible upon cessation of exposure.” The document also notes that “Airborne concentrations below AEGL–1 represent exposure levels that can produce mild and progressively increasing but transient and nondisabling odor, taste, and sensory irritation or certain asymptomatic, nonsensory effects.” *Id.* AEGL–2 are defined as “the airborne concentration (expressed as parts per million or milligrams per cubic meter) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.” *Id.*

ERPGs are “developed for emergency planning and are intended as health-based guideline concentrations for single exposures to chemicals.”<sup>15</sup> *Id.* at 1. The ERPG–1 is defined as “the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse health effects or without perceiving a clearly defined, objectionable odor.” *Id.* at 2. Similarly, the ERPG–2 is defined as “the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual’s ability to take protective action.” *Id.* at 1.

An acute REL for 1-hour exposure durations is typically lower than its corresponding AEGL–1 and ERPG–1. Even though their definitions are slightly different, AEGL–1s are often the same as the corresponding ERPG–1s, and AEGL–2s are often equal to ERPG–2s. The

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<sup>15</sup> *ERPGS Procedures and Responsibilities*. March 2014. American Industrial Hygiene Association. Available at: <https://www.aiha.org/get-involved/AIHAGuidelineFoundation/EmergencyResponsePlanningGuidelines/Documents/ERPG%20Committee%20Standard%20Operating%20Procedures%20%20-%20March%202014%20Revision%20%28Updated%2010-2-2014%29.pdf>.

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maximum HQs from our acute inhalation screening risk assessment typically result when we use the acute REL for a HAP. In cases where the maximum acute HQ exceeds 1, we also report the HQ based on the next highest acute dose-response value (usually the AEGL-1 and/or the ERPG-1).

For this source category, we used a default multiplier of 10 to provide a conservatively high estimate of acute effects.

In our acute inhalation screening risk assessment, acute impacts are deemed negligible for HAP for which acute HQs are less than or equal to 1, and no further analysis is performed for these HAP. In cases where an acute HQ from the screening step is greater than 1, we assess the site-specific data to ensure that the acute HQ is at an off-site location.

#### 4. How do we conduct the multipathway exposure and risk screening assessment?

The EPA conducts a tiered screening assessment examining the potential for significant human health risks due to exposures via routes other than inhalation (*i.e.*, ingestion). We first determine whether any sources in the source category emit any HAP known to be persistent and bioaccumulative in the environment, as identified in the EPA's Air Toxics Risk Assessment Library (see Volume 1, Appendix D, at <https://www.epa.gov/fera/risk-assessment-and-modeling-air-toxics-risk-assessment-reference-library>). For the Flexible Polyurethane Foam Fabrication Operations source category, we did not identify emissions of any PB-HAP. Because we did not identify PB-HAP emissions, no further evaluation of multipathway risk was conducted for this source category.

For further information on the multipathway assessment approach, see the *Residual Risk Assessment for the Flexible Polyurethane Foam Fabrication Operations Source Category in*

*Support of the 2020 Risk and Technology Review Proposed Rule*, which is available in the docket for this action.

5. How do we conduct the environmental risk screening assessment?

a. Adverse Environmental Effect, Environmental HAP, and Ecological Benchmarks

The EPA conducts a screening assessment to examine the potential for an adverse environmental effect as required under section 112(f)(2)(A) of the CAA. Section 112(a)(7) of the CAA defines “adverse environmental effect” as “any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas.”

The EPA focuses on eight HAP, which are referred to as “environmental HAP,” in its screening assessment: six PB-HAP and two acid gases. The PB-HAP included in the screening assessment are arsenic compounds, cadmium compounds, dioxins/furans, polycyclic organic matter (POM), mercury (both inorganic mercury and methyl mercury), and lead compounds. The acid gases included in the screening assessment are hydrochloric acid (HCl) and hydrogen fluoride (HF).

HAP that persist and bioaccumulate are of particular environmental concern because they accumulate in the soil, sediment, and water. The acid gases, HCl and HF, are included due to their well-documented potential to cause direct damage to terrestrial plants. In the environmental risk screening assessment, we evaluate the following four exposure media: terrestrial soils, surface water bodies (includes water-column and benthic sediments), fish consumed by wildlife, and air. Within these four exposure media, we evaluate nine ecological assessment endpoints, which are defined by the ecological entity and its attributes. For PB-HAP (other than lead), both

community-level and population-level endpoints are included. For acid gases, the ecological assessment evaluated is terrestrial plant communities.

An ecological benchmark represents a concentration of HAP that has been linked to a particular environmental effect level. For each environmental HAP, we identified the available ecological benchmarks for each assessment endpoint. We identified, where possible, ecological benchmarks at the following effect levels: probable effect levels, lowest-observed-adverse-effect level, and no-observed-adverse-effect level. In cases where multiple effect levels were available for a particular PB-HAP and assessment endpoint, we use all of the available effect levels to help us to determine whether ecological risks exist and, if so, whether the risks could be considered significant and widespread.

For further information on how the environmental risk screening assessment was conducted, including a discussion of the risk metrics used, how the environmental HAP were identified, and how the ecological benchmarks were selected, see Appendix 9 of the *Residual Risk Assessment for the Flexible Polyurethane Foam Fabrication Operations Source Category in Support of the 2020 Risk and Technology Review Proposed Rule*, which is available in the docket for this action.

#### b. Environmental Risk Screening Methodology

For the environmental risk screening assessment, the EPA first determined whether any facilities in the Flexible Polyurethane Foam Fabrication Operations source category emitted any of the environmental HAP. For the Flexible Polyurethane Foam Fabrication Operations source category, we identified emissions of HCl. Because one or more of the environmental HAP evaluated emitted HCl by at least one facility in the source category, we proceeded to the second step of the evaluation.

c. PB-HAP Methodology

The environmental screening assessment includes six PB-HAP, arsenic compounds, cadmium compounds, dioxins/furans, POM, mercury (both inorganic mercury and methyl mercury), and lead compounds. For the Flexible Polyurethane Foam Fabrication Operations source category, we did not identify emissions of any PB-HAP. Because we did not identify PB-HAP emissions, no further evaluation of PB-HAP for the environmental risk assessment was conducted for this source category.

For further information on the PB-HAP environmental assessment approach, see the *Residual Risk Assessment for the Flexible Polyurethane Foam Fabrication Operations Source Category in Support of the 2020 Risk and Technology Review Proposed Rule*, available in the docket for this proposed rule (Docket ID No. EPA-HQ-OAR-2020-0572).

d. Acid Gas Environmental Risk Methodology

The environmental screening assessment for acid gases evaluates the potential phytotoxicity and reduced productivity of plants due to chronic exposure to HF and HCl. The environmental risk screening methodology for acid gases is a single-tier screening assessment that compares modeled ambient air concentrations (from AERMOD) to the ecological benchmarks for each acid gas. To identify a potential adverse environmental effect (as defined in section 112(a)(7) of the CAA) from emissions of HF and HCl, we evaluate the following metrics: the size of the modeled area around each facility that exceeds the ecological benchmark for each acid gas, in acres and square kilometers; the percentage of the modeled area around each facility that exceeds the ecological benchmark for each acid gas; and the area-weighted average screening value around each facility (calculated by dividing the area-weighted average concentration over the 50-km modeling domain by the ecological benchmark for each acid gas).

For further information on the environmental screening assessment approach, see Appendix 9 of This document is a prepublication version, signed by EPA Administrator, Andrew R. Wheeler on 01/05/2021. We have taken steps to ensure the accuracy of this version, but it is not the official version.

the *Residual Risk Assessment for the Flexible Polyurethane Foam Fabrication Operations Source Category in Support of the 2020 Risk and Technology Review Proposed Rule*, which is available in the docket for this action.

6. How do we conduct facility-wide assessments?

To put the source category risks in context, we typically examine the risks from the entire “facility,” where the facility includes all HAP-emitting operations within a contiguous area and under common control. In other words, we examine the HAP emissions not only from the source category emission points of interest, but also emissions of HAP from all other emission sources at the facility for which we have data. For this source category, we conducted the facility-wide assessment using a dataset compiled from the 2014 and 2017 NEI. The source category records of that NEI dataset were removed, evaluated, and updated as described in section II.C of this preamble: *What data collection activities were conducted to support this action?* Once a quality assured source category dataset was available, it was placed back with the remaining records from the NEI for that facility. The facility-wide file was then used to analyze risks due to the inhalation of HAP that are emitted “facility-wide” for the populations residing within 50 km of each facility, consistent with the methods used for the source category analysis described above. For these facility-wide risk analyses, the modeled source category risks were compared to the facility-wide risks to determine the portion of the facility-wide risks that could be attributed to the source category addressed in this proposal. We also specifically examined the facility that was associated with the highest estimate of risk and determined the percentage of that risk attributable to the source category of interest. The *Residual Risk Assessment for the Flexible Polyurethane Foam Fabrication Operations Source Category in Support of the 2020 Risk and Technology Review Proposed Rule*, available through the docket for this action, provides the

methodology and results of the facility-wide analyses, including all facility-wide risks and the percentage of source category contribution to facility-wide risks.

7. How do we consider uncertainties in risk assessment?

Uncertainty and the potential for bias are inherent in all risk assessments, including those performed for this proposal. Although uncertainty exists, we believe that our approach, which used conservative tools and assumptions, ensures that our decisions are health and environmentally protective. A brief discussion of the uncertainties in the RTR emissions dataset, dispersion modeling, inhalation exposure estimates, and dose-response relationships follows below. Also included are those uncertainties specific to our acute screening assessments, multipathway screening assessments, and our environmental risk screening assessments. A more thorough discussion of these uncertainties is included in the *Residual Risk Assessment for the Flexible Polyurethane Foam Fabrication Operations Source Category in Support of the 2020 Risk and Technology Review Proposed Rule*, which is available in the docket for this action. If a multipathway site-specific assessment was performed for this source category, a full discussion of the uncertainties associated with that assessment can be found in Appendix 11 of that document, *Site-Specific Human Health Multipathway Residual Risk Assessment Report*.

a. Uncertainties in the RTR Emissions Dataset

Although the development of the RTR emissions dataset involved quality assurance/quality control processes, the accuracy of emissions values will vary depending on the source of the data, the degree to which data are incomplete or missing, the degree to which assumptions made to complete the datasets are accurate, errors in emission estimates, and other factors. The emission estimates considered in this analysis generally are annual totals for certain years, and they do not reflect short-term fluctuations during the course of a year or variations from year to year. The estimates of peak hourly emission rates for the acute effects screening

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assessment were based on an emission adjustment factor applied to the average annual hourly emission rates, which are intended to account for emission fluctuations due to normal facility operations.

#### b. Uncertainties in Dispersion Modeling

We recognize there is uncertainty in ambient concentration estimates associated with any model, including the EPA's recommended regulatory dispersion model, AERMOD. In using a model to estimate ambient pollutant concentrations, the user chooses certain options to apply. For RTR assessments, we select some model options that have the potential to overestimate ambient air concentrations (*e.g.*, not including plume depletion or pollutant transformation). We select other model options that have the potential to underestimate ambient impacts (*e.g.*, not including building downwash). Other options that we select have the potential to either under- or overestimate ambient levels (*e.g.*, meteorology and receptor locations). On balance, considering the directional nature of the uncertainties commonly present in ambient concentrations estimated by dispersion models, the approach we apply in the RTR assessments should yield unbiased estimates of ambient HAP concentrations. We also note that the selection of meteorology dataset location could have an impact on the risk estimates. As we continue to update and expand our library of meteorological station data used in our risk assessments, we expect to reduce this variability.

#### c. Uncertainties in Inhalation Exposure Assessment

Although every effort is made to identify all of the relevant facilities and emission points, as well as to develop accurate estimates of the annual emission rates for all relevant HAP, the uncertainties in our emission inventory likely dominate the uncertainties in the exposure assessment. Some uncertainties in our exposure assessment include human mobility, using the centroid of each census block, assuming lifetime exposure, and assuming only outdoor exposure. This document is a prepublication version, signed by EPA Administrator, Andrew R. Wheeler on 01/05/2021. We have taken steps to ensure the accuracy of this version, but it is not the official version.

exposures. For most of these factors, there is neither an under nor overestimate when looking at the MIR or the incidence, but the shape of the distribution of risks may be affected. With respect to outdoor exposures, actual exposures may not be as high if people spend time indoors, especially for very reactive pollutants or larger particles. For all factors, we reduce uncertainty when possible. For example, with respect to census-block centroids, we analyze large blocks using aerial imagery and adjust locations of the block centroids to better represent the population in the blocks. We also add additional receptor locations where the population of a block is not well represented by a single location.

#### d. Uncertainties in Dose-Response Relationships

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

Cancer UREs used in our risk assessments are those that have been developed to generally provide an upper bound estimate of risk.<sup>16</sup> That is, they represent a "plausible upper

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<sup>16</sup> IRIS glossary ([https://ofmpub.epa.gov/sor\\_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=IRIS%20Glossary](https://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=IRIS%20Glossary)).

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limit to the true value of a quantity” (although this is usually not a true statistical confidence limit). In some circumstances, the true risk could be as low as zero; however, in other circumstances the risk could be greater.<sup>17</sup> Chronic noncancer RfC and reference dose (RfD) values represent chronic exposure levels that are intended to be health-protective levels. To derive dose-response values that are intended to be “without appreciable risk,” the methodology relies upon an uncertainty factor (UF) approach,<sup>18</sup> which considers uncertainty, variability, and gaps in the available data. The UFs are applied to derive dose-response values that are intended to protect against appreciable risk of deleterious effects.

Many of the UFs used to account for variability and uncertainty in the development of acute dose-response values are quite similar to those developed for chronic durations. Additional adjustments are often applied to account for uncertainty in extrapolation from observations at one exposure duration (*e.g.*, 4 hours) to derive an acute dose-response value at another exposure duration (*e.g.*, 1 hour). Not all acute dose-response values are developed for the same purpose, and care must be taken when interpreting the results of an acute assessment of human health effects relative to the dose-response value or values being exceeded. Where relevant to the estimated exposures, the lack of acute dose-response values at different levels of severity should be factored into the risk characterization as potential uncertainties.

Uncertainty also exists in the selection of ecological benchmarks for the environmental risk screening assessment. We established a hierarchy of preferred benchmark sources to allow

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<sup>17</sup> An exception to this is the URE for benzene, which is considered to cover a range of values, each end of which is considered to be equally plausible, and which is based on maximum likelihood estimates.

<sup>18</sup> See *A Review of the Reference Dose and Reference Concentration Processes*, U.S. EPA, December 2002, and *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry*, U.S. EPA, 1994.

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selection of benchmarks for each environmental HAP at each ecological assessment endpoint. We searched for benchmarks for three effect levels (*i.e.*, no-effects level, threshold-effect level, and probable effect level), but not all combinations of ecological assessment/environmental HAP had benchmarks for all three effect levels. Where multiple effect levels were available for a particular HAP and assessment endpoint, we used all of the available effect levels to help us determine whether risk exists and whether the risk could be considered significant and widespread.

For a group of compounds that are unspiciated (*e.g.*, glycol ethers), we conservatively use the most protective dose-response value of an individual compound in that group to estimate risk. Similarly, for an individual compound in a group (*e.g.*, ethylene glycol diethyl ether) that does not have a specified dose-response value, we also apply the most protective dose-response value from the other compounds in the group to estimate risk.

#### e. Uncertainties in Acute Inhalation Screening Assessments

In addition to the uncertainties highlighted above, there are several factors specific to the acute exposure assessment that the EPA conducts as part of the risk review under section 112 of the CAA. The accuracy of an acute inhalation exposure assessment depends on the simultaneous occurrence of independent factors that may vary greatly, such as hourly emissions rates, meteorology, and the presence of a person. In the acute screening assessment that we conduct under the RTR program, we assume that peak emissions from the source category and reasonable worst-case air dispersion conditions (*i.e.*, 99<sup>th</sup> percentile) co-occur. We then include the additional assumption that a person is located at this point at the same time. Together, these assumptions represent a reasonable worst-case actual exposure scenario. In most cases, it is

unlikely that a person would be located at the point of maximum exposure during the time when peak emissions and reasonable worst-case air dispersion conditions occur simultaneously.

f. Uncertainties in the Multipathway and Environmental Risk Screening Assessments

For each source category, we generally rely on site-specific levels of PB-HAP or environmental HAP emissions to determine whether a refined assessment of the impacts from multipathway exposures is necessary or whether it is necessary to perform an environmental screening assessment. This determination is based on the results of a three-tiered screening assessment that relies on the outputs from models – Total Risk Integrated Methodology.Fate, Transport, and Ecological Exposure model (TRIM.FaTE) and AERMOD – that estimate environmental pollutant concentrations and human exposures for five PB-HAP (dioxins, POM, mercury, cadmium, and arsenic) and two acid gases (HF and HCl). For lead, we use AERMOD to determine ambient air concentrations, which are then compared to the secondary National Ambient Air Quality Standards for lead. Two important types of uncertainty associated with the use of these models in RTR risk assessments and inherent to any assessment that relies on environmental modeling are model uncertainty and input uncertainty.<sup>19</sup>

Model uncertainty concerns whether the model adequately represents the actual processes (e.g., movement and accumulation) that might occur in the environment. For example, does the model adequately describe the movement of a pollutant through the soil? This type of uncertainty is difficult to quantify. However, based on feedback received from previous EPA SAB reviews and other reviews, we are confident that the models used in the screening assessments are

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<sup>19</sup> In the context of this discussion, the term “uncertainty” as it pertains to exposure and risk encompasses both *variability* in the range of expected inputs and screening results due to existing spatial, temporal, and other factors, as well as *uncertainty* in being able to accurately estimate the true result.

appropriate and state-of-the-art for the multipathway and environmental screening risk assessments conducted in support of RTRs.

Input uncertainty is concerned with how accurately the models have been configured and parameterized for the assessment at hand. For Tier 1 of the multipathway and environmental screening assessments, we configured the models to avoid underestimating exposure and risk. This was accomplished by selecting upper-end values from nationally representative datasets for the more influential parameters in the environmental model, including selection and spatial configuration of the area of interest, lake location and size, meteorology, surface water, soil characteristics, and structure of the aquatic food web. We also assume an ingestion exposure scenario and values for human exposure factors that represent reasonable maximum exposures.

In Tier 2 of the multipathway and environmental screening assessments, we refine the model inputs to account for meteorological patterns in the vicinity of the facility versus using upper-end national values, and we identify the actual location of lakes near the facility rather than the default lake location that we apply in Tier 1. By refining the screening approach in Tier 2 to account for local geographical and meteorological data, we decrease the likelihood that concentrations in environmental media are overestimated, thereby increasing the usefulness of the screening assessment. In Tier 3 of the screening assessments, we refine the model inputs again to account for hour-by-hour plume-rise and the height of the mixing layer. We can also use those hour-by-hour meteorological data in a TRIM.FaTE run using the screening configuration corresponding to the lake location. These refinements produce a more accurate estimate of chemical concentrations in the media of interest, thereby reducing the uncertainty with those estimates. The assumptions and the associated uncertainties regarding the selected ingestion exposure scenario are the same for all three tiers.

For the environmental screening assessment for acid gases, we employ a single-tiered approach. We use the modeled air concentrations and compare those with ecological benchmarks.

For all tiers of the multipathway and environmental screening assessments, our approach to addressing model input uncertainty is generally cautious. We choose model inputs from the upper end of the range of possible values for the influential parameters used in the models, and we assume that the exposed individual exhibits ingestion behavior that would lead to a high total exposure. This approach reduces the likelihood of not identifying high risks for adverse impacts.

Despite the uncertainties, when individual pollutants or facilities do not exceed screening threshold emission rates (*i.e.*, screen out), we are confident that the potential for adverse multipathway impacts on human health is very low. On the other hand, when individual pollutants or facilities do exceed screening threshold emission rates, it does not mean that impacts are significant, only that we cannot rule out that possibility and that a refined assessment for the site might be necessary to obtain a more accurate risk characterization for the source category.

The EPA evaluates the following HAP in the multipathway and/or environmental risk screening assessments, where applicable: arsenic, cadmium, dioxins/furans, lead, mercury (both inorganic and methyl mercury), POM, HCl, and HF. These HAP represent pollutants that can cause adverse impacts either through direct exposure to HAP in the air or through exposure to HAP that are deposited from the air onto soils and surface waters and then through the environment into the food web. These HAP represent those HAP for which we can conduct a meaningful multipathway or environmental screening risk assessment. For other HAP not included in our screening assessments, the model has not been parameterized such that it can be

used for that purpose. In some cases, depending on the HAP, we may not have appropriate multipathway models that allow us to predict the concentration of that pollutant. The EPA acknowledges that other HAP beyond these that we are evaluating may have the potential to cause adverse effects and, therefore, the EPA may evaluate other relevant HAP in the future, as modeling science and resources allow.

#### **IV. Analytical Results and Proposed Decisions**

##### *A. What actions are we taking pursuant to CAA sections 112(d)(2) and 112(d)(3) for the Flexible Polyurethane Foam Fabrication Operations source category?*

We are proposing pursuant to CAA section 112(d)(2) and (3) to establish a numeric limit for HCl emissions from existing flame laminators. The results and proposed decisions based on the analyses performed pursuant to CAA section 112(d)(2) and (3) are presented below.

For the Flexible Polyurethane Foam Fabrication Operations source category, there are four unregulated existing source flame laminators at two facilities. For major sources, the EPA is required to set technology-based standards that reflect the maximum reductions of HAP achievable (after considering cost, energy requirements, and non-air health and environmental impacts) and are commonly referred to as MACT standards. Furthermore, CAA section 112(d)(3)(B) provides that MACT shall not be less stringent than “the average emission limitation achieved by the best performing five sources (for which the Administrator has or could reasonably obtain emissions information) in the category for categories with fewer than 30 sources. In this category, the MACT floor for existing sources is the average (or mean) of the four known flame lamination sources. However, emissions data for HCl emissions from only one of these units is available. As this is the only unit of which we are aware that has had emissions testing conducted for HCl, the proposed MACT floor is based on the HCl data for this unit. In order to determine the level of the MACT floor, the Upper Prediction Limit method was used in

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order to account for variability in flame laminator emissions performance, and the MACT floor was calculated at 1.45 pounds per hour of HCl.<sup>20</sup>

When establishing an emission standard pursuant to section 112 of the CAA, the EPA must also determine whether to control emissions “beyond the floor” after considering the costs, non-air quality health and environmental impacts, and energy requirements of such more stringent control. For the existing source flame laminators, the EPA evaluated whether a beyond-the-floor emissions limit would be appropriate; specifically, we evaluated whether the incremental emissions reduction achievable with a venturi scrubber would be cost effective. The venturi scrubber was the only control technology in use at flame lamination sources that was identified by the EPA with the initial promulgation of the NESHAP, and no other developments in control technologies were identified in the review of these standards. The EPA’s previous cost estimates of this technology conducted for the proposal of the NESHAP in 2001 showed that the average cost per ton of HCl emissions reduced was approximately \$18,000. As nothing has substantially changed with this technology or in how it would be implemented, the EPA assumes that the cost effectiveness today would be similar to that previously estimated, once the costs of inflation are considered. Inflated to 2020 dollars, the average incremental cost per ton of HCl emissions reduced is estimated to be approximately \$26,000. We do not find this to be cost effective for the control of HCl and, therefore, propose that floor-level MACT controls are appropriate for existing flame laminators.

*B. What are the results of the risk assessment and analyses for the Flexible Polyurethane Foam Fabrication Operations source category?*

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<sup>20</sup> *MACT Floor and Beyond-the-Floor Analysis for Existing Flame Laminators in the Flexible Polyurethane Foam Fabrication Source Category* (EPA-HQ-OAR-2020-0572).

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As described in section III.C of this preamble, for the Flexible Polyurethane Foam Fabrication Operations major source category, we conducted a risk assessment for all HAP emitted. We present results of the risk assessment briefly below and in more detail in the *Flexible Polyurethane Foam Fabrication Risk Assessment Report*, in the docket for this action (Docket ID No. EPA-HQ-OAR-2020-0572).

#### 1. Chronic Inhalation Risk Assessment Results

Table 1 below provides a summary of the results of the inhalation risk assessment for the source category. As discussed in section III.C of this preamble, we set MACT-allowable HAP emission levels equal to actual emissions. For more detail about the MACT-allowable emission levels, see Appendix 1 to the *Flexible Polyurethane Foam Fabrication Risk Assessment Report*, in the docket for this action.

TABLE 1: FLEXIBLE POLYURETHANE FOAM FABRICATION SOURCE CATEGORY  
INHALATION RISK ASSESSMENT RESULTS

Risk Assessment	Maximum Individual Cancer Risk (in 1 million)		Estimated Population at Increased Risk of Cancer $\geq 1$ -in-1 Million		Estimated Annual Cancer Incidence (cases per year)		Maximum Chronic Noncancer TOSHI <sup>21</sup>		Maximum Screening Acute Noncancer HQ <sup>22</sup>
	Based on Actual Emissions	Based on Allowable Emissions	Based on Actual Emissions	Based on Allowable Emissions	Based on Actual Emissions	Based on Allowable Emissions	Based on Actual Emissions	Based on Allowable Emissions	Based on Actual Emissions
Source Category	0	0	0	0	0	0	0.002	0.002	HQREL = <1
Whole Facility	0.1	-	0	-	0.00001	-	0.2	-	-

<sup>21</sup> The TOSHI is the sum of the chronic noncancer HQ for substances that affect the same target organ or organ system.

<sup>22</sup> The maximum estimated acute exposure concentration was divided by available short-term threshold values to develop HQ values.



The results of the inhalation risk modeling using actual emissions data, as shown in Table 1 of this preamble, indicate that no carcinogens are emitted by this category. Therefore, the cancer MIR based on actual emissions (lifetime) is zero and the total estimated annual cancer incidence (national) from these facilities based on actual emission levels is zero excess cancer cases per year. The maximum chronic noncancer TOSHI value based on actual emissions is 0.002 driven by HCl.

## 2. Screening Level Acute Risk Assessment Results

Table 1 of this preamble shows the acute risk results for the Flexible Polyurethane Foam Fabrication source category. The screening analysis for acute impacts was based on an emissions multiplier of 10 for all emissions sources, to estimate the peak emission rates from the average rates. The maximum screening acute noncancer HQ value (off-facility site) is 0.003 driven by HCl. For more detailed acute risk screening results, refer to the *Flexible Polyurethane Foam Fabrication Risk Assessment Report*, in the docket for this action.

## 3. Multipathway Risk Screening Results

No PB-HAP are emitted from the Flexible Polyurethane Foam Fabrication source category, therefore, a multipathway assessment was not conducted.

## 4. Environmental Risk Screening Results

As described in section III.A of this document, we conducted an environmental risk screening assessment for the Flexible Polyurethane Foam Fabrication source category for HCl.

For HCl, the average modeled concentration around each facility (*i.e.*, the average concentration of all off-site data points in the modeling domain) did not exceed any ecological benchmark. In addition, each individual modeled concentration of HCl and HF (*i.e.*, each off-site data point in the modeling domain) was below the ecological benchmarks for all facilities. Based

on the results of the environmental risk screening analysis, we do not expect an adverse environmental effect as a result of HAP emissions from this source category.

## 5. Facility-Wide Risk Results

As shown in Table 1, the maximum facility-wide cancer MIR is 0.1-in-1 million, driven by 2,4/2,6-toluene diisocyanate mixture (TDI) emissions from a vertical non-category point source and a non-category fugitive point source. The total estimated cancer incidence from the whole facility is 0.00001 excess cancer cases per year, or one excess case in every 100,000 years. No people were estimated to have cancer risks above 1-in-1 million from exposure to HAP emitted from both MACT and non-MACT sources at the three facilities in this source category. The maximum facility-wide TOSHI for the source category is estimated to be 0.2, mainly driven by 2,4/2,6-TDI emissions from a vertical non-category point source and a non-category fugitive point source.

## 6. What demographic groups might benefit from this regulation?

To examine the potential for any environmental justice issues that might be associated with the Flexible Polyurethane Foam Fabrication Operations major source category, we performed a demographic analysis, which is an assessment of risks to individual demographic groups of the populations living within 5 km and within 50 km of the facilities. In the analysis, we evaluated the distribution of HAP-related cancer and noncancer risks from the Flexible Polyurethane Foam Fabrication Operations major source category across different demographic groups within the populations living near facilities.<sup>23</sup>

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<sup>23</sup> Demographic groups included in the analysis are: White, African American, Native American, other races and multiracial, Hispanic or Latino, children 17 years of age and under, adults 18 to 64 years of age, adults 65 years of age and over, adults without a high school diploma, people living below the poverty level, people living two times the poverty level, and linguistically isolated people.

Results of the demographic analysis for the source category indicate that the minority population is slightly higher within 5 km of the three facilities than the national percentage (40 percent versus 38 percent). This difference is accounted for by the larger African American population around the facilities (17 percent versus 12 percent nationally). In addition, the percentage of the population living within 5 km of facilities in the source category is greater than the corresponding national percentage for the demographic groups, “Ages 0 to 17” and “Below the Poverty Level.” When examining the risk levels of those exposed to emissions from Flexible Polyurethane Foam Fabrication facilities, we find that no one is exposed to a cancer risk at or above 1-in-1 million or to a chronic noncancer TOSHI greater than 1. The methodology and the results of the demographic analysis are presented in a technical report, *Risk and Technology Review – Analysis of Demographic Factors for Populations Living Near Flexible Polyurethane Foam Fabrication Operations Source Category*, September 2020 (hereafter referred to as the Flexible Polyurethane Foam Fabrication Demographic Analysis Report), available in the docket for this action.

*C. What are our proposed decisions regarding risk acceptability, ample margin of safety, and adverse environmental effect?*

#### 1. Risk Acceptability

As noted in section III.A of this preamble, we weigh all health risk factors in our risk acceptability determination, including the cancer MIR, the number of persons in various cancer and noncancer risk ranges, cancer incidence, the maximum noncancer TOSHI, the maximum acute noncancer HQ, the extent of noncancer risks, the distribution of cancer and noncancer risks in the exposed population, and risk estimation uncertainties (54 FR 38044, September 14, 1989).

For the Flexible Polyurethane Foam Fabrication Operations major source category, the risk analysis indicates that there is no cancer risk due to actual emissions or allowable emissions. This document is a prepublication version, signed by EPA Administrator, Andrew R. Wheeler on 01/05/2021. We have taken steps to ensure the accuracy of this version, but it is not the official version.

Since there is no cancer risk, the risks are considerably less than 100-in-1 million, which is the presumptive upper limit of acceptable risk. The risk analysis also shows we did not identify a potential for adverse chronic noncancer health effects. The acute noncancer risks based on actual emissions are low at an HQ of less than 1 (based on the REL) for HCl. Therefore, we find there is little potential concern of acute noncancer health impacts from actual emissions. In addition, the risk assessment indicates no significant potential for multipathway health effects.

Considering all of the health risk information and factors discussed above, including the uncertainties discussed in section III.C.7 of this preamble, we propose to find that the risks from the Flexible Polyurethane Foam Fabrication source category are acceptable.

## 2. Ample Margin of Safety Analysis

We are proposing that the risks from the Flexible Polyurethane Foam Fabrication Operations major source category are acceptable. No carcinogens are emitted by the Flexible Polyurethane Foam Fabrication source category. Therefore, there are no individuals in the exposed population with lifetime cancer risks above 1-in-1 million as a result of actual or allowable emissions from this category. In addition, the maximum chronic noncancer TOSHI value based on actual and allowable emissions is well below 1 (0.002 and 0.2, respectively) and the maximum screening acute noncancer HQ value (off-facility site) is also well below 1 (0.003). Therefore, we are proposing that additional emissions controls for flexible polyurethane foam fabrication facilities are not necessary to provide an ample margin of safety to protect public health.

## 3. Environmental Effect

The emissions data for the Flexible Polyurethane Foam Fabrication Operations major source category indicate that one environmental HAP is emitted by sources within this source category: HCl. The screening-level evaluation of the potential for adverse environmental effects

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associated with emissions of HCl from the Flexible Polyurethane Foam Fabrication source category indicated that each individual concentration (*i.e.*, each off-site data point in the modeling domain) was below the ecological benchmarks for all facilities. In addition, we are unaware of any adverse environmental effects caused by HAP emitted by this source category. Therefore, we do not expect there to be an adverse environmental effect as a result of HAP emissions from this source category, and we are proposing that it is not necessary to set a more stringent standard to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

*D. What are the results and proposed decisions based on our technology review for the Flexible Polyurethane Foam Fabrication Operations major source category and for the Flexible Polyurethane Foam Production and Fabrication area source categories?*

As described in section III.B of this preamble, our technology review focused on the identification and evaluation of potential developments in practices, processes, and control technologies that have occurred since the major source and area source NESHAP for Flexible Polyurethane Foam Fabrication were promulgated in 2003 and 2007, respectively. During the technology review we identified existing flame laminators as an unregulated process in the major source category. This proposal included the establishment of MACT standards for that process is described in section IV.A of this preamble. In conducting the technology review, we reviewed various information sources regarding the emissions from flexible polyurethane foam fabrication operations facilities and flexible polyurethane foam production facilities. We conducted separate but similar reviews for the Flexible Polyurethane Foam major source category and the two area source categories. The reviews included a search of the RBLC database, reviews of air permits for flexible polyurethane foam fabrication operations facilities and flexible polyurethane foam production facilities, and a review of emissions standards for similar source categories. We

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reviewed these data sources for information on practices, processes, and control technologies that were not considered during the development of the Flexible Polyurethane Foam Fabrication Operations NESHAP and the Flexible Polyurethane Foam Production and Fabrication area source NESHAP. We also looked for information on improvements in practices, processes, and control technologies that have been employed since development of the NESHAP. Through searches of the data sources described in section IV.D of this preamble, one development in a practice, process, or control technology was identified for loop slitter use in the Flexible Polyurethane Foam Fabrication Operations major source category.

A loop slitter is a large machine used to create thin sheets of foam from the large blocks of foam or “buns” created at a foam production plant. A slitter consists of a large, vertical, oval conveyor belt and a cutting mechanism, which cuts a thin sheet of foam to the desired thickness. When the buns are mounted on the conveyor of the slitter, they are glued end-to-end, forming a loop. Loop slitter emissions of HAP can occur from the application of the adhesives used to glue the foam buns together if the adhesive used contains HAP. The application of the adhesive is performed at the beginning of the loop slitting process, which can run for several hours before the bun is fully cut and the machine is loaded with new buns of foam.

At the time of the development of the NESHAP, the EPA found that the foam fabrication industry had effectively discontinued the use of adhesives containing methylene chloride, which was the primary HAP in the adhesives used, and had switched to other adhesives that did not contain methylene chloride or other HAP. As a result, for both existing and new loop slitters, the MACT standard for loop slitters proposed in 2001 was the prohibition of HAP-based adhesives. The definition in the 2001 proposed standards for a HAP-based adhesive was an adhesive containing detectable HAP. In comments on the proposed standards, industry representatives

indicated that the adhesives used contained small amounts of HAP rather than the estimated zero HAP content. In response to these comments, the definition of HAP-based adhesive was revised in the promulgated rule to be an adhesive containing 5 percent (by weight) or greater of HAP.

For new and existing loop slitters, we identified a potential development in existing practices and control techniques not currently required by the Flexible Polyurethane Foam Fabrication Operations MACT standards. Through the review of other air toxics MACT standards, we noted that several other NESHAP, developed both before and after the Flexible Polyurethane Foam Fabrication Operations NESHAP, include a definition of non-HAP adhesive or coating (where the coating definition included adhesives) with a lower percentage of HAP content than that of the definition included in the Flexible Polyurethane Foam Fabrication Operations rule.

Additionally, through review of SDS provided by industry, we found that the current adhesives used in loop slitting operations are less than 1-percent HAP content by total weight. Based on the current industry standards of adhesive usage containing less than 1-percent HAP and the definition for HAP-based adhesive from similar source categories regulating adhesives, we are proposing to revise the definition of “HAP-based adhesive” to read: “an adhesive containing 1 percent (by weight) or more of HAP, according to EPA Method 311 (appendix A to 40 CFR part 63) or another approved alternative.” This lowering of the total HAP weight of an adhesive from 5 percent to 1 percent is not expected to yield any reductions in emissions but will codify current industry practices and prevent backsliding.

We propose to amend 40 CFR 63.8802(a)(1)(i) and (a)(3)(i), which describe how to determine the mass fraction of HAP in each material used, to remove references to Occupational Safety and Health Administration (OSHA)-defined carcinogens as specified in 29 CFR

1910.1200(d)(4). The reference to OSHA-defined carcinogens as specified in 29 CFR 1910.1200(d)(4) was intended to specify which compounds must be included in calculating total HAP content of a coating material if they are present at 0.1-percent or greater by mass. We are proposing to remove these references because 29 CFR 1910.1200(d)(4) has been amended and no longer readily defines which compounds are carcinogens. We are proposing to replace these references to OSHA-defined carcinogens and 29 CFR 1910.1200(d)(4) with a list (in proposed new Table 8 to 40 CFR part 63, subpart M) of those HAP that must be included in calculating total HAP content of a coating material if they are present at 0.1 percent or greater by mass.

We propose to include HAP in proposed Table 8 to 40 CFR part 63, subpart M if they were categorized in the EPA's *Prioritized Chronic Dose-Response Values for Screening Risk Assessments* (May 9, 2014), as a "human carcinogen," "probable human carcinogen," or "possible human carcinogen" according to *The Risk Assessment Guidelines of 1986* (EPA/600/8-87/045, August 1987),<sup>24</sup> or as "carcinogenic to humans," "likely to be carcinogenic to humans," or with "suggestive evidence of carcinogenic potential" according to the *Guidelines for Carcinogen Risk Assessment* (EPA/630/P-03/001F, March 2005).<sup>25</sup>

For the Flexible Polyurethane Foam Production and Flexible Polyurethane Foam Fabrication area source categories, we find that there are no additional emissions of the listed urban HAP methylene chloride. As noted in section II.B of this document, methylene chloride is no longer used within either source category. Additionally, we did not find any advances in technologies during our review of the source categories. Detailed information of the technology

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<sup>24</sup> See <https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants>.

<sup>25</sup> See <https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment>.

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review can be found in the memorandum titled *Technology Review for the Flexible Polyurethane Foam Production and Fabrication Area Source Categories*, which is available in the docket for this proposed rule (Docket ID No. EPA-HQ-OAR-2020-0572).

*E. What other actions are we proposing?*

In addition to the proposed actions described above, we are proposing additional revisions to the NESHAP. We are proposing revisions to the SSM provisions of the MACT rule in order to ensure that they are consistent with the decision in *Sierra Club v. EPA*, 551 F. 3d 1019 (D.C. Cir. 2008), in which the court vacated two provisions that exempted sources from the requirement to comply with otherwise applicable CAA section 112(d) emission standards during periods of SSM. We also are proposing various other changes to reporting and recordkeeping requirements and to periodic testing requirements. Our analyses and proposed changes related to these issues are discussed below.

In its 2008 decision in *Sierra Club v. EPA*, 551 F.3d 1019 (D.C. Cir. 2008), the court vacated portions of two provisions in the EPA's CAA section 112 regulations governing the emissions of HAP during periods of SSM. Specifically, the court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some CAA section 112 standards apply continuously.

We are proposing the elimination of SSM exemptions in this rule, including any reference to requirements included in 40 CFR part 63, subpart A (General Provisions).

Consistent with *Sierra Club v. EPA*, we are proposing standards in this rule that apply at all times. We are also proposing several revisions to Table 7 to 40 CFR part 63, subpart M, which

as is explained in more detail below. For example, we are proposing to eliminate the incorporation of the General Provisions' requirement that each source develop an SSM plan. We also are proposing to eliminate and revise certain recordkeeping and reporting requirements related to the SSM exemption as further described below.

The EPA has attempted to ensure that the provisions we are proposing to eliminate are inappropriate, unnecessary, or redundant in the absence of the SSM exemption. We are specifically seeking comment on whether we have successfully done so.

In proposing the standards in this rule, the EPA has taken into account startup and shutdown periods and, for the reasons explained below, has not proposed alternate standards for those periods.

Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. Malfunctions, in contrast, are neither predictable nor routine. Instead, they are, by definition, sudden, infrequent, and not reasonably preventable failures of an emissions control, process, or monitoring equipment. (40 CFR 63.2, Definition of malfunction). The EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards, and this reading has been upheld as reasonable by the court. See *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 606-610 (2016). 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 sources when setting emission standards. The court has recognized that the phrase "average

emissions limitation achieved by the best performing 12 percent of” sources “says nothing about how the performance of the best units is to be calculated.” *Nat’l Ass’n of Clean Water Agencies v. EPA*, 734 F.3d 1115, 1141 (D.C. Cir. 2013). While the EPA accounts for variability in setting emissions standards, nothing in CAA section 112 requires the Agency to consider malfunctions as part of that analysis. The EPA is not required to treat a malfunction in the same manner as the type of variation in performance that occurs during routine operations of a source. A malfunction is a failure of the source to perform in a “normal or usual manner” and no statutory language compels the EPA to consider such events in setting CAA section 112 standards.

As the court recognized in *U.S. Sugar Corp.*, accounting for malfunctions in setting standards would be difficult, if not impossible, given the myriad 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. *U.S. Sugar Corp.* at 608 (“The EPA would have to conceive of a standard that could apply equally to the wide range of possible boiler malfunctions, ranging from an explosion to minor mechanical defects. Any possible standard is likely to be hopelessly generic to govern such a wide array of circumstances.”). As such, the performance of units that are malfunctioning is not “reasonably” foreseeable. See, e.g., *Weyerhaeuser Co. 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.”).

Moreover, emissions during a malfunction event can be significantly higher than emissions at any other time of source operation. For example, if an air pollution control device with 99-percent removal goes off-line as a result of a malfunction (as might happen if, for example, the bags in a baghouse catch fire) and the emission unit is a steady state-type unit that would take days to shut down, the source would go from 99-percent control to zero control until the control device was repaired. The source's emissions during the malfunction would be 100 times higher than during normal operations. As such, the emissions over a 4-day malfunction period would exceed the annual emissions of the source during normal operations. As this example illustrates, accounting for malfunctions could lead to standards that are not reflective of (and are significantly less stringent than) levels that are achieved by a well-performing non-malfunctioning source. It is reasonable to interpret CAA section 112 to avoid such a result. The EPA's approach to malfunctions is consistent with CAA section 112 and is a reasonable interpretation of the statute.

Although no statutory language compels the EPA to set standards for malfunctions, the EPA has the discretion to do so where feasible. For example, in the Petroleum Refinery Sector RTR, the EPA established a work practice standard for unique types of malfunction that result in releases from pressure relief devices or emergency flaring events because the EPA had information to determine that such work practices reflected the level of control that applies to the best performers. 80 FR 75178, 75211 through 14 (December 1, 2015). The EPA considers whether circumstances warrant setting standards for a particular type of malfunction and, if so, whether the EPA has sufficient information to identify the relevant best-performing sources and establish a standard for such malfunctions. We also encourage commenters to provide any such information.

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

If the EPA determines in a particular case that an enforcement action against a source for violation of an emission standard is warranted, the source can raise any and all defenses in that enforcement action and the federal district court will determine what, if any, relief is appropriate. The same is true for citizen enforcement actions. Similarly, the presiding officer in an administrative proceeding can consider any defense raised and determine whether administrative penalties are appropriate.

In summary, the EPA interpretation of the CAA and, in particular, CAA section 112 is reasonable and encourages practices that will avoid malfunctions. Administrative and judicial procedures for addressing exceedances of the standards fully recognize that violations may occur despite good faith efforts to comply and can accommodate those situations. See *U.S. Sugar Corp.*, 830 F.3d at 606-610. Therefore, we are proposing to change the requirements for SSM by removing the exemption for new flame laminators from the requirements to meet the standard during SSM periods and by removing the requirement to develop and implement an SSM plan. The EPA is proposing revisions to Table 7 of subpart M, The Applicability of General Provisions, to remove SSM exemptions and plan development for new flame lamination sources.

*Electronic reporting.* The EPA is proposing that owners or operators of flexible polyurethane foam fabrication operations facilities submit electronic copies of required performance test reports, performance evaluation reports, and periodic reports through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). A description of the electronic data submission process is provided in the memorandum, *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules*, available in the docket for this action. The proposed rule requires that performance test results collected using test methods that are supported by the EPA's Electronic Reporting Tool (ERT) as listed on the ERT website<sup>26</sup> at the time of the test be submitted in the format generated through the use of the ERT or an electronic file consistent with the xml schema on the ERT website, and other performance test results be submitted in portable document format (PDF) using the attachment module of the ERT. The proposed rule requires that Notification of Compliance Status reports be submitted as a PDF upload in CEDRI.

For performance test reports, performance evaluation reports, and periodic reports, the proposed rule requires that owners or operators use the appropriate spreadsheet template to submit information to CEDRI. A draft version of the proposed template(s) for these reports is included in the docket for this action.<sup>27</sup> The EPA specifically requests comment on the content, layout, and overall design of the template(s).

Additionally, the EPA has identified two broad circumstances in which electronic reporting extensions may be provided. These circumstances are (1) outages of the EPA's CDX or

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<sup>26</sup> <https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert>.

<sup>27</sup> See Flexible Foam Fabrication ERT templates, available at Docket ID. No. EPA-HQ-OAR-2020-0572.

CEDRI which preclude an owner or operator from accessing the system and submitting required reports and (2) *force majeure* events, which are defined as events that will be or have been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevent an owner or operator from complying with the requirement to submit a report electronically. Examples of *force majeure* events are acts of nature, acts of war or terrorism, or equipment failure or safety hazards beyond the control of the facility. The EPA is providing these potential extensions to protect owners or operators from noncompliance in cases where they cannot successfully submit a report by the reporting deadline for reasons outside of their control. In both circumstances, the decision to accept the claim of needing additional time to report is within the discretion of the Administrator, and reporting should occur as soon as possible.

The electronic submittal of the reports addressed in this proposed rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements, and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the

public. Moreover, electronic reporting is consistent with the EPA’s plan<sup>28</sup> to implement Executive Order 13563 and is in keeping with the EPA’s Agency-wide policy<sup>29</sup> developed in response to the White House’s Digital Government Strategy.<sup>30</sup> For more information on the benefits of electronic reporting, see the memorandum, *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules*, referenced earlier in this section.

*F. What compliance dates are we proposing?*

The EPA is proposing that affected sources that commenced construction or reconstruction on or before **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, must comply with all of the amendments, with the exception of the proposed electronic format for submitting notifications and compliance reports, no later than 180 days after the effective date of the final rule, or upon startup, whichever is later. Affected sources that commence construction or reconstruction after **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, must comply with all requirements of the subpart, including the amendments being proposed, with the exception of the proposed electronic format for submitting notifications and compliance reports, no later than the effective date of the final rule or upon startup, whichever is later. All affected facilities would have to continue to meet the current requirements of 40 CFR part 63, subpart M, until the applicable compliance date of the

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<sup>28</sup> The EPA’s *Final Plan for Periodic Retrospective Reviews*, August 2011. Available at: <https://www.regulations.gov/document?D=EPA-HQ-OA-2011-0156-0154>.

<sup>29</sup> *E-Reporting Policy Statement for EPA Regulations*, September 2013. Available at <https://www.epa.gov/sites/production/files/2016-03/documents/epa-ereporting-policy-statement-2013-09-30.pdf>.

<sup>30</sup> *Digital Government: Building a 21<sup>st</sup> Century Platform to Better Serve the American People*, May 2012. Available at <https://obamawhitehouse.archives.gov/sites/default/files/omb/egov/digital-government/digital-government.html>.



amended rule. The final action is not expected to be a “major rule” as defined by 5 U.S.C. 804(2), so the effective date of the final rule will be the promulgation date as specified in CAA section 112(d)(10).

For existing sources, we are proposing four changes that would impact ongoing compliance requirements for 40 CFR part 63, subpart M. As discussed elsewhere in this preamble, we are proposing to add numeric limits for HCl emissions from existing flame laminators. We are also proposing a requirement that notifications, performance test results, and compliance reports be submitted electronically.

Our experience with similar industries that are required to convert reporting mechanisms to install necessary hardware and software, become familiar with the process of submitting performance test results electronically through the EPA’s CEDRI, test these new electronic submission capabilities, and reliably employ electronic reporting shows that a time period of a minimum of 90 days, and, more typically, 180 days, is generally necessary to accomplish these revisions. For the proposed SSM revisions, we recognize that there are no facilities that are currently using the SSM provisions for new flame laminators, since there have not been any new sources since the standard was promulgated. As a result, we do not believe that any additional time is needed for compliance with the revised SSM provisions.

We have consulted with the regulated industry regarding the proposed limits for existing flame laminators, and the requirement to conduct performance testing to demonstrate initial compliance within 180 days of the publication of the final rule and no less than every 5 years thereafter, to better understand the likely implications of the proposed revisions. There are two impacted facilities, owned by one parent company, and representatives from that company have indicated that performance testing could be done within the proposed time frame for compliance.

For the proposed limit for existing sources, we believe that the two facilities that would be subject to the standards are able to meet the limit without add-on controls. However, we do recognize that facilities will need time to conduct performance tests and demonstrate compliance with the proposed emission limit.

The EPA recognizes the confusion that multiple and different compliance dates for individual requirements would create and the additional burden such an assortment of dates would impose. From our assessment of the timeframe needed for compliance with the entirety of the revised requirements, the EPA considers a period of 180 days to be the most expeditious compliance period practicable and is, thus, proposing that all affected sources that commenced construction or reconstruction on or before **[DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER]**, be in compliance with all of this regulation's revised requirements within 180 days of the regulation's effective date, with the exception of the electronic reporting requirements.

We solicit comment on the proposed compliance periods, and we specifically request submission of information from sources in this source category regarding specific actions that would need to be undertaken to comply with the proposed amended requirements and the time needed to make the adjustments for compliance with any of the revised requirements. We note that information provided may result in changes to the proposed compliance dates.

## **V. Summary of Cost, Environmental, and Economic Impacts**

### *A. What are the affected sources?*

Currently, three major sources subject to the Flexible Polyurethane Foam Fabrication Operations NESHAP are operating in the United States. The affected sources under the NESHAP include flexible polyurethane foam fabrication plant sites that operate loop slitters and/or flame laminators. Facilities that use loop splitter adhesive processes would be required to

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comply with a ban on the use of adhesives containing air toxics. However, the EPA estimates that current air toxic emissions from loop slitter adhesive users are essentially zero as the result of changes in adhesive composition required by OSHA's permissible exposure limit for methylene chloride prior to the promulgation of the original MACT standard. Additionally, the EPA estimates that current air toxic emissions from flame laminators for the entire source category are less than 3.5 tpy.

Currently, there are approximately 32 area sources subject to the Flexible Polyurethane Foam Production and Fabrication NESHAP. The area source standard only regulates methylene chloride emissions and, similar to the major source standards, emissions of methylene chloride are essentially zero as required by OSHA's permissible exposure limit for methylene chloride prior to the promulgation of the original GACT standards. Based on information provided by industry, there are no emissions of methylene chloride from these sources. For detailed information please see the memorandum titled *Technology Review for the Flexible Polyurethane Foam Production and Fabrication Area Source Categories*, located in the docket for this action.

*B. What are the air quality impacts?*

Current estimated emissions from the Flexible Polyurethane Foam Fabrication Operations source category are approximately 3.5 tpy. We do not estimate any HAP emission reductions from the proposed requirement for MACT limits for existing flame laminators nor from the proposed revision to the definition of HAP-based adhesives for loop slitters. Both proposed revisions reflect current practices.

*C. What are the cost impacts?*

The proposed revisions to the Flexible Polyurethane Foam Fabrication Operations NESHAP for major sources are expected to have minimal cost impacts. The costs are associated with periodic emissions performance testing, electronic reporting, and reviewing the proposed

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rule. Three major source facilities are affected by these costs. The one-time cost associated with reviewing the proposed rule and becoming familiar with the electronic reporting system is estimated to be \$2,200 per facility in 2019 dollars. The EPA estimates the cost of the HCl emissions testing requirement to be \$12,000 per test. This test is required every 5 years. Prior to the initial test, installation and calibration of equipment is required which costs an estimated \$3,200. The total cost per facility in Year 1 is estimated to be \$17,300, and subsequent costs are estimated to be \$12,000 every 5 years thereafter.

*D. What are the economic impacts?*

The proposed revisions to the Flexible Polyurethane Foam Fabrication Operations NESHAP for major sources and the Flexible Polyurethane Foam Production and Fabrication NESHAP for area sources are not expected to have market impacts. Over a 10-year timeframe from 2021 to 2030, the net present value of the estimated cost impacts is \$83,000 at a 3-percent discount rate and \$77,600 at a 7-percent discount rate in 2019 dollars. The equivalent annualized value of the cost impacts is \$9,700 at a 3-percent discount rate and \$11,000 at a 7-percent discount rate. Since the costs associated with the proposed rule are minimal, no significant economic impacts are anticipated due to the proposed revisions. See the memorandum titled *Economics Memo Flex Foam NESHAP Proposal*, in the docket for discussion of the facility-level cost estimates as well as the net present value and equivalent annualized value estimates.

*E. What are the benefits?*

Although the EPA does not anticipate any significant reductions in HAP emissions as a result of the proposed amendments, the action, if finalized as proposed, would result in improvements to the rule and prevent backsliding. Specifically, the proposed amendments codify existing industry practices both for existing flame laminators and for new and existing sources of adhesives used with loop slitters. The proposed revisions also amend the standards such that they

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apply at all times. Additionally, the proposed amendments requiring electronic submittal of initial notifications, performance test results, and semiannual reports will increase the usefulness of the data, are in keeping with current trends of data availability, will further assist in the protection of public health and the environment, and will ultimately result in less burden on the regulated community. See section IV.E of this preamble for more information.

## **VI. Request for Comments**

We solicit comments on this proposed action. In addition to general comments on this proposed action, we are also interested in additional data that may improve the risk assessments and other analyses. We are specifically interested in receiving any improvements to the data used in the site-specific emissions profiles used for risk modeling. Such data should include supporting documentation in sufficient detail to allow characterization of the quality and representativeness of the data or information. Section VII of this preamble provides more information on submitting data.

## **VII. Submitting Data Corrections**

The site-specific emissions profiles used in the source category risk and demographic analyses and instructions are available for download on the RTR website at <https://www.epa.gov/stationary-sources-air-pollution/flexible-polyurethane-foam-fabrication-operations-national-emission>. The data files include detailed information for each HAP emissions release point for the facilities in the source category.

If you believe that the data are not representative or are inaccurate, please identify the data in question, provide your reason for concern, and provide any “improved” data that you have, if available. When you submit data, we request that you provide documentation of the basis for the revised values to support your suggested changes. To submit comments on the data

downloaded from the RTR website, complete the following steps:

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1. Within this downloaded file, enter suggested revisions to the data fields appropriate for that information.

2. Fill in the commenter information fields for each suggested revision (*i.e.*, commenter name, commenter organization, commenter email address, commenter phone number, and revision comments).

3. Gather documentation for any suggested emissions revisions (*e.g.*, performance test reports, material balance calculations).

4. Send the entire downloaded file with suggested revisions in Microsoft® Access format and all accompanying documentation to Docket ID No. EPA-HQ-OAR-2020-0572 (through the method described in the **ADDRESSES** section of this preamble).

5. If you are providing comments on a single facility or multiple facilities, you need only submit one file for all facilities. The file should contain all suggested changes for all sources at that facility (or facilities). We request that all data revision comments be submitted in the form of updated Microsoft® Excel files that are generated by the Microsoft® Access file. These files are provided on the project website at <https://www.epa.gov/stationary-sources-air-pollution/flexible-polyurethane-foam-fabrication-operations-national-emission>.

## VIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

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

This action is not a significant regulatory action and was, therefore, not submitted to OMB for review.

### *B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs*

This action is not expected to be an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

### *C. Paperwork Reduction Act (PRA)*

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2027.08. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The ICR is specific to information collection associated with the Flexible Polyurethane Foam Fabrication Operations source category, through amendments to 40 CFR part 63, subpart M. (The subject rulemaking imposes no new information collection associated with either the Flexible Polyurethane Foam Production area source category or the Flexible Polyurethane Foam Fabrication area source category.) We are proposing changes to the recordkeeping and reporting requirements associated with 40 CFR part 63, subpart M, in the form of: requiring periodic (every 5 years) performance tests at major sources; eliminating the SSM plan and reporting requirements; including reporting requirements for deviations in the semiannual report; and including the

requirement for electronic submittal of reports. In addition, the number of facilities subject to the standards changed. The number of respondents was reduced from 20 to 3 based on consultation with industry representatives and state/local agencies.

*Respondents/affected entities:* The respondents to the recordkeeping and reporting requirements are owners or operators of flexible polyurethane foam fabrication operations subject to 40 CFR part 63, subpart M.

*Respondent's obligation to respond:* Mandatory (40 CFR part 63, subpart M).

*Estimated number of respondents:* 3 facilities.

*Frequency of response:* The frequency of responses varies depending on the burden item.

Responses include one-time review of rule amendments, reports of periodic performance tests, and semiannual compliance reports.

*Total estimated burden:* The annual recordkeeping and reporting burden for responding facilities to comply with all of the requirements in the NESHAP, averaged over the 3 years of this ICR, is estimated to be 148 hours (per year). The average annual burden to the Agency over the 3 years after the amendments are final is estimated to be 51 hours (per year) for the Agency. Burden is defined at 5 CFR 1320.3(b).

*Total estimated cost:* The annual recordkeeping and reporting cost for responding facilities to comply with all of the requirements in the NESHAP, averaged over the 3 years of this ICR, is estimated to be \$15,000 (rounded, per year). There are no estimated capital and operation and maintenance costs. The total average annual Agency cost over the first 3 years after the amendments are final is estimated to be \$2,500.



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 the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA\_submission@omb.eop.gov*, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. The EPA will respond to any ICR-related comments in the final rule.

*D. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule. As proposed, this action would potentially impose new requirements only on major sources, and none of the major sources in the Flexible Polyurethane Foam Fabrication Operations source category are considered a small entity. We have, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

*E. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

*F. 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.

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

This action does not have tribal implications as specified in Executive Order 13175. No tribal facilities are known to be engaged in the industries that would be affected by this action nor are there any adverse health or environmental effects from this action. Thus, Executive Order 13175 does not apply to this action.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in sections III.A, IV.B, and IV.C of this preamble.

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

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

*J. National Technology Transfer and Advancement Act (NTTAA)*

This rulemaking does not involve technical standards.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

The documentation for this decision is contained in sections IV.B and IV.C of this preamble. As discussed in sections IV.B and IV.C of this preamble, we performed a demographic analysis for the Flexible Polyurethane Foam Fabrication Operations major source category, which is an assessment of risks to individual demographic groups, of the population close to the facilities (within 50 km and within 5 km). In our analysis, we evaluated the distribution of HAP-related cancer risks and noncancer hazards from the Flexible Polyurethane Foam Fabrication Operations major source category across different social, demographic, and economic groups within the populations living near operations identified as having the highest risks. Results of the demographic analysis performed for the Flexible Polyurethane Foam Fabrication Operations major source category indicate that the minority population is slightly higher within 5 km of the three facilities than the national percentage (40 percent versus 38 percent). This difference is accounted for by the larger African American population around the facilities (17 percent versus 12 percent nationally). In addition, the percentage of the population living within 5 km of facilities in the source category is greater than the corresponding national percentage for the demographic groups, “Ages 0 to 17” and “Below the

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Poverty Level.” When examining the risk levels of those exposed to emissions from flexible polyurethane foam fabrication facilities, we find that no one is exposed to a cancer risk at or above 1-in-1 million or to a chronic noncancer TOSHI greater than 1.

**List of Subjects in 40 CFR Part 63**

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

**Andrew Wheeler,**

*Administrator.*