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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 56, 57, 60, 70, 71, 72, 75, and 90

[Docket No. MSHA–2023–0001]

RIN 1219-AB36

Lowering Miners' Exposure to Respirable Crystalline Silica and Improving Respiratory Protection

AGENCY: Mine Safety and Health Administration (MSHA), Department of Labor.

ACTION: Proposed rule; request for comments; notice of public hearings.

SUMMARY: The Mine Safety and Health Administration (MSHA) proposes to amend its existing standards to better protect miners against occupational exposure to respirable crystalline silica, a carcinogenic hazard, and to improve respiratory protection for all airborne hazards. MSHA has preliminarily determined that under the Agency's existing standards, miners at metal and nonmetal mines and coal mines face a risk of material impairment of health or functional capacity from exposure to respirable crystalline silica. MSHA proposes to set the permissible exposure limit of respirable crystalline silica at 50 micrograms per cubic meter of air ($\mu g/m^3$) for a full shift exposure, calculated as an 8-hour time-weighted average, for all miners. MSHA's proposal would also include other requirements to protect miner health, such as exposure sampling, corrective actions to be taken when miner exposure exceeds the permissible exposure limit, and medical surveillance for metal and nonmetal miners. Furthermore, the proposal would replace existing requirements for respiratory protection and incorporate by reference *ASTM*

F3387-19 Standard Practice for Respiratory Protection. The proposed uniform approach to respirable crystalline silica occupational exposure and improved respiratory protection for all airborne hazards would significantly improve health protections for all miners and lower the risk of material impairment of health or functional capacity.

DATES: *Written comments.* Written comments, including comments on the information collection requirements described in this preamble, must be received or postmarked by midnight Eastern Time on [INSERT DATE 45 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

Public Hearings. MSHA will hold two public hearings on [INSERT DATE 21 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER] in Arlington, Virginia and [INSERT DATE 37 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER] in Denver, Colorado. For more information on the public hearings, see SUPPLEMENTARY INFORMATION.

ADDRESSES: All submissions must include RIN 1219-AB36 or Docket No. MSHA–2023–0001. You should not include personal or proprietary information that you do not wish to disclose publicly. If you mark parts of a comment as "business confidential" information, MSHA will not post those parts of the comment. Otherwise, MSHA will post all comments without change, including any personal information provided. MSHA cautions against submitting personal information.

You may submit comments and informational materials, clearly identified by RIN 1219-AB36 or Docket Id. No. MSHA–2023–0001, by any of the following methods:

Federal E-Rulemaking Portal: https://www.regulations.gov. Follow the online instructions for submitting comments.

Email: zzMSHA-comments@dol.gov. Include "RIN 1219-AB36" in the subject line of the message.

Regular Mail: MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202-5450.

Hand Delivery or Courier: MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia, between 9:00 a.m. and 5:00 p.m. Monday through Friday, except Federal holidays. Before visiting MSHA in person, call 202-693-9440 to make an appointment. Special health precautions may be required.

Facsimile: 202-693-9441. Include "RIN 1219-AB36" in the subject line of the message.

Information Collection Requirements. Comments concerning the information collection requirements of this proposed rule must be clearly identified with "RIN 1219-AB36" or "Docket No. MSHA–2023–0001," and sent to MSHA by one of the methods previously explained.

Docket. For access to the docket to read comments and background documents, go to *https://www.regulations.gov*. The docket can also be reviewed in person at MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, Virginia, between 9 a.m. and 5 p.m. Monday through Friday, except Federal holidays. Before visiting MSHA in person, call 202-693-9440 to make an appointment. Special health precautions may be required.

Email Notification. To subscribe to receive an email notification when MSHA publishes rulemaking documents in the **Federal Register**, go to https://public.govdelivery.com/accounts/USDOL/subscriber/new.

FOR FURTHER INFORMATION CONTACT: S. Aromie Noe, Director, Office of Standards, Regulations, and Variances, MSHA, at: silicaquestions@dol.gov (email); 202-693-9440 (voice); or 202-693-9441 (facsimile). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

MSHA will hold two public hearings to provide industry, labor, and other interested parties with an opportunity to present oral statements, written comments, and other information on the proposed rule. The public hearings will begin at 9 a.m. local time and end after the last presenter speaks on the following dates:

Date	Location	Contact number
[INSERT DATE 21 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]	Mine Safety and Health Administration 201 12th Street South Room 7W202 Arlington, VA 22202	202-693-9440
[INSERT DATE 37 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]	Denver Federal Center Building 25 Lecture Hall West 6th Avenue and Kipling Street Denver, CO 80225	202-693-9440

The public hearings will begin with an opening statement from MSHA, followed by an opportunity for members of the public to make oral presentations. Speakers and other attendees may present information to MSHA for inclusion in the rulemaking record. The hearings will be conducted in an informal manner. Formal rules of evidence or cross examination will not apply.

A verbatim transcript of each of the proceedings will be prepared and made a part of the rulemaking record. Copies of the transcripts will be available to the public. MSHA will make the transcript of the hearings available at http://www.regulations.gov and on MSHA's website at https://arlweb.msha.gov/currentcomments.asp.

MSHA will accept post-hearing written comments and other appropriate information for the record from any interested party, including those not presenting oral statements, received by midnight (Eastern Time) on [INSERT DATE 45 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

Pre-registration is not required to attend the hearings. Interested parties may attend the hearings virtually or in person. Interested parties who intend to present testimony at the hearings are asked to register in advance on MSHA's website (http://www.msha.gov). Speakers will be called in the order in which they signed up. Those who do not register in advance will have an opportunity to speak after all those who pre-registered have spoken. You may submit hearing testimony and documentary evidence, identified by docket number (MSHA–2023–0001), by any

of the methods previously identified. Additional information on how to access the public hearings will be posted when available at https://www.msha.gov/regulations/rulemaking.

The preamble to the proposed standard follows this outline:

I. Introduction
II. Request for Comments
III. Background
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VI. Preliminary Risk Analysis Summary
VII. Section-by-Section Analysis
VIII. Technological Feasibility
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X. Initial Regulatory Flexibility Analysis
XI. Paperwork Reduction Act
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XIV. Appendix

Acronyms and Abbreviations:

COPD	chronic obstructive pulmonary disease
ESRD	end-stage renal disease
FEV	forced expiratory volume
FVC	forced vital capacity
L/min	liter per minute
mg	milligram
mg/m^3	milligrams per cubic meter
mL	milliliter
$\mu g/m^3$	micrograms per cubic meter
MNM	metal and nonmetal
NMRD	nonmalignant respiratory disease
PEL	permissible exposure limit
PMF	progressive massive fibrosis
RCMD	respirable coal mine dust
REL	recommended exposure limit
SiO_2	silica
TB	tuberculosis
TLV®	Threshold Limit Value
TWA	time-weighted average

I. Introduction

With the passage of the Federal Mine Safety and Health Act of 1977 (Mine Act), Congress declared that "the first priority and concern of all in the coal or other mining industry

must be the health and safety of its most precious resource—the miner[.]" 30 U.S.C. 801(a). In furtherance of that clear guiding principle, this proposed rule promotes MSHA's mission and statutory mandate to prevent death, illness, and injury from mining and promote safe and healthful workplaces for U.S. miners. This proposal provides the public with the opportunity to comment on the Agency's proposed uniform and streamlined regulatory approach to lowering miners' exposure to respirable crystalline silica and improving respiratory protection.

Exposure to silica dust causes adverse health effects, including silicosis (acute silicosis, accelerated silicosis, simple chronic silicosis, and progressive massive fibrosis (PMF)), nonmalignant respiratory diseases (NMRD) (e.g., emphysema and chronic bronchitis), lung cancer, and renal diseases. Each of these effects is chronic, irreversible, and potentially disabling or fatal. Silica dust is generated in most mining activities, including cutting, sanding, drilling, crushing, grinding, sawing, scraping, jackhammering, excavating, and hauling materials that contain silica, and is found in all mines -- underground and surface metal and nonmetal (MNM) and coal mines. In a mining context, silica exposures may occur in respirable dust together with exposures to other airborne contaminants and combustion biproducts.

MSHA's existing standards, established in the early 1970s, help protect miners from the most dangerous levels of exposure to respirable crystalline silica. However, since their promulgation, scientific understanding of respirable crystalline silica toxicity has advanced, and the National Institute for Occupational Safety and Health (NIOSH) has recommended a respirable crystalline silica exposure level of 50 $\mu g/m^3$ for workers. In 2016, the Occupational Safety and Health Administration (OSHA) established a permissible exposure limit (PEL) of 50 $\mu g/m^3$ in many industry sectors that it regulates.

To provide miners with exposure limits consistent with workers in other industries and NIOSH's recommendation, and to improve miners' health, MSHA proposes to lower its existing exposure limits to 50 $\mu g/m^3$ for respirable crystalline silica in MNM and coal mines. MSHA considered exposure limits below 50 $\mu g/m^3$. However, MSHA believes, based on a review of the

Agency's available silica sample data, that an exposure limit of 25 $\mu g/m^3$ may not be achievable for all mines. The proposed PEL would be expressed as a full-shift exposure, calculated as an 8-hour time-weighted average (TWA). Importantly, a uniform proposed PEL for all mines would make compliance simpler -- especially for coal mines by eliminating the existing respirable dust standard when quartz is present.

To meet the requirements of the proposed PEL, mine operators would have to implement engineering controls, followed by administrative controls if supplementary protection is needed. Engineering controls, which are most effective, are designed to remove or reduce the hazard at the source and could include the installation of proper ventilation systems, use of water sprays or wetting agents to suppress airborne contaminants, installation of machine-mounted dust collectors to capture respirable crystalline silica and other contaminants, and the installation of control booths or environmental cabs to enclose equipment operators. Administrative controls, which are often less effective than engineering controls, are designed to change the way miners work. One example would be ensuring that miners safely clean dust off their work clothes so that they are not exposed to respirable dust after their shift ends.

MSHA's proposed rule would further protect all miners by requiring exposure sampling and corrective actions when miners' exposures exceed the proposed PEL, as well as periodic sampling when miners' exposure levels meet or exceed the proposed action level. The proposed rule also includes medical surveillance requirements for MNM miners (medical surveillance requirements already exist for coal miners). Proposed medical examinations would include chest X-rays, spirometry, symptom assessment, and occupational history and would be provided at no cost to the miner.

Finally, the proposed rule would incorporate by reference an updated respiratory protection standard, ASTM F3387-19, "*Standard Practice for Respiratory Protection*" (ASTM F3387-19), for respirable crystalline silica and all other regulated airborne contaminants. This voluntary consensus standard represents up-to-date advancements in respiratory protection

technologies, practices, and techniques, including proper selection, use, and maintenance of respirators. The proposed incorporation of ASTM F3387-19 by reference would better protect all miners from airborne hazards. However, respiratory protection should only be relied upon as an exposure control measure in limited situations and on a temporary basis, and to supplement engineering controls, followed by administrative controls.

Taken together, all elements of the proposed rule are technologically and economically feasible. MSHA's 2014 final rule, *Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors* (Coal Dust Rule) improved health protections for coal miners by lowering exposure limits to respirable coal mine dust and establishing sampling requirements that included the use of a Continuous Personal Dust Monitor (79 FR 24813, May 1, 2014). Coal mine operators have generally achieved compliance with the respirable dust standards primarily by implementing or adjusting existing engineering controls. Coal mine operators' sampling data and MSHA's compliance data show that operators have lowered coal miners' exposures to respirable coal mine dust and to respirable crystalline silica. Data show that average exposures in coal mines are below the proposed PEL of 50 $\mu g/m^3$, and therefore, corrective measures would often not be needed. Similarly, for MNM miners, MSHA data also show that most exposures to respirable crystalline silica are below the proposed PEL. However, at MNM and coal mines where elevated exposures are found, operators will be able to reduce exposures to the proposed PEL through some combination of properly maintaining existing engineering controls, implementing new engineering controls, and requiring safe work practices. Mines and laboratories will be able to meet exposure monitoring requirements with existing validated and widely used sampling and analytical methods. The proposed revision to the respiratory protection standard is technologically feasible because MSHA's existing respiratory protection requirements for selecting, fitting, using, and maintaining respiratory protection include similar requirements.

MSHA's Preliminary Risk Analysis (PRA) suggests that exposure consistent with a lower proposed PEL of 50 $\mu g/m^3$ would deliver many health benefits to miners who currently experience exposures above the proposed PEL by reducing the likelihood of respirable crystalline silica-related diseases. For those miners working only under the proposed PEL, MSHA estimates that the proposed rule would result in a total of 799 lifetime avoided deaths (63 in coal and 736 in MNM mines) and 2,809 lifetime avoided morbidity cases (244 in coal and 2,566 in MNM mines) over a 60-year period. MSHA expects full implementation and compliance to reduce lifetime mortality risk due specifically to silica exposures by 9.5 percent and to reduce silicosis morbidity risk by 41.9 percent. The latter statistic is particularly important to coal miners given surveillance findings noted by the National Academies of Sciences, Engineering, and Medicine that severe pneumoconiosis where respirable crystalline silica is likely an important contributor is presenting in relatively young miners, sometimes in their late 30's and early 40's.

MSHA's economic analysis estimates that the proposed respirable crystalline silica rule would cost an average of $56.1 million per year in 2021 dollars at an undiscounted rate, $57.6 million at a 3 percent discount rate, and $59.9 million at a 7 percent discount rate. Based on the results of the Preliminary Regulatory Impact Analysis (PRIA), MSHA estimates that the proposed rule's benefits would exceed its costs, with or without discount rates. Monetized benefits are estimated from avoidance of 410 deaths related to NMRD, silicosis, ESRD, and lung cancer and 1,420 cases of silicosis associated with silica exposure over the first 60-year period after the promulgation of the final rule. The estimated annualized net benefit is approximately $212.8 million at an undiscounted rate, $118.2 million at a 3 percent discount rate, and $36.3 million at a 7 percent discount rate.

A rule is significant under Executive Order 12866 Section 3(f)(1), as amended by E.O. 14094, if it is likely to result in "an annual effect on the economy of $200 million or more or . . . adversely affect in a material way the economy, a sector of the economy, productivity,

competition, jobs, the environment, public health or safely, or State, local, or tribal governments or communities." The Office of Management and Budget has determined that the proposed rule is significant within the meaning of E.O. 12866 Section 3(f)(1).

The proposed rule would strengthen MSHA's existing regulatory framework. It would establish a uniform proposed PEL that provides all MNM and coal miners with the same exposure limits for respirable crystalline silica consistent with exposure limits that other U.S. workers currently receive in non-mining industries. It would update the existing respiratory protection standard to require mine operators to provide miners with NIOSH-approved respiratory equipment that has been fitted, selected, maintained, and used in accordance with recent consensus standards. The proposed rule would also include requirements for all MNM operators to provide medical surveillance in the form of a medical examination regime similar to what coal miners already receive. Cumulatively, the proposed provisions would lower miners' risk of developing chronic, irreversible, disabling, and potentially fatal health conditions, consistent with MSHA's mission and statutory mandate to prevent occupational diseases and protect U.S. miners from suffering material health impairments.

II. Request for Comments

MSHA requests comments on the proposed rule and all relevant issues, including the review and conclusions of the health effects discussion, preliminary risk analysis, feasibility analysis, preliminary regulatory impact analysis and regulatory alternatives, and preliminary regulatory flexibility analysis. While MSHA invites comments on any aspect of its proposed rule and related documents, the Agency particularly seeks information and data in response to questions posed in this section and any other aspect of this proposed rule. Instructions for submitting and viewing comments are provided under the **DATES** heading. MSHA will consider all timely comments and may change the proposed rule based on such comments.

MSHA requests that commenters organize their comments, to the extent possible, around the following numbered questions. The Agency is interested in receiving responses to the listed questions and any information or data supporting the responses.

Health Effects

1. In the standalone, background document entitled "Health Effects of Respirable Crystalline Silica" and as summarized in Section V. Health Effects Summary of this preamble, MSHA has made a preliminary determination that miners' exposure to respirable crystalline silica presents a risk of material health impairment due to the risk of developing silicosis, NMRD, lung cancer, and renal disease, based on its extensive review of the health effects literature. MSHA requests comments on this preliminary determination and its literature review, which draws heavily from the review conducted by OSHA for its 2016 rulemaking. Are there additional adverse health effects that should be included or more recent literature that offers a different perspective? MSHA requests that commenters submit information, data, or additional studies or their citations. Please be specific regarding the basis for any recommendation to include additional adverse health effects.

Preliminary Risk Analysis

2. In the standalone, background document entitled "Preliminary Risk Analysis" and as summarized in Section VI. Preliminary Risk Analysis Summary of this preamble, MSHA relied on risk models that OSHA used in support of its 2016 respirable crystalline silica final rule. Does the context of the MSHA rule suggest that the model would benefit from changes? If so, please describe both the justification for those changes and the likely impact on the final risk estimates. Are there additional studies or sources of data that MSHA should consider? What is the rationale for recommending the use of these additional studies or data?
3. MSHA's risk analysis of lung cancer mortality uses the exposure-response model from Miller and MacCalman (2010) instead of Steenland et al. (2001a), on which OSHA's risk

assessment of lung cancer mortality was based. MSHA uses Miller and MacCalman (2010) for several reasons. First, it covers coal mining-specific cohort large enough (with 45,000 miners) to provide adequate statistical power to detect low levels of risk, and it covers an extended follow-up period (1959-2006). Second, the study provided data on cumulative exposure of cohort members and adjusted for or addressed confounders such as smoking and exposure to other carcinogens. Finally, it developed quantitative assessments of exposure-response relationships using appropriate statistical models or otherwise provided sufficient information that permitted MSHA to do so. The Agency is requesting comment on MSHA's reliance on the Miller and MacCalman (2010) study in assessing lung cancer mortality. Please provide any other studies or information that MSHA should take into account in determining the risk of lung cancer mortality among miners.

Technological Feasibility of the Proposed Rule

4. As discussed in Section VIII. Technological Feasibility of this preamble, MSHA has preliminarily determined that it is technologically feasible for mine operators to conduct air sampling and analysis and to achieve the proposed PEL using commercially available samplers. MSHA has also determined that these technologically feasible samplers are widely available, and a number of commercial laboratories provide the service of analyzing dust containing respirable crystalline silica. In addition, MSHA has determined that technologically feasible engineering controls are readily available, can control crystalline silica-containing dust particles at the source, provide reliable and consistent protection to all miners who would otherwise be exposed to respirable dust, and can be monitored. MSHA has also determined that administrative controls, used to supplement engineering controls, can further reduce and maintain exposures at or below the proposed PEL. Moreover, MSHA has preliminarily determined the proposed respiratory protection practices for respirator use are technologically feasible for mine operators to implement. MSHA requests comments on these preliminary conclusions. What methods have you used

that proved effective in reducing miners' exposure to respirable crystalline silica in mining operations? Please explain how those methods were effective in reducing miners' exposures. To what extent do existing controls that reduce exposure to other airborne hazards (e.g., coal dust, diesel particulate matter) already reduce exposures to respirable crystalline silica below the proposed PEL? To what extent does the proposed rule including the PEL facilitate MSHA's workplace health and safety goals? Please provide supporting information, such as quantitative data if available.

5. MSHA has determined that the proposed medical surveillance requirements for MNM are technologically feasible. MSHA requests comments on this preliminary conclusion. Please provide supporting information, such as quantitative data if available.

Preliminary Regulatory Impact Analysis and Regulatory Alternatives

6. In the standalone background document entitled "*Preliminary Regulatory Impact Analysis*" and as summarized in Section IX. Summary of Preliminary Regulatory Impact Analysis and Regulatory Alternatives of this preamble, MSHA developed estimated costs of compliance with the proposed rule and estimated monetized benefits associated with averted cases of respirable crystalline silica-related diseases. MSHA requests comments on the methodologies, baseline, assumptions, and estimates presented in the Preliminary Regulatory Impact Analysis. Please provide any data or quantitative information that may be useful in evaluating the estimated costs and benefits associated with the proposed rule.
7. MSHA considered two regulatory alternatives in developing the proposed rule discussed in Section IX. Summary of Preliminary Regulatory Impact Analysis and Regulatory Alternatives. In the regulatory alternatives presented, MSHA discussed alternatives to the proposed PEL, action level, sampling requirements, and semi-annual evaluations. MSHA requests comments on these and other regulatory alternatives and information on any other alternatives that the Agency should consider, including different average working-life spans and different average shift lengths. Please provide supporting information about how

these alternatives could affect miners' protection from respirable crystalline silica exposure and affect mine operators' costs.

Initial Regulatory Flexibility Analysis

8. As summarized in Section X. Initial Regulatory Flexibility Analysis of this preamble, MSHA examined the impact of the proposed rule on small mines in accordance with the Regulatory Flexibility Act. MSHA estimated that small-entity controllers would be expected to incur, on average, additional regulatory costs equaling approximately 0.122 percent of their revenues (or $1,220 for every $1 million in revenues). MSHA is interested in how the proposed rule would affect small mines, including their ability to comply with the proposed requirements. Please provide information and data that supports your response. If you operate a small mine, please provide any projected impacts of the proposal on your mine, including the specific rationale supporting your projections.

Scope and Effective Date

9. MSHA is proposing a unified regulatory and enforcement framework for controlling miners' exposures to respirable crystalline silica for the mining industry. MSHA requests comments on this unified regulatory and enforcement framework. MSHA requests the views and recommendations of stakeholders regarding the scope of proposed part 60, which would include all surface and underground MNM and coal mines. MSHA requests comments on whether separate standards should be developed for the MNM mining industry and the coal mining industry. Please provide supporting information.
10. MSHA is proposing that the final rule would be effective 120 days after its publication in the Federal Register. This period is intended to provide mine operators time to evaluate existing engineering and administrative controls, update their respiratory protection programs, and prepare to comply with other provisions of the rule including recordkeeping requirements. Please provide your views on the proposed effective date. In your response, please include the rationale for your position.

Definitions

11. MSHA requests comments on the proposed action level. Stakeholders should provide specific information and data in support of or against a proposed action level. Stakeholders should include a discussion of how the use of a proposed action level would impact their mines, including the cost of monitoring respirable crystalline silica above the proposed action level, and other relevant information. Please provide supporting information.
12. MSHA requests comments on the proposed definition for "objective data." Is it appropriate to allow mine operators to use objective data instead of a second baseline sample? Please provide supporting information.

Proposed Permissible Exposure Limit

13. MSHA is proposing a PEL for respirable crystalline silica of 50 $\mu g/m^3$ for a full-shift exposure, calculated as an 8-hour TWA for MNM and coal miners. MSHA has made a preliminary determination that the proposed PEL would reduce miners' risk of suffering material impairment of health or functional capacity over their working lives. MSHA seeks the views and recommendations of stakeholders on the proposed PEL. MSHA solicits comments on the approach of having a standalone PEL and whether to eliminate the reduced standard for total respirable dust when quartz is present at coal mines. Please provide evidence to support your response.
14. MSHA is proposing a PEL of 50 ug/m^3 and an action level of 25 $\mu g/m^3$ for respirable crystalline silica exposure. Which proposed requirements should be triggered by exposure at, above, or below the proposed action level? Please provide supporting information.

Methods of Compliance

15. MSHA requests comments on the proposed prohibition against rotation of miners as an administrative control. Please include a discussion of the potential effectiveness of this non-exposure approach and its impact on miners at specific mines. Please provide supporting information.

16. MSHA requests comments on the proposed requirement that mine operators must install, use, and maintain feasible engineering and administrative controls to keep miners' exposures to respirable crystalline silica below the proposed PEL. Please provide supporting information.

Proposed Exposure Monitoring

17. MSHA requests comments and information from stakeholders concerning the proposed approaches to monitoring exposures, and other approaches to accurately monitor miner exposure to respirable crystalline silica in MNM and coal mines. Please provide supporting information and data.
18. MSHA proposes to require mine operators to collect a respirable crystalline silica sample for a miner's regular full shift during typical mining activities. Many potential sources of respirable crystalline silica are present only when the mine is operating under typical conditions. MSHA requests comments on this requirement and whether to specify environmental conditions under which samples should be taken to ensure that samples accurately reflect actual levels of respirable crystalline silica exposure. In MSHA's experience, for example, environmental conditions such as precipitation (e.g., rain or snow) or wind could affect the actual levels of respirable crystalline silica exposure at miners' normal or regular workplaces throughout their typical workday. Please provide supporting information and data.
19. MSHA recognizes that some mining facilities operate seasonally or intermittently and that cumulative exposures for miners at these facilities may be lower than that of miners working at year-round operations. MSHA requests comments on the exposure monitoring approach under proposed § 60.12, including the frequency of exposure monitoring necessary to safeguard the health of miners at seasonal or intermittent operations. Please provide supporting information and data.

20. MSHA is proposing that each mine operator perform baseline sampling within 180 days after the rule becomes effective to assess the respirable crystalline silica exposure of each miner who is or may reasonably be expected to be exposed to respirable crystalline silica. MSHA requests comments on this proposed baseline sampling requirement. MSHA also requests comment on the ability of service providers used by mines such as industrial hygiene suppliers and consultants, and accredited laboratories that conduct respirable crystalline silica analysis, to meet the demand created by the baseline sampling requirements within the proposed timeline. Please include alternative approaches that might be equally protective of miners that should be implemented for assessing a miner's initial exposure to respirable crystalline silica.
21. MSHA is proposing a requirement that mine operators qualitatively evaluate every 6 months any changes in production, processes, engineering controls, personnel, administrative controls, or other factors, beginning 18 months after the effective date. MSHA requests comments on the timing of the proposed semi-annual evaluation requirements, and in particular, whether miners would possibly be exposed unnecessarily to respirable crystalline silica levels above the PEL due to the gap between the effective date and the proposed requirements. Please provide supporting information.
22. MSHA has determined that most occupations related to extraction and processing would meet the "reasonably be expected" threshold for baseline sampling. MSHA recognizes that some miners may work in areas or perform tasks where exposure is not reasonably expected, if at all. MSHA solicits comments on the assumption that most miners are exposed to at least some level of respirable crystalline silica, and on the proposed requirement that these miners should be subject to baseline sampling. Please provide supporting information.
23. MSHA is proposing that mine operators would not be required to conduct periodic sampling if the baseline sampling result, together with another sampling result or objective

data, as defined in proposed § 60.2, confirms miners' exposures are below the proposed action level. MSHA seeks comments on this proposal. Please provide supporting information and data.

24. MSHA is proposing that mine operators conduct periodic sampling within 3 months where the most recent sampling indicates miner exposures are at or above the proposed action level but at or below the proposed PEL and continue to sample within 3 months of the previous sampling until two consecutive samplings indicate that miner exposures are below the action level. MSHA solicits comments on the proposed frequency for periodic sampling, including whether the consecutive samples should be at least 7 days apart. Please provide supporting information and data.
25. MSHA is proposing that mine operators may discontinue periodic sampling when two consecutive samples indicate that miner exposures are below the proposed action level. MSHA requests comments on this proposal. Please provide supporting information and data.
26. MSHA is proposing that mine operators conduct semi-annual evaluations to evaluate whether any changes in production, processes, engineering controls, personnel, administrative controls, or other factors may reasonably be expected to result in new or increased respirable crystalline silica exposures. Please provide comments on this proposal, as well as alternative approaches that would be appropriate for evaluating any potential new or increased respirable crystalline silica exposures. Please provide supporting information and data.
27. MSHA is proposing that miners' exposures are measured using personal breathing-zone air samples for MNM operations and occupational environmental samples collected in accordance with §§ 70.201(c), 71.201(b), or 90.201(b) for coal operations. MSHA requests comments on this proposal. Please provide supporting information and data.

28. MSHA is proposing the use of representative sampling. Where several miners perform the same task on the same shift and in the same work area, the mine operator may sample a representative fraction of miners to meet the proposed exposure monitoring requirements. MSHA seeks comments on the use of representative sampling. Please provide supporting information and data.
29. MSHA is proposing that mine operators use laboratories accredited to ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," where the accreditation has been issued by a body that is compliant with ISO/IEC 17011 "Conformity assessment – requirements for accreditation bodies accrediting conformity assessment bodies." MSHA solicits comments on this proposal. Are there additional requirements that should be incorporated into this proposal to ensure accurate sample analysis methods? Please provide supporting information and data.
30. MSHA seeks comments on the proposal that mine operators ensure that laboratories evaluate all respirable crystalline silica samples using respirable crystalline silica analytical methods specified by MSHA, NIOSH, or OSHA. Are there additional requirements that should be incorporated into this proposal to ensure accurate sample analysis? Please provide supporting information and data.
31. MSHA seeks comments and information on mine operator and stakeholder experience using NIOSH's rapid field-based quartz monitoring (RQM) monitors for determining miners' exposures to respirable crystalline silica. Please provide any information and data.

Proposed Medical Surveillance for Metal and Nonmetal Miners

32. MSHA is proposing to require medical surveillance for MNM miners. Medical surveillance is already required for coal miners under 30 CFR 72.100 and has played an important role in tracking the burden of pneumoconiosis in coal miners but is not currently required for MNM miners. MSHA's proposal would require MNM mine operators to provide each miner new to the mining industry with an initial medical examination and a

follow-up examination no later than 3 years after the initial examination, at no cost to the miner. It would also require MNM mine operators to provide examinations for all miners at least every 5 years, which would be voluntary for miners. Is there an alternative strategy or schedule, such as voluntary initial or follow-up examinations, tying the medical surveillance requirement to miners reasonably expected to be exposed to any level of silica or to the action level that would be more appropriate for new MNM miners? Should the rule make each 5-year examination mandatory? Should the 5-year examination be mandatory for coal mine operators as well? Please provide data or cite references to support your position.

33. MSHA's proposed medical surveillance requirements for MNM miners do not include some requirements that are in MSHA's existing medical surveillance requirements for coal mine operators in 30 CFR 72.100. For example, § 72.100 requires coal mine operators to use NIOSH-approved facilities for medical examinations. Should MNM operators be required to use NIOSH-approved facilities for medical examinations? Coal mine operators also are required to submit for approval to NIOSH a plan for providing miners with the examinations specified. This is because NIOSH administers medical surveillance for coal miners with requirements for coal operators, but not MNM operators, in NIOSH standards (42 CFR part 37). Should the plan requirements be extended to MNM operators? However, the proposed requirements also include some requirements for MNM operators that are not included for coal operators. For example, the proposed provisions require operators of MNM mines to provide MNM miners with periodic medical examinations performed by physicians or other licensed health care professionals (PLHCP) or specialists including a history and physical examination focused on the respiratory system, a chest X-ray, and a spirometry test. The proposed rule also requires a written medical opinion be provided by the PLHCP or specialist to the mine operator regarding the miner's ability to wear a respirator. MSHA seeks comment on the differences between the medical

surveillance requirements for MNM operators in this proposed rule and the existing medical surveillance requirements for coal mine operators in § 72.100. MSHA also seeks comment on how best to collect health surveillance data from PLHCPs and specialists to track MNM miners' health, for example how to know when pneumoconiosis cases occur. MSHA seeks comments on alternative approaches to scheduling periodic medical surveillance. MSHA proposes to require operators to keep medical surveillance information for the duration of a miner's employment plus 6 months. The Agency seeks comments on this proposed requirement and on any alternative recordkeeping schedules that would be appropriate. Please provide supporting information.

34. MSHA's proposed medical surveillance requirements for MNM miners would require operators of MNM mines to provide miners with periodic medical examinations performed by PLHCP or specialists, including a history and physical examination focused on the respiratory system, a chest X-ray, and a spirometry test. MSHA seeks comment on whether use of any new diagnostic technology (e.g., high-resolution computed tomography) for the purposes of medical surveillance should be used.
35. MSHA's proposed medical surveillance requirements would require that the MNM mine operator provide a mandatory follow-up examination to the miner no later than 3 years after the miner's initial medical examination. If a miner's 3-year follow-up examination shows evidence of a respirable crystalline silica-related disease or decreased lung function, the operator would be required to provide the miner with another mandatory follow-up examination with a specialist within 2 years. For examinations that show evidence of disease or decreased lung function, MSHA seeks comment on how, and to whom, test results should be communicated.
36. MSHA requests comments as to whether the proposed provisions should include a medical removal option for MNM miners who have developed evidence of silica-related disease that is equivalent to the transfer rights and exposure monitoring provided to coal miners in

30 CFR part 90 (part 90). Under part 90, any coal miner who has evidence of the development of pneumoconiosis based on a chest X-ray or other medical examinations has the option to work in an area of the mine where the average concentration of respirable dust in the mine atmosphere during each shift to which that miner is exposed is continuously maintained at or below the applicable standard. Under part 90, coal miners are entitled to retention of pay rate, future actual wage increases, and future work assignment, shift and respirable dust protection. MSHA seeks comment on whether this medical removal option should be provided to MNM miners. What would be the economic impact of providing MNM miners a medical removal option? Please provide supporting information and data.

Proposed Respiratory Protection Standard

37. MSHA requests comments concerning the temporary, non-routine use of respirators and whether there are other instances or occupations in which the Agency should allow the use of respirators as a supplemental control. Please discuss any impacts on particular mines and mining conditions and the cost of air-purifying respirators, if applicable. MSHA also solicits comments on the proposed requirement that affected miners wear respiratory protection to maintain protection during temporary and non-routine use of respirators. Please provide supporting information.

38. MSHA is proposing to incorporate by reference ASTM F3387-19, published in 2019. Whenever respiratory protective equipment is needed, mine operators would be required to follow practices for program administration, standard operating procedures, medical evaluations, respirator selection, training, fit testing, and maintenance, inspection, and storage in accordance with the requirements of ASTM F3387-19. Beyond these elements, MSHA is proposing to provide operators the flexibility to select the elements in ASTM F3387-19 that are applicable to their practices of respirator use at their mines. Should mine operators have the flexibility to choose the ASTM F3387-19 elements that are appropriate for their mine-specific hazards because the need for respirators may vary due to the

variability of mining processes, activities, airborne hazards, and commodities mined? What, specifically, do you think should factor into the determination of what is applicable? MSHA seeks comments on its proposed approach and the impact it would have on mine operators and on miners' life and health.

39. ASTM F3387-19 identifies a variety of respiratory protection practice elements. MSHA proposes to require certain minimally acceptable program elements: program administration; standard operating procedures; medical evaluations; respirator selection; training; fit testing; and maintenance, inspection, and storage. Please comment on whether these are the appropriate elements to require, or if there are any other elements of ASTM F3387-19 that should be minimally included in any respiratory protection program. MSHA also welcomes comments on whether it would be appropriate to require the standard in its entirety. Please identify those elements that would ensure that approved respirators are selected, fitted, used, cleaned, and maintained so that the life and health of miners are safeguarded. MSHA also seeks data and information on the impact these changes would have on mine operators, especially smaller operators. What would be the economic impact if all or parts of ASTM F3387-19 were required respirator program elements? Please be specific with your response and provide details on respirator use at your mine to include information and data on mining processes and environmental conditions; level of exposures to airborne contaminants; frequency and duration of exposures; type and amount of work or physical labor, including frequency and duration; and medical evaluation on respirator use, if applicable.

Recordkeeping Requirements

40. MSHA is proposing to require recordkeeping for records of evaluations, records of samplings, records of corrective actions, and written determination records received from a PLHCP. The proposed rule's recordkeeping requirements are discussed in the Section-by-Section Analysis section of this Preamble. MSHA seeks comment on the utility of these

recordkeeping requirements as well as the costs of making and maintaining these records. Please provide supporting information.

Training Requirements

41. MSHA requests the views and recommendations of stakeholders regarding whether training requirements for miners should be included in proposed part 60. Please provide supporting information and data.

Conforming Changes

42. MSHA requests comments on the proposed conforming changes to remove the reduced coal dust standard from 30 CFR and the potential impact on coal mines and miners and on whether to retain the reduced standard for part 90 miners. Please provide supporting information.

43. MSHA is not proposing to adopt a similar approach as the OSHA Table 1 for the construction industry, where MSHA would prescribe specific exposure control methods for task-based work practices when working with materials containing respirable crystalline silica. See 29 CFR 1926.1153(c)(1). MSHA requests comments on specific tasks and exposure control methods appropriate for a Table 1-approach for the mining industry that also would adequately protect miners from risk of exposure to respirable crystalline silica. Please provide specific rationale and supporting information, including data on how such an approach would be implemented.

III. Background

The purpose of this proposed rule is to reduce miners' risk of developing occupational lung disease and other diseases caused by exposure to respirable crystalline silica and to better protect all miners from occupational exposure to airborne hazards. In promulgating mandatory standards dealing with toxic materials or harmful physical agents, MSHA is required to "set standards which most adequately assure on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity . . ." 30 U.S.C. 811(a)(6)(A).

A. Statutory Authority

The statutory authority for this proposal is provided by the Mine Act under sections 101(a), 103(h), and 508. 30 U.S.C. 811(a), 813(h), and 957. MSHA implements the provisions of the Mine Act to prevent death, illness, and injury from mining and promote safe and healthful workplaces for miners. The Mine Act requires the Secretary of Labor (Secretary) to develop and promulgate improved mandatory health or safety standards to prevent hazardous and unhealthy conditions and protect the health and safety of the nation's miners. 30 U.S.C. 811(a).

Congress passed the Mine Act to address these dangers, finding "an urgent need to provide more effective means and measures for improving the working conditions and practices in the Nation's coal or other mines in order to prevent death and serious physical harm, and in order to prevent occupational diseases originating in such mines." 30 U.S.C. 801(c). Congress concluded that "the existence of unsafe and unhealthful conditions and practices in the Nation's coal or other mines is a serious impediment to the future growth of the coal or other mining industry and cannot be tolerated." 30 U.S.C. 801(d). Accordingly, "the Mine Act evinces a clear bias in favor of miner health and safety." *Nat'l Mining Ass'n* v. *Sec'y, U.S. Dep't of Lab.*, 812 F.3d 843, 866 (11th Cir. 2016).

Section 101(a) of the Mine Act gives the Secretary the authority to develop, promulgate, and revise, as appropriate, mandatory health standards to address toxic materials or harmful physical agents. Under Section 101(a), standards must protect lives and prevent injuries in mines and be "improved" over any standard that it replaces or revises. Moreover, "the Mine Act does not contain the 'significant risk' threshold requirement . . . from the OSH Act." *Nat'l Mining Ass'n* v. *United Steel Workers*, 985 F.3d 1309, 1319 (11th Cir. 2021); see also *Nat'l Min. Ass'n* v. *Mine Safety & Health Admin.*, 116 F.3d 520, 527-28 (D.C. Cir. 1997) (contrasting the OSH Act at 29 U.S.C. 652 with the Mine Act at 30 U.S.C. 811(a) and noting that "[a]rguably, *this* language does not mandate the same risk-finding requirement as OSHA" and holding that "[a]t

most, ... [MSHA] was required to identify a significant risk associated with having no oxygen standard at all" (emphasis in original)).

The Secretary must set standards to assure, based on the best available evidence, that no miners will suffer material impairment of health or functional capacity from exposure to toxic materials or harmful physical agents over their working lives. 30 U.S.C. 811(a)(6)(A). In developing standards that attain the "highest degree of health and safety protection for the miner," the Mine Act requires that the Secretary consider the latest available scientific data in the field, the feasibility of the standards, and experience gained under the Mine Act and other health and safety laws. *Id.* However, MSHA's "duty to use the best evidence and to consider feasibility . . . cannot be wielded as counterweight to MSHA's overarching role to protect the life and health of workers in the mining industry." *Nat'l Mining Ass'n*, 812 F.3d at 866. Instead, "when MSHA itself weighs the evidence before it, it does so in light of its congressional mandate." *Id.*

Section 103(h) of the Mine Act gives the Secretary the authority to promulgate standards involving recordkeeping and reporting. 30 U.S.C. 813(h). In general, section 103(h) requires that every mine operator establish and maintain records, make reports, and provide this information, if required by the Secretary. *Id.* Also, section 508 of the Mine Act gives the Secretary the authority to issue regulations to carry out any provision of the Mine Act. 30 U.S.C. 957.

MSHA's proposal to lower the exposure limits for respirable crystalline silica and adopt an integrated monitoring approach across all mining sectors and to update the existing respiratory protection requirements would fulfill Congress' direction by preventing miners from suffering material impairment of health or functional capacity caused by exposure to respirable crystalline silica and other airborne contaminants.

B. Respirable Crystalline Silica Hazard and Mining

Silica is a common component of rock composed of silicon and oxygen (chemical formula SiO_2), existing in amorphous and crystalline states. Silica in the crystalline state is the focus of this rulemaking. Respirable crystalline silica consists of small particles of crystalline silica that can be inhaled and reach the alveolar region of the lungs, where they can accumulate and cause disease. In crystalline silica, the silicon and oxygen atoms are arranged in a three-dimensional repeating pattern. The crystallization pattern varies depending on the circumstances of crystallization, resulting in a polymorphic state – several different structures with the same chemical composition. The most common form of crystalline silica found in nature is quartz, but cristobalite and tridymite may also be found in limited circumstances. Quartz accounts for the overwhelming majority of naturally occurring crystalline silica. In fact, quartz accounts for almost 12 percent of the earth's crust by volume. All soils contain at least trace amounts of quartz and it is present in varying amounts in almost every type of mineral. Quartz is also abundant in most rock types, including granites, sandstones, and shale. Moreover, quartz is commonly found in limestone formations, although limestone itself does not contain quartz. Because of its abundance, crystalline silica in the form of quartz is present in nearly all mining operations.

Cristobalite and tridymite are formed at very high temperatures and are associated with volcanic activity. Naturally occurring cristobalite and tridymite are rare, but they can be found in volcanic ash and in a relatively small number of rock types limited to specific geographic regions. Although rare, exposure to cristobalite occurs when volcanic deposits are mined. In addition, when other materials are mined, miners can potentially be exposed to cristobalite during certain processing steps (e.g., heating silica-containing materials) and contact with refractory materials (e.g., replacing fire bricks in mine processing facility furnaces). Tridymite is rarely found in nature and miner exposure to tridymite is much more infrequent.

Most mining activities generate silica dust because silica is often contained in the ore being mined or in the overburden (i.e., the soil and surface material surrounding the commodity

being mined). Such activities include, but are not limited to, cutting, sanding, drilling, crushing, grinding, sawing, scraping, jackhammering, excavating, and hauling materials that contain silica. These activities can generate respirable crystalline silica and may therefore lead to miner exposure.

Inhaled small particles of silica dust can be deposited throughout the lungs. A large number of crystalline silica particles can reach and remain in the deep lung (i.e., alveolar region), although some small particles are cleared from the lungs. Because respirable crystalline silica particles are not water-soluble and do not undergo metabolism into less toxic compounds, those particles remaining in the lungs for prolonged periods result in a variety of cellular responses that may lead to pulmonary disease. The respirable crystalline silica particles that are cleared from the lungs can be distributed to lymph nodes, blood, liver, spleen, and kidneys, potentially accumulating in those other organ systems and causing renal disease and other adverse health effects.

In the U.S. in 2021, a total of 12,162 mines produced a variety of commodities. As shown in Table III-1, of those 12,162 total mines, 11,231 mines were MNM mines and 931 mines were coal mines. MNM mines can be broadly divided into five commodity groups: metal, nonmetal, stone, crushed limestone, and sand and gravel. These broad categories encompass approximately 98 different commodities.[1] Table III-1 shows that a majority of MNM mines produce sand and gravel, while the largest number of MNM miners work at metal mines (not including MNM contract workers (i.e., independent contractors and employees of independent contractors who are engaged in mining operations)).

[1] Commodities such as sand, gravel, silica, and/or stone for example are used in road building, concrete construction, manufacture of glass and ceramics, molds for metal castings in foundries, abrasive blasting operations, plastics, rubber, paint, soaps, scouring cleansers, filters, hydraulic fracturing, and various architectural applications. Some commodities naturally contain high levels of crystalline silica, such as high-quartz industrial and construction sands and granite dimension stone and gravel (both produced for the construction industry).

Table III-1: Number of Mines and Miners by Commodity in 2021

	Number of Mines	Number of Miners
MNM Mines		
Metal	264	35,864
Nonmetal	549	15,736
Stone	2,320	33,031
Crushed Limestone	1,866	23,691
Sand and Gravel	6,232	33,296
MNM Contract Workers	–	57,426*
MNM Subtotal	11,231	199,044
Coal Mines		
Underground	211	21,108
Surface	720	17,571
Coal Contract Workers	–	16,151*
Coal Subtotal	931	54,830
Grand Total	**12,162**	**253,874**

* The number of MNM and coal contract workers is presented in aggregate because commodity data for contract workers is unavailable.
Source: MSHA MSIS Data (reported on MSHA Form 7000-2).

The 931 coal mines – underground and surface – produce bituminous, subbituminous, anthracite, and lignite coal. Coal mining activities generate mixed coal mine dust that contains respirable silicates such as kaolinite, oxides such as quartz, as well as other components (IARC, 1997). These activities include the general mining activities previously mentioned (e.g., cutting, sanding, drilling, crushing, and hauling materials), as well as roof bolter operations, continuous mining machine operations, longwall mining, and other activities. Table III-1 shows that there are more surface coal mines than underground coal mines, but more miners are working in underground coal mines than surface coal mines (not including coal contract workers).

IV. Existing Standards and Implementation

MSHA has maintained health standards to protect MNM and coal miners from excessive exposure to respirable crystalline silica for decades. MSHA's existing standards, established in the early 1970s, limit miners' exposures to respirable crystalline silica. These standards require mine operators to monitor occupational exposures to respirable crystalline silica and to use engineering controls as the primary means of suppressing, diluting, or diverting dust generated by mining activities. They also require mine operators to provide respiratory protection in

limited situations and on a temporary basis. The existing standards for MNM and coal mines differ in some respects, including exposure limits and monitoring. This section describes MSHA's existing standards for respirable crystalline silica and presents respirable crystalline silica sampling data to show how MNM and coal mine operators have complied with them in recent years.

A. Existing Standards – Metal and Nonmetal Mines

MSHA's existing standards for exposure to airborne contaminants, including respirable crystalline silica, in MNM mines are found in 30 CFR part 56, subpart D (Air Quality and Physical Agents), and 30 CFR part 57, subpart D (Air Quality, Radiation, Physical Agents, and Diesel Particulate Matter). These standards include PELs for airborne contaminants (§§ 56.5001 and 57.5001), exposure monitoring (§§ 56.5002 and 57.5002), and control of exposure to airborne contaminants (§§ 56.5005 and 57.5005).

Permissible Exposure Limits. The existing PELs for the three polymorphs of respirable crystalline silica are based on the *TLVs® Threshold Limit Values for Chemical Substances in Workroom Air Adopted by the American Conference of Governmental Industrial Hygienists (ACGIH) for 1973*, incorporated by reference in 30 CFR 56.5001 and 57.5001 (ACGIH, 1974). The 1973 TLV® establishes limits for respirable dust containing 1 percent quartz or greater and is calculated in milligrams per cubic meter of air (mg/m^3) for each respirable dust sample. The TLV® for quartz is calculated by dividing the percent of respirable quartz plus 2, into the number 10. The TLV® for cristobalite and the TLV® for tridymite, respectively, are calculated by multiplying the same mass formula by one-half using the percentages of either cristobalite or tridymite found in the sample. Thus, the resulting TLVs® for respirable dust containing 1 percent respirable crystalline silica or greater are designed to limit exposures to less than 0.1 mg/m^3 or 100 $\mu g/m^3$ for quartz, to less than 0.05 mg/m^3 or 50 $\mu g/m^3$ for cristobalite, and to less than 0.05 mg/m^3 or 50 $\mu g/m^3$ for tridymite. Throughout the remainder of this preamble, the concentrations of respirable dust and respirable crystalline silica are expressed in $\mu g/m^3$.

Exposure Monitoring. Under 30 CFR 56.5002 and 57.5002, MNM mine operators must conduct respirable dust "surveys . . . as frequently as necessary to determine the adequacy of control measures." Mine operators can satisfy the survey requirement through various activities, such as respirable dust sampling and analysis, walk-through inspections, wipe sampling, examining dust control system and ventilation system maintenance, and reviewing information obtained from injury, illness, and accident reports.

MSHA encourages MNM mine operators to conduct sampling for airborne contaminants to ensure a healthy and safe work environment for miners because sampling provides more accurate information about miners' exposures to harmful airborne contaminants and the effectiveness of existing controls in reducing such exposures. When a mine operator's respirable dust survey indicates that miners have been overexposed to any airborne contaminant, including respirable crystalline silica, the operator is expected to adjust its control measures (e.g., exhaust ventilation) to reduce or eliminate the identified hazard. After doing so, the mine operator is expected to conduct additional surveys to determine whether these efforts were successful. Re-surveying should be done as frequently as necessary to ensure that the implemented control measures remain adequate. MSHA's determination of whether a mine operator has surveyed frequently enough is based on several factors, including whether sampling results comply with the permissible exposure limit, whether there have been changes in the mining operation or process, and whether controls such as local exhaust ventilation systems need routine or special maintenance.

Exposure Controls. MSHA's existing standards for controlling a miner's exposure to harmful airborne contaminants (§§ 56.5005 and 57.5005) require, if feasible, prevention of contamination, removal by exhaust ventilation, or dilution with uncontaminated air. The use of respiratory protective equipment is also allowed under specified circumstances such as when engineering controls are being developed or are not feasible. When respiratory protective equipment is used, the operator must have a respiratory protection program consistent with the

requirements of *American National Standards Practices for Respiratory Protection ANSI Z88.2-1969.*

Consistent with widely accepted industrial hygiene principles and NIOSH's recommendations, MSHA requires the use of engineering controls, supplemented by administrative controls, in its enforcement for the control of occupational exposure to respirable crystalline silica and other airborne contaminants (NIOSH, 1974). Engineering controls designed to remove or reduce the hazard at the source are the most effective. Examples of engineering controls include the installation of proper ventilation systems, use of water sprays or wetting agents to suppress airborne contaminants, installation of machine-mounted dust collectors to capture respirable crystalline silica and other contaminants, and the installation of control booths or environmental cabs to enclose equipment operators.

Although considered a supplementary or secondary measure to engineering controls, mine operators may use administrative controls to further reduce miners' exposures to respirable crystalline silica and other airborne contaminants. In applying administrative controls, mine operators can direct miners to perform certain activities in specific manners. For instance, as an administrative control, operators can specify adequate housekeeping procedures for miners to clean spills or handle contaminated clothing which could reduce occupational exposure to airborne contaminants, including respirable crystalline silica.

In addition, respiratory protective equipment can be used in controlling miners' exposures to airborne contaminants, including respirable crystalline silica, on a temporary basis or under non-routine, limited conditions. The use of respiratory protection is, however, considered to be a supplement, not an alternative to any engineering or administrative control, in reducing or eliminating a miner's exposure to airborne contaminants including respirable crystalline silica.

Under the existing standards in §§ 56.5005 and 57.5005, in circumstances where engineering controls are not yet developed or where it is necessary for miners to enter hazardous

atmospheres to establish controls or to perform non-routine maintenance or investigation, a miner using appropriate respiratory protection "may work for reasonable periods of time" in concentrations of airborne contaminants which exceed exposure limits. Respirators approved by NIOSH and suitable for their intended purpose must be provided by mine operators at no cost to the miner and must be used by miners to protect themselves against the health and safety hazards of airborne contaminants. Whenever respiratory protection is used, MNM mine operators are required to have a respirator program consistent with the requirements specified in ANSI Z88.2-1969.

B. Existing Standards – Coal Mines

Under existing standards, there is no separate standard for respirable crystalline silica for coal mines. MSHA's existing standards for exposure to respirable quartz in coal mines, found in 30 CFR 70.101 and 71.101, establish a respirable dust standard when quartz is present for underground and surface coal mines, respectively. Under 30 CFR part 90 (Mandatory Health Standards - Coal Miners Who Have Evidence of the Development of Pneumoconiosis), § 90.101 also sets the respirable dust standard when quartz is present for coal miners. Under these respirable dust standards, coal miners' exposures to respirable quartz are indirectly regulated through reductions in the overall respirable dust standard.

Under its existing respirable coal mine dust standards, MSHA defines quartz as crystalline silicon dioxide (SiO_2), which includes not only quartz but also two other polymorphs, cristobalite and tridymite.[2] Therefore, quartz and respirable crystalline silica are used interchangeably in the discussions of MSHA's existing standards for controlling exposures to

[2] Quartz is defined in 30 CFR 70.2, 71.2, and 90.2 as crystalline silicon dioxide (SiO_2) not chemically combined with other substances and having a distinctive physical structure. Crystalline silicon dioxide is most commonly found in nature as quartz but sometimes occurs as cristobalite or, rarely, as tridymite. Quartz accounts for the overwhelming majority of naturally occurring crystalline silica and is present in varying amounts in almost every type of mineral.

respirable crystalline silica in coal mines.

Exposure Limits. The exposure limit for respirable crystalline silica during a coal miner's shift is 100 $\mu g/m^3$, reported as an equivalent concentration as measured by the Mining Research Establishment (MRE) instrument. This equivalent concentration of respirable crystalline silica must not be exceeded during the miner's entire shift, regardless of duration. When the equivalent concentration of respirable quartz exceeds 100 $\mu g/m^3$, under §§ 70.101, 71.101, and 90.101, MSHA imposes a reduced respirable dust standard designed to ensure that respirable quartz will not exceed 100 $\mu g/m^3$. The applicable dust standard, when the equivalent concentration of respirable crystalline silica exceeds 100 $\mu g/m^3$, is computed by dividing the percent of quartz into the number 10. The result of this calculation becomes the exposure limit for respirable coal mine dust (RCMD), for the sections of the mine represented by the sample. Various sections within a mine may have different reduced RCMD exposure limits. Therefore, when a respirable dust sample collected by MSHA indicates that the average concentration of respirable quartz dust exceeds the exposure limit, the mine operator is required to comply with the applicable dust standard. By reducing the amount of respirable dust to which miners are exposed during their shifts, the miners' exposures to respirable crystalline silica are reduced to a level at or below the exposure limit of 100 $\mu g/m^3$.

Exposure Monitoring. Under §§ 70.208, 70.209, 71.206, and 90.207, coal mine operators are required to sample for respirable dust on a quarterly basis for specified occupations and work areas. The occupations and work areas specified in the existing coal standards are the occupations and work areas at a coal mine that are expected to have the highest concentrations of respirable dust -- typically in locations where respirable dust is generated. In addition, respirable dust sampling must be representative of respirable dust exposures during a normal production shift. Also, sampling must occur while miners are performing routine, day-to-day activities. Part 90 miners must be sampled for the air they breathe while performing their normal work duties, from the start of their work day to the end of their work day, in their normal work

locations.[3]

Exposure Controls. Under §§ 70.208, 70.209, 71.206, and 90.207, coal mine operators are required to use engineering or environmental controls as the primary means of complying with the respirable dust standards. Similar to the MNM standards, engineering and environmental controls include the use of dust collectors, water sprays, and ventilation controls. For many underground coal mines, providing adequate ventilation is the primary engineering control for respirable dust, ensuring that dust concentrations are continuously diluted with fresh air and exhausted away from miners.

When a respirable dust sample exceeds the exposure limit of 100 $\mu g/m^3$ for respirable quartz, the operator must reduce the average concentration of RCMD to a level designed to maintain the quartz level at or below 100 $\mu g/m^3$. If operators exceed the reduced RCMD standard, they are required to take corrective action to reduce exposure and comply with the reduced standard. Corrective actions that lower respirable coal mine dust, thus lowering respirable quartz exposures, are selected after evaluating the cause or causes of the overexposure. Corrective actions can include increasing air flow, improving ventilation controls, repairing and maintaining existing dust suppression controls, adding water sprays or other controls, cleaning dust filters or collectors more frequently, or repositioning the miner away from the dust source.

When taking corrective actions to reduce the exposure to respirable dust, coal mine operators must make approved respiratory equipment available to miners under §§ 70.208 and 71.206. Whenever respiratory protection is used, § 72.700 requires coal mine operators to comply with requirements specified in ANSI Z88.2-1969.

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[3] A "Part 90 miner" is defined in 30 CFR 90.3 as a miner employed at a coal mine who shows evidence of having contracted pneumoconiosis based on a chest X-ray or based on other medical examinations, and who is afforded the option to work in an area of a mine where the average concentration of respirable dust in the mine atmosphere during each shift to which that miner is exposed is continuously maintained at or below the applicable standard.

C. MSHA Inspection and Respirable Dust Sampling

MSHA collects respirable dust samples at mines and analyzes them for respirable crystalline silica to determine whether the respirable crystalline silica exposure limits are met and whether exposure controls are adequate. This section describes the respirable dust samples collected at MNM and coal mines in recent years and presents the results of the sample data analyses.

1. Respirable Dust Sample Collection

This subsection offers a brief description of how MSHA samples for respirable crystalline silica under the existing standards. Upon their arrival at mines, MSHA inspectors determine which areas of the mine and which miners to select for respirable dust sampling. At MNM mines, the MSHA inspector often determines sampling locations based on sample results from previous inspections and on the inspector's onsite observations of work practices and work areas. At coal mines, the MSHA inspector conducts sampling among the occupations or from the work areas that are specified for operator sampling under 30 CFR parts 70, 71, and 90. Generally speaking, MSHA inspectors collect respirable dust samples from the common occupations during typical and normal activities at the mine and from the positions that are commonly known to have the highest concentration of respirable dust.

After identifying which miners and which areas at the mine will be sampled for respirable dust, MSHA inspectors place gravimetric samplers on the selected miners or at the selected locations. Gravimetric samplers consist of a portable air-sampling pump connected to a particle-size separator (i.e., cyclone) and collection medium (i.e., filter). MSHA inspectors use Dorr-Oliver 10-mm nylon cyclones operated at a 1.7 liters per minute (L/min) flow rate for MNM mine sampling and at a 2.0 L/min flow rate (reported as MRE-equivalent concentrations) for coal

mine sampling.[4] For the entire duration of the work shift, the gravimetric sampler captures air from the breathing zone of each selected miner or occupation and from each selected work area.

MSHA inspectors use the full-shift sampling approach. When miners work longer than an 8-hour shift, which is common, those miners are sampled continuously throughout the extended work shifts. Full-shift sampling is used to minimize errors associated with fluctuations in airborne contaminant concentrations during the miners' work shifts and to avoid any speculation about the miners' exposures during unsampled periods of the work shift. Once sampling is completed, the inspectors send the cassettes containing the full-shift respirable dust samples to the MSHA Laboratory for analysis.

2. Respirable Dust Sample Analysis

The MSHA Laboratory analyzes inspectors' respirable dust samples, following its standard operating procedures (SOPs) summarized below.[5] Any samples that are broken, torn, or visibly wet are voided and removed before analysis. Once weighing of the samples is completed, samples are again screened based on mass gain and examined for validity. All valid samples that meet the minimum mass gain criteria per the associated MSHA analytical method are then analyzed for respirable crystalline silica and for the compliance determination.[6]

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[4] This type of sampling equipment was developed to separate the airborne particles by size in a manner similar to the size-selective deposition and retention characteristics of the human respiratory system. It is important to note that size-selective sampling does not measure the deposition of respirable particles in the lung. Rather, it provides a measure of the particulate mass available for deposition to the deep lung during breathing (Raabe and Stuart, 1999).

[5] The MSHA Laboratory has fulfilled the requirements of the AIHA Laboratory Accreditation Programs (AIHA-LAP), LLC accreditation to the ISO/IEC 17025:2017 international standard for industrial hygiene.

[6] The minimum mass gain criteria used by the MSHA Laboratory for the different samples are:

- MNM mine respirable dust samples: greater than or equal to 0.100 mg;
- Underground coal mine respirable dust samples: greater than or equal to 0.100 mg; and
- Surface coal mine respirable dust samples: greater than or equal to 0.200 mg.

The MSHA Laboratory uses two analytical methods to determine the concentration of quartz (and cristobalite and tridymite, if requested): X-ray diffraction (XRD) for respirable dust samples from MNM mines, and Fourier transform infrared spectroscopy (FTIR) for respirable coal mine dust samples.[7] The XRD method uses X-rays to distinguish and measure the structure, composition, and physical properties of a sample. The FTIR method relies on the absorption of infrared light to determine the composition of a sample. The percentage of silica in the MNM mine dust sample is calculated using the mass of quartz or cristobalite determined from the XRD analysis and the measured mass of respirable dust. The percentage of silica is used to calculate MSHA's PELs for quartz and cristobalite, in accordance with §§ 56.5001 and 57.5001. Similarly, in the respirable coal mine dust sample, the percentage of quartz is calculated using the quartz mass determined from the FTIR analysis and the sample's mass of dust. Current FTIR methods, however, cannot quantify quartz and cristobalite, and/or tridymite, in the same sample.

Exception: For six surface occupations that have been deemed "high risk," the laboratory uses a minimum mass gain criterion of greater than or equal to 0.100 mg.

If cristobalite analysis is requested for MNM mine respirable dust samples, filters having a mass gain of 0.05 mg or more are analyzed. In the rare instance when tridymite analysis is requested, a qualitative analysis for the presence of the polymorph is conducted concurrently with the cristobalite analysis.

[7] Details on MSHA's analytical procedures for respirable crystalline silica analysis can be found in "MSHA P-2: X-Ray Diffraction Determination of Quartz and Cristobalite in Respirable Metal/Nonmetal Mine Dust" and "MSHA P-7: Determination of Quartz in Respirable Coal Mine Dust by Fourier Transform Infrared Spectroscopy." Department of Labor, Mine Safety and Health Administration, Pittsburgh Safety and Health Technology Center, X-Ray Diffraction Determination of Quartz and Cristobalite in Respirable Metal/Nonmetal Mine Dust. https://arlweb.msha.gov/Techsupp/pshtcweb/MSHA%20P2.pdf. Department of Labor, Mine Safety and Health Administration, Pittsburgh Safety and Health Technology Center, MSHA P-7: Determination of Quartz in Respirable Coal Mine Dust By Fourier Transform Infrared Spectroscopy. https://arlweb.msha.gov/Techsupp/pshtcweb/MSHA%20P7.pdf.

For coal mines, the percentage of quartz is used to calculate the reduced dust standard when the quartz concentration exceeds 100 μg/m^3 (MRE).

It is worth noting how MSHA calculates full-shift exposure to respirable crystalline silica (and other airborne contaminants). When a miner who works an 8-hour shift is sampled, the miner's 8-hour TWA exposure is calculated as follows:

$$\textbf{8-}\ \boldsymbol{hour\ TWA} = \frac{\boldsymbol{Total\ weight\ of\ contaminant\ (\mu g)\ collected\ over\ 8\ hours}}{\boldsymbol{Flow\ rate\ (LPM)\ x\ 480\ mins\ x\ 0.001\ \ m^3/L}}$$

However, for work shifts that last longer than 8 hours, a coal miner's full-shift exposure is calculated differently than an MNM miner's full-shift exposure. In accordance with § 70.2, the coal miner's extended full-shift exposure has, since 2014, been calculated in the following way:

$$\boldsymbol{(Coal)\ Extended\ full\text{-}\ shift\ TWA} = \frac{\boldsymbol{Total\ weight\ of\ contaminant\ (\mu g)\ collected\ over\ the\ full\ shift}}{\boldsymbol{Flow\ rate\ (LPM)\ x\ Entire\ duration\ of\ the\ full\ shift\ (mins)\ x\ 0.001\ \ m^3/L}}$$

For the MNM miner, MSHA calculates extended full-shift exposure according to the following formula:

$$\boldsymbol{(MNM)\ Shift\ Weighted\ Average} = \frac{\boldsymbol{Total\ weight\ of\ contaminant\ (\mu g)\ collected\ over\ the\ full\ shift}}{\boldsymbol{Flow\ rate\ (LPM)\ x\ 480\ mins\ x\ 0.001\ \ m^3/L}}$$

For respirable dust samples from MNM mines, 480 minutes is used in the denominator regardless of the actual sampling time. Contaminants collected over extended shifts (e.g., 600-720 minutes) are calculated as if they had been collected over 480 minutes. MSHA has used this calculation approach (also known as "shift-weighted average") since the 1970s.

Under the shift-weighted average approach, exposures for work schedules greater than 8 hours are proportionately adjusted to allow direct comparison with the 8-hour PEL. The ACGIH TLVs® adopted by MSHA are based on exposure periods of no more than 8 hours per day and 40 hours per week, with 16 hours of recovery time between shifts.

D. Respirable Crystalline Silica Sampling Results – Metal and Nonmetal Mines

This section presents the results of respirable dust samples that were collected by MSHA inspectors at MNM mines from 2005 to 2019. From January 1, 2005, to December 31, 2019, a total of 104,354 valid samples were collected. Of this total, 57,769 samples that met the minimum mass gain criteria were analyzed for respirable crystalline silica. The vast majority of the 46,585 valid samples that were excluded from the analysis in this rulemaking did not meet the mass gain criteria described earlier and therefore the lab did not determine their silica concentration. Further information on the valid respirable dust samples that are excluded from the analysis in this rulemaking can be found in Appendix A of the preamble.

The respirable crystalline silica concentration is calculated using the measured mass of each of the polymorphs and the air sampling volume. As discussed above, the existing PEL for quartz in MNM mines is approximately equivalent to 100 $\mu g/m^3$ for a full-shift exposure, calculated as an 8-hour TWA, while the existing PELs for cristobalite and tridymite, respectively, are approximately equivalent to 50 $\mu g/m^3$ for a full-shift exposure, calculated as an 8-hour TWA.[8]

1. Annual Results of MNM Respirable Crystalline Silica Samples

Table IV-1 below shows the variation between 2005 and 2019 in: (1) the numbers of MNM respirable dust samples analyzed for respirable crystalline silica; and (2) the number and percentage of samples that had concentrations of respirable crystalline silica greater than 100 $\mu g/m^3$. Of the 57,769 MNM respirable dust samples analyzed for respirable crystalline silica over the 15-year period, about 6 percent (3,539 samples) had respirable crystalline silica concentrations exceeding the existing PEL of 100 $\mu g/m^3$. The average annual rates of overexposure ranged from a maximum of approximately 10 percent in 2006 (the second year) to

[8] If more than one polymorph is present the equation used to calculate the TLV® for respirable dust containing quartz is modified per Appendix C of the 1973 ACGIH TLV® Handbook, and the equation is modified as follows: 10 / [(% quartz + 2) + 2 (% cristobalite + 2)].

a minimum of approximately 4 percent in 2019 (the last year of the time series). Compared with the rates in 2005-2008, overexposure rates were substantially lower in 2009–2017, with a further drop in 2018–19.

Table IV-1: MNM Respirable Dust Samples, 2005–2019

Year	Number of Samples	Number of Samples with Respirable Crystalline Silica Concentration Greater than 100 µg/m^3	Percent of Samples with Respirable Crystalline Silica Concentration Greater than 100 µg/m^3
2005	6,982	503	7.2%
2006	3,385	338	10.0%
2007	3,879	297	7.7%
2008	2,806	269	9.6%
2009	5,937	320	5.4%
2010	4,992	259	5.2%
2011	3,938	234	5.9%
2012	3,422	205	6.0%
2013	3,150	140	4.4%
2014	3,067	153	5.0%
2015	3,015	169	5.6%
2016	2,958	150	5.1%
2017	3,526	205	5.8%
2018	3,227	152	4.7%
2019	3,485	145	4.2%
Total	**57,769**	**3,539**	**6.1%**

Source: MSHA MSIS respirable crystalline silica data for the MNM industry, January 1, 2005, through December 31, 2019 (version 20220812).

2. Analysis of MNM Respirable Crystalline Silica Samples by Commodity

Because the MNM mining industry produces commodities that contain varying degrees of respirable crystalline silica, it is important to examine each commodity separately. MNM mines can be grouped by five commodities: metal, sand and gravel, stone, crushed limestone, and nonmetal (where nonmetal includes all other materials that are not metals, besides sand, gravel, stone, and limestone). This grouping is based on the mine operator-reported mining products and the North American Industry Classification System (NAICS) codes. (Appendix B

of the preamble provides a list of the NAICS codes relevant for MNM mining and how each code is assigned to one of the five commodities.)

Table IV-2 shows the distribution of the respirable dust samples analyzed for respirable crystalline silica by mine commodity. The percentage of samples with respirable crystalline silica concentrations greater than the existing exposure limit of 100 µg/m^3 varies across the different commodities. It is highest for the metal, sand and gravel, and stone commodities (at approximately 11, 7, and 7 percent, respectively), and lowest for the nonmetal and crushed limestone commodities (at approximately 4 and 3 percent, respectively).

Table IV-2: MNM Respirable Dust Samples by Commodity, 2005-2019

Commodity	Number of Samples	Number of Samples with Respirable Crystalline Silica Concentration Greater than 100 µg/m^3	Percent of Samples with Respirable Crystalline Silica Concentration Greater than 100 µg/m^3
Metal Mines	3,499	376	10.8%
Nonmetal Mines	5,165	232	4.5%
Stone Mines	15,415	1,134	7.4%
Crushed Limestone Mines	15,184	434	2.9%
Sand and Gravel Mines	18,506	1,363	7.4%
Total	**57,769**	**3,569**	**6.1%**

Source: MSHA MSIS respirable crystalline silica data for the MNM industry, January 1, 2005, through December 31, 2019 (version 20220812).

3. Analysis of MNM Respirable Crystalline Silica Samples by Occupation

To examine how miners who perform different tasks differ in occupational exposure to respirable crystalline silica, MSHA grouped MNM mining jobs into 11 occupational categories. These categories include jobs that are similar in terms of tasks performed, equipment used, and engineering or administrative controls used to control miners' exposure. For example, backhoe operators, bulldozer operators, and tractor operators were grouped into "operators of large powered haulage equipment," whereas belt crew, belt cleaners, and belt vulcanizers were grouped into "conveyer operators." The 121 MNM job codes used by MSHA inspectors were

grouped into the following occupational categories:[9]

(1) Drillers (e.g., Diamond Drill Operator, Wagon Drill Operator, and Drill Helper),

(2) Stone Cutting Operators (e.g., Jackhammer Operator, Cutting Machine Operator, and Cutting Machine Helper),

(3) Kiln, Mill, and Concentrator Workers (e.g., Ball Mill Operator, Leaching Operator, and Pelletizer Operator),

(4) Crushing Equipment and Plant Operators (e.g., Crusher Operator/Worker, Scalper Screen Operator, and Dry Screen Plant Operator),

(5) Packaging Equipment Operators (e.g., Bagging Operator and Packaging Operations Worker),

(6) Conveyor Operators (e.g., Belt Cleaner, Belt Crew, and Belt Vulcanizer),

(7) Truck Loading Station Tenders (e.g., Dump Operator and Truck Loader),

(8) Operators of Large Powered Haulage Equipment (e.g., Tractor Operators, Bulldozer Operator, and Backhoe Operators),

(9) Operators of Small Powered Haulage Equipment (e.g., Bobcat Operator, Scoop-Tram Operator, and Forklift Operator),

(10) Mobile Workers (e.g., Laborers, Electricians, Mechanics, and Supervisors), and

(11) Miners in Other Occupations (e.g., Welder, Dragline Operator, Ventilation Crew and Dredge/Barge Operator).

Table IV-3 shows sample numbers and overexposure rates by MNM occupation. Operators of large powered haulage equipment accounted for the largest number of samples analyzed for silica (17,016 samples), whereas conveyor operators accounted for the fewest (215

[9] For a full crosswalk of job codes included in each of these 11 Occupational Categories, please see Appendix C of the preamble. Also, note that the order of the presentation of the 11 Occupational Categories here follows the general sequence of mining activities: first development and production, then ore/mineral processing, then loading, hauling, and dumping, and finally all others.

samples). Table IV-3 also shows the number and percentage of the samples exceeding the existing respirable crystalline silica PEL of 100 µg/m^3. In every occupational category, some MNM miners were exposed to respirable crystalline silica levels above the existing PEL. In 9 out of the 11 occupational categories, the percentage of samples exceeding the existing PEL is less than 10 percent, although two have higher rates, ranging up to more than 19 percent (in the case of stone cutting operators).

Table IV-3: MNM Respirable Dust Samples by Occupation, 2005-2019

Occupation	Number of Samples	Number of Samples with Respirable Crystalline Silica Concentration Greater than 100 µg/m^3	Percent of Samples with Respirable Crystalline Silica Concentration Greater than 100 µg/m^3
Drillers	2,092	107	5.1%
Stone Cutting Operators	2,446	474	19.4%
Kiln, Mill, and Concentrator Workers	1,802	125	6.9%
Crushing Equipment Operators and Plant Operators	11,565	816	7.1%
Packing Equipment Operators	2,980	278	9.3%
Conveyor Operators	215	24	11.2%
Truck Loading Station Tenders	453	32	7.1%
Operators of Large Powered Haulage Equipment	17,016	378	2.2%
Operators of Small Powered Haulage Equipment	1,110	77	6.9%
Mobile Workers	15,216	1,108	7.3%
Miners in Other Occupations	2,874	120	4.2%
Total	**57,769**	**3,539**	**6.1%**

Source: MSHA MSIS respirable crystalline silica data for the MNM industry, January 1, 2005, through December 31, 2019 (version 20220812).

4. Conclusion

This analysis of MSHA inspector sampling data shows that MNM operators have generally met the existing standard. Of the 57,769 respirable dust samples from MNM mines, approximately 6 percent exceeded the existing respirable crystalline silica PEL of 100 µg/m^3, although there are several outliers with much higher overexposures. For 9 of the 11 occupational

categories, less than 10 percent of the respirable dust samples had concentrations over the existing PEL of 100 μg/m^3 for respirable crystalline silica. In addition, about 80 percent of samples taken from stone cutting operators did not exceed the existing PEL, which historically has had high exposures to respirable dust and respirable crystalline silica;[10] nevertheless, this occupation continues to experience the highest overexposures relative to other MNM occupations. For the categories of drillers, miners in other occupations, and operators of large powered haulage equipment, approximately 5 percent or less of the respirable dust samples showed concentrations over the existing exposure limit.

MSHA believes that improved technology, engineering controls, and better training contributed to the reductions in exposures for miners who work in occupations exposed to the highest levels of respirable crystalline silica. In summary, the analysis of MSHA inspector sampling data indicates that the controls that MNM mine operators are using, together with MSHA's enforcement, have generally been effective in keeping miners' exposure at or below the existing limit of 100 μg/m^3.

E. Respirable Crystalline Silica Sampling Results – Coal Mines

To examine coal mine operators' compliance with existing respirable crystalline silica standards, MSHA analyzed RCMD samples collected by MSHA inspectors from 2016 to 2021. (The data analyses for this rulemaking do not include any respirable dust samples collected by coal mine operators.) The analysis below is based on the samples collected by inspectors starting on August 1, 2016, when Phase III of MSHA's 2014 Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors (Coal Dust Rule) (79 FR 24813, May 1, 2014) went into effect. At that time, the exposure limits for RCMD were lowered from 2.0 mg/m^3 to 1.5 mg/m^3 (MRE equivalent) at underground and surface coal mines, and from 1.0

[10] Analysis of MSHA respirable dust samples from 2005 to 2010 showed that stone and rock saw operators had approximately 20 percent of the sampled exposures exceeding the PEL. Watts *et al*. (2012).

mg/m^3 to 0.5 mg/m^3 (MRE equivalent) for intake air at underground coal mines and for Part 90 miners. From August 1, 2016, to July 31, 2021, MSHA inspectors collected a total of 113,607 valid RCMD samples. Of these valid samples, only those collected from the breathing zones of miners were used in the analysis for this rulemaking; no environmental dust samples were included.[11] Of those samples, 63,127 samples that met the minimum mass gain criteria and had no other disqualifying issues were analyzed for respirable quartz and quartz concentrations were determined. The majority of the non-environmental valid samples excluded from this rulemaking analysis were excluded due to insufficient mass. Further information on the valid respirable dust samples that are not included in the rulemaking analysis can be found in Appendix A of the preamble.

Of the 63,127 valid samples analyzed for respirable crystalline silica and used for this analysis, about 1 percent (777 samples) were over the existing quartz exposure limit of 100 µg/m^3 (MRE equivalent) for a full shift, calculated as a TWA.[12] Overexposure rates (the percent of samples above the exposure limit, on average across all coal mining occupations) decreased by nearly a quarter between the first half and the second half of the 2016-2021 period. As in MNM mines, different miner occupations had different overexposure rates. Using broader groupings, surface mines experienced higher rates of overexposure than underground mines (2.4 percent versus 1.0 percent, respectively).

1. Annual Results of Coal Respirable Crystalline Silica Samples

In examining trends from one year to the next, the discussion below focuses on the

[11] Environmental samples were not included in the analysis to be consistent with the proposed sampling requirements to determine individual miner exposure.

[12] The conversion between ISO values and MRE values uses the NIOSH conversion factor of 0.857. In the 1995b Criteria Document, NIOSH presented an empirically derived conversion factor of 0.857 for comparing current (MRE) and recommended (ISO) respirable dust sampling criteria using the 10 mm Dorr-Oliver nylon cyclone operated at 2.0 and 1.7 L/min, respectively (i.e., 1.5 mg/m^3 BMRC-MRE = 1.29 mg/m^3 ISO).

samples collected in the 6 calendar years from 2016 to 2021. The number of samples per year was stable from 2017 to 2019 before decreasing in 2020.[13] The overexposure rate decreased across the entire 2016 to 2021 period, from 1.41 percent in 2016 to 0.95 percent in 2021. As shown in Table IV-4, a review of the 6 calendar years reveals that the overexposure rate decreased by nearly a quarter from 2016-2018 (1.38 percent) to 2019-2021 (1.07 percent).

Table IV-4: Respirable Coal Mine Dust Samples, 2016–2021

Year	Number of Samples	Number of Samples with Respirable Crystalline Silica Concentration Greater than 100 µg/m^3 MRE	Percent of Samples with Respirable Crystalline Silica Concentration Greater than 100 µg/m^3 MRE
2016*	4,879	69	1.4%
2017	13,787	190	1.4%
2018	14,054	194	1.4%
2019	13,745	153	1.1%
2020	10,267	110	1.1%
2021*	6,395	61	1.0%
Total	**63,127**	**777**	**1.2%**

* The 2016 data represents respirable crystalline silica samples from August 1 to December 31, 2016, and the 2021 data represents respirable crystalline silica samples from January 1 to July 31, 2021.
Source: MSHA MSIS respirable crystalline silica data for the Coal Industry, August 1, 2016, through July 31, 2021 (version 20220617).

2. Analysis of Coal Respirable Crystalline Silica Samples by Location

Coal mining activities differ depending on the characteristics and locations of coal seams. When coal seams are several hundred feet below the surface, miners tunnel into the earth and use underground mining equipment to extract coal, whereas miners at surface coal mines remove topsoil and layers of rock to expose coal seams. Due to these differences, it is important to examine the respirable crystalline silica data by location to determine how underground and surface coal miners differ in occupational exposure to respirable crystalline silica.

Table IV-5, which presents the overexposure rate by type of mine where respirable coal

[13] The coal samples for 2016 begin in August of that year and the coal samples for 2021 end in July of that year.

mine dust samples were collected, shows that samples from surface coal mines reflected higher rates of overexposure than samples from underground mines. Out of the 53,095 respirable coal mine dust samples from underground mines, 1 percent (537 samples) were over the existing exposure limit. By contrast, there were 10,032 samples from surface coal mines, and approximately 2.4 percent (240 samples) of those samples were over the existing exposure limit.

Table IV-5: Respirable Coal Mine Dust Samples by Location, 2016 - 2021

Location	Number of Samples	Number of Samples with Respirable Crystalline Silica Concentration Greater than 100 µg/m^3 MRE	Percent of Samples with Respirable Crystalline Silica Concentration Greater than 100 µg/m^3 MRE
Underground Mines	53,095	537	1.0%
Surface Mines	10,032	240	2.4%
Total	**63,127**	**777**	**1.2%**

Source: MSHA MSIS respirable crystalline silica data for the Coal Industry, August 1, 2016, through July 31, 2021 (version 20220617).

3. Analysis of Coal Respirable Crystalline Silica Samples by Occupation

To assess the exposure to respirable crystalline silica of miners in different occupations, MSHA has consolidated the 220 job codes for coal mines into 9 occupational categories (using a similar process to the one it used for the MNM mines, but with different job codes and categories). For the coal mine occupational categories,[14] a distinction is made between occupations based on whether the job tasks are being performed at the surface of a mine or underground. For example, bulldozer operators are assigned to the operators of large powered haulage equipment grouping and then sorted into separate occupational categories based on whether they are working at the surface of a mine or underground.

Of the nine occupational categories used for coal miners, the five underground categories are:

[14] For a full crosswalk of which job codes were included in each of these nine Occupational Categories, please see Appendix C of the preamble.

(1) Continuous Mining Machine Operators (e.g., Coal Drill Helper and Coal Drill Operator),

(2) Longwall Workers (e.g., Headgate Operator and Jack Setter (Longwall)),

(3) Roof Bolters (e.g., Roof Bolter and Roof Bolter Helper),

(4) Operators of Large Powered Haulage Equipment (e.g., Shuttle Car Operator, Tractor Operator/Motorman, Scoop Car Operator), and

(5) All Other Underground Miners (e.g., Electrician, Mechanic, Belt Cleaner and Laborer, etc.).

The four surface occupational categories are:

(1) Drillers (e.g., Coal Drill Operator, Coal Drill Helper, and Auger Operator),

(2) Crusher Operators (e.g., Crusher Attendant, Washer Operator, and Scalper-Screen Operator),

(3) Operators of Large Powered Haulage Equipment (e.g., Backhoe Operator, Forklift Operator, and Bulldozer Operator), and

(4) Mobile Workers (e.g., Electrician, Mechanic, Blaster, Laborer, etc.).

The most sampled occupational category was operators of large powered haulage equipment (underground), representing approximately 34 percent of the samples taken. The least sampled occupational category was crusher operators (surface), consisting of 1 percent of the samples taken. Table IV-6 displays the number and percent of respirable coal mine dust samples with quartz greater than the existing exposure limit for each occupational category.

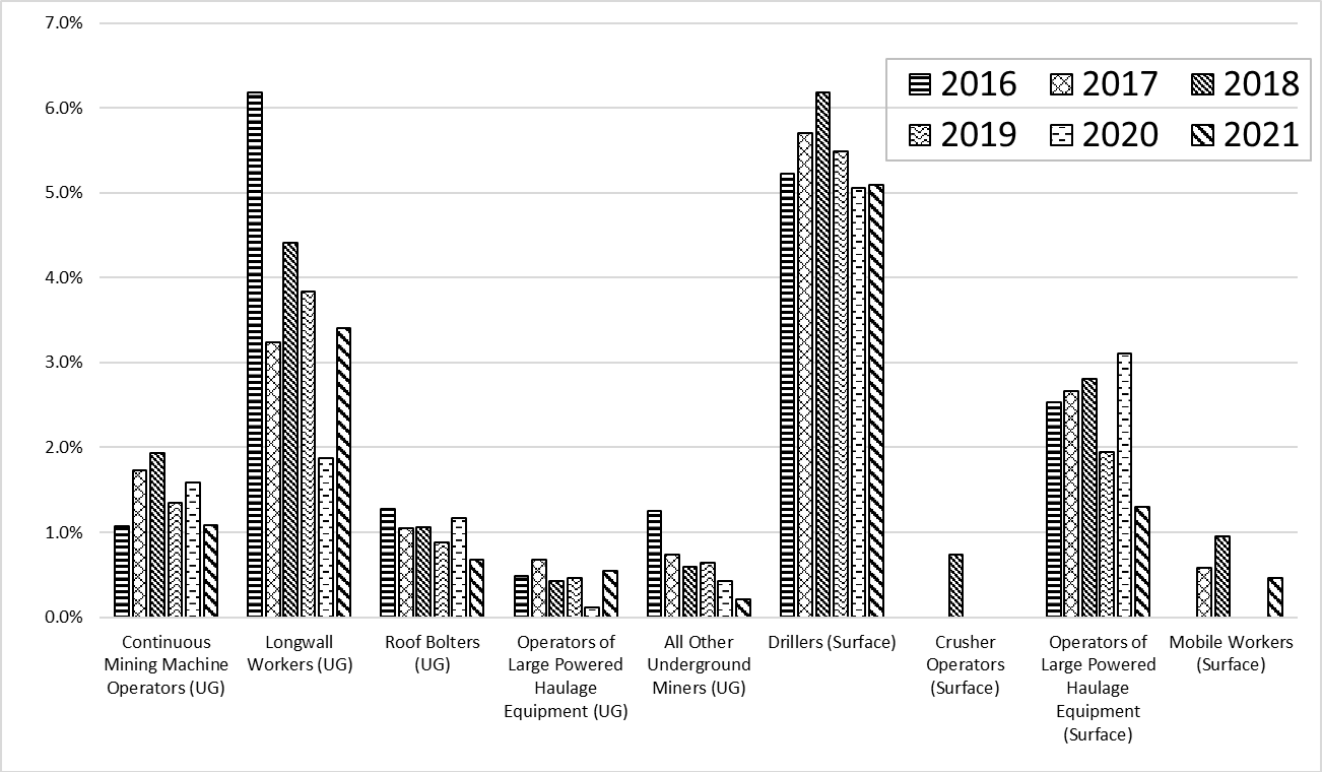
Table IV-6: Respirable Coal Mine Dust Samples by Occupation, 2016–2021

Occupation	Number of Samples	Number of Samples with Respirable Crystalline Silica Concentration Greater than 100 µg/m^3 MRE	Percent of Samples with Respirable Crystalline Silica Concentration Greater than 100 µg/m^3 MRE
Continuous Mining Machine Operators (UG)	9,910	154	1.6%
Longwall Workers (UG)	3,176	115	3.6%
Roof Bolters (UG)	14,306	145	1.0%
Operators of Large Powered Haulage Equipment (UG)	21,777	99	0.5%
All Other Underground Miners (UG)	3,926	24	0.6%
Drillers (Surface)	1,762	98	5.6%
Crusher Operators (Surface)	631	1	0.2%
Operators of Large Powered Haulage Equipment (Surface)	5,313	132	2.5%
Mobile Workers (Surface)	2,326	9	0.4%
Total	**63,127**	**777**	**1.2%**

Source: MSHA MSIS respirable crystalline silica data for the Coal Industry, August 1, 2016, through July 31, 2021 (version 20220617).

Looking at trends, every occupational category shows a decrease in overexposure rates over time. See Figure IV-1. Most of the nine categories had lower rates of overexposure in the 2019-2021 period than in the 2016-2018 period.

Figure IV-1: Percent of RCMD Samples with Respirable Crystalline Silica Concentration greater than 100 MRE µg/m³ (MRE) by Occupational Category*



* For Crusher Operators (Surface), only one sample with a quartz concentration greater than 100 µg/m³ MRE occurred (in 2018); and for Mobile Workers (Surface), only nine samples with a quartz concentration greater than 100 µg/m³ MRE occurred (three in 2017, five in 2018 and one in 2021).
Source: MSHA MSIS respirable crystalline silica data for the Coal Industry, August 1, 2016, through July 31, 2021 (version 20220617).

In all occupational categories, coal miners were sometimes exposed to respirable crystalline silica levels above the existing exposure limit. But the sampling data showed that coal mine operators can generally comply with the existing exposure limit. For example, although mining tasks performed by the occupational category of roof bolters (underground) historically resulted in high levels of overexposure to quartz, the low levels of overexposure for that occupation in 2016-2021 (i.e., 1 percent) suggest that roof bolters now benefit from the improved respirable dust standard, improved technology, and better training.[15] Over the 2016-2021 period, coal miners in the occupational category drillers (surface) were the most frequently overexposed, with approximately 6 percent of samples over the existing quartz limit; they were

[15] The drilling operation in the roof bolting process, especially in hard rock, generates excessive respirable coal and quartz dusts, which could expose the roof bolting operator to continued health risks (Jiang and Luo, 2021).

followed by longwall workers (underground) (about 4 percent), operators of large powered haulage equipment (surface) (about 3 percent), and continuous mining machine operators (underground) (about 2 percent). For all other occupational categories, the overexposure rate was less than 1 percent.

4. Conclusion

This analysis of MSHA inspector sampling data shows that coal mine operators can generally comply with the existing standards related to quartz. Of the 63,127 valid respirable dust samples from coal mines over the most recent 5-year period, 1.2 percent had respirable quartz over the existing exposure limit of 100 $\mu g/m^3$ (MRE equivalent) for a full-shift exposure, calculated as a TWA. Seven of the nine occupational categories had overexposure rates of 2.5 percent or less. Roof bolters (underground), which historically have had high exposures to respirable dust and respirable crystalline silica, had overexposure rates of 1 percent over this recent period. The data demonstrates that the controls that coal mine operators are using, together with MSHA's enforcement, have generally been effective in keeping miners' exposure to respirable crystalline silica at or below the existing exposure limit.

V. Health Effects Summary

This section summarizes the health effects from occupational exposure to respirable crystalline silica. MSHA's full analysis is contained in the standalone document, entitled *Effects of Occupational Exposure to Respirable Crystalline Silica on the Health of Miners* (Health Effects document), which has been placed in the rulemaking docket for the MSHA silica rulemaking (RIN 1219-AB36, Docket ID no. MSHA–2023–0001) and is available on MSHA's website.

The purpose of the Agency's scientific review is to present MSHA's preliminary findings on the nature of the hazards presented by exposure to respirable crystalline silica and to present the basis for the Preliminary Risk Analysis (PRA) to follow. (A PRA summary is presented in Section VI of this preamble and a standalone document entitled *Preliminary Risk Analysis* has

been placed in the rulemaking docket for the MSHA silica rulemaking (RIN 1219-AB36, Docket ID no. MSHA–2023–0001) and is available on MSHA's website.) MSHA reviewed a wide range of health research literature that included more than 600 studies exploring the relationship between respirable crystalline silica exposure and resultant health effects in miners and other workers across various industries. After discussing the toxicity of respirable crystalline silica, MSHA's review of the literature covers the following topics:

(1) Silicosis;

(2) NMRD, excluding silicosis;

(3) Lung cancer and cancer at other sites;

(4) Renal disease; and

(5) Autoimmune diseases.

To develop this literature review, MSHA expanded upon OSHA's (2013b) review of the health effects literature to support its final respirable crystalline silica rule (81 FR 16286, March 25, 2016). MSHA also drew upon numerous studies conducted by NIOSH, the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), and other researchers. These studies provided epidemiological data, morbidity (having a disease or a symptom of disease) and mortality (disease resulting in death) analyses, progression and pathology evaluations, death certificate and autopsy reviews, medical surveillance data, health hazard assessments, *in vivo* (animal) and *in vitro* toxicity data, and other toxicological reviews. These sources are cited throughout this summary and are listed in the References section of the Health Effects document. Additionally, these sources appear in the rulemaking docket.

MSHA's literature review is based on a weight-of-evidence approach, in which studies are evaluated for their overall quality. Causal inferences are drawn based on a determination of whether there is substantial evidence that exposure increases the risk of a particular adverse health effect. Factors MSHA considered in this weight-of-evidence analysis include: size of the cohort studied and power of the study to detect a sufficiently low level of disease risk, duration

of follow-up of the study population, potential for study bias (such as selection bias or healthy worker effects), and adequacy of underlying exposure information for examining exposure-response relationships. Of the studies examined in the Health Effects document, studies were deemed suitable for inclusion in the PRA if there was adequate quantitative information on exposure and disease risks and the study was judged to be of sufficiently high quality according to the above criteria.

The understanding of how respirable crystalline silica causes adverse health effects has evolved greatly in the more than 45 years since the Mine Act was passed in 1977. Based on its extensive review of health research literature, MSHA has preliminarily determined that occupational exposure to respirable crystalline silica causes silicosis (acute silicosis, accelerated silicosis, simple chronic silicosis, and PMF), NMRD (including COPD), and lung cancer, and it also causes end-stage renal disease (ESRD). In addition, MSHA believes that respirable crystalline silica exposure is causally related to the development of some autoimmune disorders through inflammation pathways. Each of these effects is exposure-dependent, chronic, irreversible, and potentially disabling or fatal. MSHA's review of the literature indicates that under the existing standards found in 30 CFR parts 56, 57, 70, 71, and 90, miners are still developing preventable diseases that are material impairments of health and functional capacity. Based on the assessment of health effects of respirable crystalline silica, MSHA preliminarily concludes that the proposed rule, which would lower the exposure limits in MNM and coal mining to 50 $\mu g/m^3$ and establish an action level of 25 $\mu g/m^3$ for a full-shift exposure, calculated as an 8-hour TWA, would reduce the risk of miners developing silicosis, NMRD, lung cancer, and renal disease.

A. Toxicity of Respirable Crystalline Silica

Respirable crystalline silica is released into the environment during mining or milling processes, thus creating an airborne hazard. The particles may be freshly generated or re-suspended from surfaces on which it is deposited in mines or mills. Respirable crystalline silica

particles may be irregularly shaped and variable in size. Inhaled respirable crystalline silica can be deposited throughout the lungs. Some pulmonary clearance of particles deposited in the deep lung (i.e., alveolar region) may occur, but a large number of particles can be retained and initiate or advance the disease process. The toxicity of these retained particles is amplified because the particles are not water-soluble and do not undergo metabolism into less toxic compounds. This is important biologically and physiologically, as insoluble dusts may remain in the lungs for prolonged periods, resulting in a variety of cellular responses that can lead to pulmonary disease (ATSDR, 2019). Respirable crystalline silica particles that are cleared from the lungs by the lymphatic system are distributed to the lymph nodes, blood, liver, spleen, and kidneys, potentially accumulating in these other organ systems and causing renal disease and other adverse health effects (ATSDR, 2019).

Physical characteristics relevant to the toxicity of respirable crystalline silica primarily relate to its size and surface characteristics. Researchers believe that the size and surface characteristics play important roles in how respirable crystalline silica causes tissue damage. Any factor that influences or modifies these physical characteristics may alter the toxicity of respirable crystalline silica by affecting the mechanistic processes (OSHA, 2013b; ATSDR, 2019).

Inflammation pathways affect disease development in various systems and tissues in the human body. For instance, it has been proposed that lung fibrosis caused by exposure to respirable crystalline silica results from a cycle of cell damage, oxidant generation, inflammation, scarring, and ultimately fibrosis. This has been reported by Nolan *et al.* (1981), Shi *et al.* (1989, 1998), Lapp and Castranova (1993), Brown and Donaldson (1996), Parker and Banks (1998), Castranova and Vallyathan (2000), Castranova (2004), Fubini *et al*. (2004), Hu *et al*. (2017), Benmerzoug *et al*. (2018), and Yu *et al*. (2020).

Respirable crystalline silica entering the lungs could cause damage by a variety of mechanisms, including direct damage to lung cells. In addition, activation or stimulation by

respirable crystalline silica of alveolar macrophages (after phagocytosis) and/or alveolar epithelial cells may lead to: (1) release of cytotoxic enzymes, reactive oxygen species (ROS), reactive nitrogen species (RNS), inflammatory cytokines and chemokines, (2) eventual cell death with the release of respirable crystalline silica, and (3) recruitment and activation of polymorphonuclear leukocytes (PMNs) and additional alveolar macrophages. The elevated production of ROS/RNS would result in oxidative stress and lung injury that stimulates alveolar macrophages, ultimately resulting in fibroblast activation and pulmonary fibrosis. The prolonged recruitment of macrophages and PMN causes a persistent inflammation, regarded as a primary step in the development of silicosis.

The strong immune response in the lung following exposure to respirable crystalline silica may also be linked to a variety of extra-pulmonary adverse effects such as hypergammaglobulinemia, production of rheumatoid factor, anti-nuclear antibodies, and release of other immune complexes (Parks *et al.,* 1999, Haustein and Anderegg, 1988; Green and Vallyathan, 1996). Respirable crystalline silica exposure has also been associated with nonmalignant renal disease through the initiation of immunological injury to the glomerulus of the kidney (Calvert *et al*., 1997).

Proposed mechanisms involved in respirable crystalline silica-induced carcinogenesis have included: direct DNA damage, inhibition of the p53 tumor suppressor gene, loss of cell cycle regulation; stimulation of growth factors, and production on oncogenes (Brown and Donaldson, 1996; Castranova, 2004; Fubini *et al*., 2004; Nolan *et al.*, 1981; Shi *et al.*, 1989, 1998).

B. Diseases

1. Silicosis

Silicosis is a progressive occupational disease that has long been identified as a cause of lung disease in miners. Based on its review of the literature, MSHA has preliminarily determined that exposure to respirable crystalline silica causes silicosis (acute silicosis,

accelerated silicosis, simple chronic silicosis, and PMF) in MNM and coal miners, which is a significant cause of serious morbidity and early mortality in this occupational cohort (Mazurek and Attfield, 2008; Mazurek and Wood, 2008a, 2008b; Mazurek *et al.*, 2015, 2018).

When respirable crystalline silica particles accumulate in the lungs, they cause an inflammatory reaction, leading to lung damage and scarring. Silicosis can continue to develop even after silica exposure has ceased. It is not reversible, and there is only symptomatic treatment, including bronchodilators to maintain open airways, oxygen therapy, and lung transplants in the most severe cases (Cochrane *et al.*, 1956; Ng *et al.*, 1987a; Lee *et al.*, 2001; Mohebbi and Zubeyri, 2007; Kimura *et al.*, 2010; Laney *et al.*, 2017; Almberg *et al.*, 2020; Hall *et al.*, 2022).

Respirable crystalline silica exposure in MNM miners can lead to all three forms of silicosis (acute, accelerated, and chronic). These forms differ in the rate of exposure, pathology (i.e., the structural and functional changes produced by the disease), and latency period from exposure to disease onset. Acute silicosis is an aggressive inflammatory process following intense exposure to respirable crystalline silica for "periods measured in months rather than years" (Cowie and Becklake, 2016). It causes alveolar proteinosis (accumulation of lipoproteins in the alveoli of the lungs). This restructuring of the lungs leads to symptoms such as coughing and difficult or labored breathing, and it often progresses to profound disability and death due to respiratory failure or infectious complications. In addition, symptoms often advance even after exposure has stopped, primarily due to the massive amount of protein debris and fluid that collects in the alveoli, which can suffocate the patient. The radiographic (X-ray) appearance and results of microscopic examination of acute silicosis are like those of idiopathic pulmonary alveolar proteinosis.

Chronic silicosis is the most frequently observed form of silicosis in the United States today (Banks, 2005; OSHA, 2013b; Cowie and Becklake, 2016). It is also the most common form of silicosis diagnosed in miners. Chronic silicosis is a fibrotic process that typically

follows less intense respirable crystalline silica exposure of 10 or more years (Becklake, 1994; Balaan and Banks, 1998; NIOSH, 2002b, Kambouchner and Bernaudin, 2015; Cowie and Becklake, 2016; Rosental, 2017; ATSDR, 2019; Barnes *et al*., 2019; Hoy and Chambers, 2020). It is identified by the presence of the silicotic islet or nodule that is an agent-specific fibrotic lesion and is recognized by its pathology (Balaan and Banks, 1998). Chronic silicosis develops slowly and creates rounded whorls of scar tissue that progressively destroy the normal structure and function of the lungs. In addition, the scar tissue opacities become visible by chest X-ray or computerized tomography (CT) only after the disease is well established and the lesions become large enough to view. As a result, surveys based on chest X-ray films usually underestimate the true prevalence of silicosis (Craighead and Vallathol, 1980; Hnizdo *et al*., 1993; Rosenman *et al*., 1997; Cohen and Velho, 2002). However, the lesions eventually advance and result in lung restriction, reduced lung volumes, decreased pulmonary compliance, and reduction in the gas exchange capabilities of the lungs (Balaan and Banks, 1998). As the disease progresses, affected miners may have a chronic cough, sputum production, shortness of breath, and reduced pulmonary function.

Accelerated silicosis includes both inflammation and fibrosis and is associated with intense respirable crystalline silica exposure. Accelerated silicosis usually manifests over a period of 3 to 10 years (Cowie and Becklake, 2016), but it can develop in as little as 2 to 5 years if exposure is sufficiently intense (Davis, 1996). Accelerated silicosis may have features of both chronic and acute silicosis (i.e., alveolar proteinosis in addition to X-ray evidence of fibrosis). Although the symptoms are similar to those of chronic silicosis, the clinical and radiographic progression of accelerated silicosis evolves more rapidly, and often leads to PMF, severe respiratory impairment, and respiratory failure. Accelerated silicosis can progress with associated morbidity and mortality, even if exposure ceases.

Among coal miners, silicosis is usually found in conjunction with simple coal worker's pneumoconiosis (CWP) (Castranova and Vallyathan, 2000) because of their exposures to RCMD

that contains respirable crystalline silica. Coal miners also face an added risk of developing mixed-dust pneumoconiosis (MDP) (includes the presence of coal dust macules), mixed-dust fibrosis (MDF), and/or silicotic nodules (Honma *et al*., 2004, see Figure 2, Green 2019). The autopsy studies on coal miners that MSHA reviewed support a pathological relationship between mixed-RCMD or respirable crystalline silica exposures and PMF, silicosis, and CWP (Attfield *et al*., 1994; Cohen *et al*., 2016, 2019, 2022; Davis *et al*., 1979; Douglas *et al*., 1986; Fernie and Ruckley, 1987; Green *et al*., 1989, 1998b; Ruckley *et al*., 1981, 1984; Vallyathan *et al*., 2011). Autopsy studies in British coal miners indicated that the more advanced the disease, the more mixed coal mine dust components were retained in the lung tissue (Ruckley *et al*., 1984; Douglas *et al*., 1986). Green *et al*. (1998b) determined that of 4,115 coal miners with pneumoconiosis autopsied as part of the National Coal Workers' Autopsy Study (NCWAS), 39 percent had mixed dust nodules and 23 percent had silicotic nodules.

PMF or "complicated silicosis" has been diagnosed in both coal and MNM miners exposed to dusts containing respirable crystalline silica. Recent literature on the pathophysiology of PMF supports the importance of crystalline silica as a cause of PMF in silica-exposed workers such as coal miners from the United States (Cohen *et al*., 2016, 2022), sandblasters (Abraham and Wiesenfeld, 1997; Hughes *et al*., 1982), industrial sand workers (Vacek *et al.*, 2019), hard rock miners (Verma *et al*., 1982, 2008), and gold miners (Carneiro *et al*., 2006a; Tse *et al*., 2007b).

a. Classifying Radiographic Findings of Silicosis

Two classification methods used to characterize the radiographic findings of silicosis in chest X-rays are described in this literature review: the International Labour Office (ILO) Standardized System and the Chinese categorization system.[16]

[16] The "Radiological Diagnostic Criteria of Pneumoconiosis and Principles for Management of Pneumoconiosis" (GB5906-86) (Chen *et al.*, 2001; Yang *et al.*, 2006).

To describe the presence and severity of pneumoconiosis from chest X-rays or digital radiographic images, the ILO developed a standardized system to classify the opacities identified (ILO, 1980, 2002, 2011, 2022). The ILO system grades the size, shape, and profusion (frequency) of opacities in the lungs. The density of opacities is classified on a 4-point major category scale (category 0, 1, 2, or 3), with each major category divided into three subcategories, giving a 12-point scale between 0/- and 3/+. Differences between ILO categories are subtle. For each subcategory, the top number indicates the major category that the profusion most closely resembles, and the bottom number indicates the major category that was given secondary consideration. For example, film readers may assign classifications such as 1/0, which means the reader classified it as category 1, but category 0 (normal) was also considered (ILO, 2022). Major category 0 indicates the absence of visible opacities and categories 1 to 3 reflect increasing profusion of opacities and a concomitant increase in severity of disease.

MSHA's analysis of silicosis studies uses NIOSH's surveillance case definition to determine the presence of silicosis. NIOSH defines the presence of silicosis in terms of the ILO system and considers a small opacity profusion score of 1/0 or greater to indicate pneumoconiosis (NIOSH, 2014b). This definition originated from testimony before Congress regarding the 1969 Coal Act where the Public Health Service recommended that miners be removed from dusty environments as soon as they showed "minimal effects" of dust exposure on a chest X-ray (i.e., pinpoint, dispersed micro-nodular lesions).[17] MSHA interprets "minimal effects" to mean an X-ray ILO profusion score of category 1/0 or greater.

[17] On March 26, 1969, Charles C. Johnson, Jr., Administrator, Consumer Protection and Environmental Health Service, PHS, U.S. Department of Health, Education, and Welfare, testified before the General Subcommittee on Labor and presented remarks of the Surgeon General. They are referenced in the 91st Congress House of Representatives Report, 1st Session No. 91–563, Federal Coal Mine Health and Safety Act, October 13, 1969 (https://arlweb.msha.gov/SOLICITOR/COALACT/69hous.htm).

However, some studies in MSHA's literature review use the Chinese categorization scheme, which includes four categories of silicosis: a suspected case (0+), stage I, stage II, or stage III. The four categories correspond to ILO profusion category 0/1, category 1, category 2, and category 3, respectively. A suspected case of silicosis (0+) in a dust-exposed worker refers to a dust response in the lung and its corresponding lymph nodes, or a scale and severity of small opacities that fall short of the level observed in a stage I case of silicosis (Chen *et al.*, 2001; Yang *et al.*, 2006). Under this scheme, a panel of three radiologists determines the presence and severity of radiographic changes consistent with pneumoconiosis.

b. Progression and Associated Impairment

Progression of silicosis is shown when there are changes or worsening of the opacities in the lungs, and sequential chest radiographs are classified higher by one or more subcategories (e.g., from 1/0 to 1/1) because of changes in the location, thickness, or extent of lung abnormalities and/or the presence of calcifications. The higher the category number, the more severe the disease. Due to the uncertainty in scoring films, some investigators count progression as advancing two or more subcategories, such as 1/0 to 1/2.

MSHA reviewed studies referenced by OSHA (2013b) that examined the relationship between exposure and progression, as well as between X-ray findings and pulmonary function. Additionally, MSHA considered more recent literature (Dumavibhat *et al*., 2013; Mohebbi and Zubeyri, 2007; Wade *et al.*, 2011) not previously reviewed by OSHA (2013b).

Overall, the studies indicate that progression is more likely with continued exposure, especially high average levels of exposure. Progression is also more likely for miners with higher ILO profusion classifications. As discussed previously, progression of disease may continue after miners are no longer exposed to respirable crystalline silica (Almberg *et al.*, 2020; Cochrane *et al.*, 1956; Hall *et al.*, 2020b; Hurley *et al.*, 1987; Kimura *et al.*, 2010; Maclaren *et al.*, 1985). In addition, although lung function impairment is highly correlated with chest X-ray

films indicating silicosis, researchers cautioned that respirable crystalline silica exposure could impair lung function before it is detected by X-ray.

Of the studies in which silicosis progression was documented in populations of workers, four included quantitative exposure data that were based on either existing exposure levels or historical measurements of respirable crystalline silica (Hessel *et al.*, 1988 study of gold miners; Miller and MacCalman, 2010 study of coal miners; Miller *et al.*, 1998 study of coal miners; Ng *et al.*, 1987a study of granite miners). In some studies, episodic exposures to high average concentrations were documented and considered in the analysis. These exposures were strong predictors of more rapid progression beyond that predicted by cumulative exposure alone. Otherwise, the variable most strongly associated in these studies with progression of silicosis was cumulative respirable crystalline silica exposure (i.e., the product of the concentration times duration of exposure, which is summed over time) (Hessel *et al.*, 1988; Ng *et al*., 1987a; Miller and MacCalman, 2010; Miller *et al*., 1998). In the absence of concentration measurements, duration of employment in specific occupations known to involve exposure to high levels of respirable dust has been used as a surrogate for cumulative exposure to respirable crystalline silica. It has also been found to be associated with the progression of silicosis (Ogawa *et al.*, 2003a).

Miller *et al*. (1998) examined the impact of high quartz exposures on silicosis disease progression on 547 British coal miners from 1990 to 1991 and evaluated chest X-ray changes after the mines closed in 1981. The study reviewed chest X-rays taken during health surveys conducted between 1954 and 1978 and data from extensive exposure monitoring conducted between 1964 and 1978. For some occupations, exposure was high because miners had to dig through a sandstone stratum to reach the coal. For example, quarterly mean respirable crystalline silica (quartz) concentrations ranged from 1,000 to 3,000 $\mu g/m^3$ (1 – 3 mg/m^3), and for a brief period, concentrations exceeded 10,000 $\mu g/m^3$ (10 mg/m^3) for one job. Some of these high exposures were associated with accelerated disease progression.

Buchanan *et al*. (2003) reviewed the exposure history and chest X-ray progression of 371 retired miners and found that short-term exposures (i.e., "a few months") to high concentrations of respirable crystalline silica (e.g., > 2,000 $\mu g/m^3$, > 2 mg/m^3) increased the silicosis risk by three-fold (compared to the risk of cumulative exposure alone) (see the separate *Preliminary Risk Analysis* document).

The risks of increased rate of progression, predicted by Buchanan *et al.* (2003) have been seen in coal miners (e.g., Cohen *et al.*, 2016; Laney *et al*., 2010, 2017; Miller *et al*., 1998), metal (Hessel *et al*., 1988; Hnizdo and Sluis-Cremer, 1993; Nelson, 2013), and nonmetal miners such as silica plant and ground silica mill workers, whetstone cutters, and silica flour packers (Mohebbi and Zubeyri, 2007; NIOSH 2000a,b; Ogawa *et al.*, 2003a). Accordingly, it is important to limit higher exposures to respirable crystalline silica in order to minimize the risk of rapid progressive pneumoconiosis (RPP) in miners.

The results of many surveillance studies conducted by NIOSH as part of the Coal Workers' Health Surveillance Program indicate that the pathology of pneumoconiosis in coal miners has changed over time, in part due to increased exposure to respirable crystalline silica. The studies of Cohen *et al*. (2016, 2022) indicate that a RPP develops due to increased exposure to respirable crystalline silica among contemporary coal miners as compared to historical coal miners. Through the examination of pathologic materials from 23 contemporary (born in or after 1930) and 62 historical coal miners (born between 1910 and 1930) with severe pneumoconiosis, who were autopsied as part of NCWAS, Cohen *et al*. (2022) found a significantly higher proportion of silica-type PMF among contemporary miners (57 percent vs. 18 percent, $p<0.001$). They also found that mineral dust alveolar proteinosis (MDAP) was more common in the current generation of miners and that the lung tissues of contemporary coal miners contained a significantly greater percentage and concentration of silica particles than those of past generations of miners.

c. Occupation-Based Epidemiological Studies

MSHA reviewed the occupation-based epidemiological literature (i.e., studies that examine health outcomes among workers and their potential association with conditions in the workplace). MSHA's review included the occupation-based literature OSHA cited in developing its respirable crystalline silica standard (OSHA, 2013b). Overall, OSHA found substantial evidence suggesting that occupational exposure to respirable crystalline silica increases the risk of silicosis, and MSHA concurs with this conclusion. MSHA also reviewed additional occupation-based literature specific to respirable crystalline silica exposure in MNM and coal miners and preliminarily concludes that respirable crystalline silica exposure increases the risk of silicosis morbidity and early mortality. One study examined the acute and accelerated silicosis outbreak that occurred during and after construction of Hawk's Nest Tunnel in West Virginia from 1930 to 1931. There, an estimated 2,500 men worked in a tunnel drilling rock consisting of 90 percent silica or more. The study later estimated that at least 764 of the 2,500 workers (30.6 percent) died from acute or accelerated silicosis (Cherniack, 1986). There was also high turnover among the tunnel workers, with an average length of employment underground of only about 2 months.

In a population of granite quarry workers (mean length of employment: 23.4 years) exposed to an average respirable crystalline silica concentration of 480 $\mu g/m^3$ (0.48 mg/m^3), 45 percent of those diagnosed with simple silicosis showed radiological progression of disease 2 to 10 years after diagnosis (Ng *et al*., 1987a). Among a population of gold miners, 92 percent showed progression after 14 years (Hessel *et al*., 1988). Chinese factory workers and miners who were categorized under the Chinese system of X-ray classification as "suspected" silicosis cases (analogous to ILO 0/1) had a progression rate to stage I (analogous to ILO major category 1) of 48.7 percent, with an average interval of about 5.1 years (Yang *et al.*, 2006).

Strong evidence has shown that lung function deteriorates more rapidly in miners exposed to respirable crystalline silica, especially in those with silicosis (Hughes *et al*., 1982; Ng and Chan, 1992; Malmberg *et al*., 1993; Cowie, 1998). The rates of decline in lung function are

greater where disease shows evidence of radiologic progression (Bégin *et al*., 1987; Ng *et al*., 1987a; Ng and Chan, 1992; Cowie, 1998). The average deterioration of lung function exceeds that in smokers (Hughes *et al*., 1982).

Blackley *et al*. (2015) found progressive lung function impairment across the range of radiographic profusion of simple CWP in a cohort of 8,230 coal miners that participated in the Enhanced Coal Workers' Health Surveillance Program from 2005 to 2013. There, 269 coal miners had category 1 or 2 simple CWP. This study also found that each increase in profusion score was associated with decreases in various lung function parameters: 1.5 percent (95 percent CI, 1.0 percent – 1.9 percent) in forced expiratory volume in one second (FEV_1) percent predicted, 1.0 percent (95 percent CI, 0.6 percent – 1.3 percent) forced vital capacity (FVC) percent predicted, and 0.6 percent (95 percent CI, 0.4 percent – 0.8 FEV_1/FVC).

Overall, MSHA preliminarily agrees with OSHA's conclusion that substantial evidence suggests that occupational exposure to respirable crystalline silica increases the risk of silicosis. MSHA also preliminarily concludes that respirable crystalline silica exposure increases the risk of silicosis morbidity and early mortality among miners.

d. Surveillance Data

In addition to occupation-based epidemiological studies, MSHA reviewed surveillance studies, which provide and interpret data to facilitate the prevention and control of disease, and preliminarily finds that the prevalence of silicosis generally increases with duration of exposure (work tenure). However, the available statistics may underestimate silicosis-related morbidity and mortality in miners. For example, the following have been reported: (1) misclassification of causes of death (e.g., as TB, chronic bronchitis, emphysema, or *cor pulmonale*); (2) errors in recording occupation on death certificates; and (3) misdiagnosis of disease (Windau *et al.*, 1991; Goodwin *et al.*, 2003; Rosenman *et al.*, 2003, Blackley *et al*., 2017). Furthermore, chest X-ray findings may lead to missed silicosis cases when fibrotic changes in the lung are not yet visible on chest X-rays. In other words, silicosis may be present but not yet detectable by chest X-ray,

or may be more severe than indicated by the assigned profusion score (Craighead and Vallyathan, 1980; Hnizdo *et al*., 1993; Rosenman *et al*., 1997).

e. Pulmonary Tuberculosis

Finally, in addition to the relationship between silica exposure and silicosis, studies indicate a relationship between silica exposure, silicosis, and pulmonary TB. OSHA reviewed these and concluded that silica exposure and silicosis increase the risk of pulmonary TB (Cowie, 1994; Hnizdo and Murray, 1998; teWaterNaude *et al.,* 2006). MSHA agrees with this conclusion.

Although early descriptions of dust diseases of the lung did not distinguish between TB and silicosis and most fatal cases described in the first half of the 20th century were likely a combination of silicosis and TB (Castranova *et al*., 1996), more recent findings have demonstrated that respirable crystalline silica exposure, even without silicosis, increases the risk of infectious (i.e., active) pulmonary TB (Sherson and Lander, 1990; Cowie, 1994; Hnizdo and Murray, 1998; teWaterNaude *et al*., 2006). These co-morbid conditions hasten the development of respiratory impairment and increased mortality risk even beyond the risk in unexposed persons with active TB (Banks, 2005).

Ng and Chan (1991) hypothesized that silicosis and TB "act synergistically" (i.e., are more than additive) to increase fibrotic scar tissue (leading to massive fibrosis) or to enhance susceptibility to active mycobacterial infection. The authors found that lung fibrosis is common to both diseases, and that both diseases decrease the ability of alveolar macrophages to aid in the clearance of dust or infectious particles.

These findings are also supported by new studies (Ndlovu *et al.,* 2019; Oni and Ehrlich, 2015) published since OSHA's review (2013b). Oni and Ehrlich (2015) reviewed a case of silico-TB in a former gold miner with ILO category 2/2 silicosis. Ndlovu *et al*. (2019) found that in a study sample of South African gold miners who had died from causes other than silicosis between 2005 and 2015, 33 percent of men (n=254) and 43 percent of women (n=29) at autopsy

were found to have TB, whereas 7 percent of men (n=54) and 3 percent of women (n=4) were found to have pulmonary silicosis.

Overall, MSHA agrees with OSHA's conclusion that silica exposure increases the risk of pulmonary TB and that pulmonary TB is a complication of chronic silicosis.

2. Nonmalignant Respiratory Disease (Excluding Silicosis)

In addition to causing silicosis (acute silicosis, accelerated silicosis, simple chronic silicosis, and PMF), exposure to respirable crystalline silica causes other NMRD. NMRD includes emphysema and chronic bronchitis, which are both diagnoses within the category of COPD. Patients with COPD may have chronic bronchitis, emphysema, or both (ATS, 2010a).

Based on its review of the literature, MSHA preliminarily concludes that exposure to respirable crystalline silica increases the risk for mortality from NMRD. The following summarizes MSHA's review of the literature.

a. Emphysema

Emphysema involves the destruction of lung architecture in the alveolar region, causing airway obstruction and impaired gas exchange. In its literature review, OSHA (2013b) concluded that exposure to respirable crystalline silica can increase the risk of emphysema, regardless of whether silicosis is present. OSHA also concluded that this is the case for smokers and that smoking amplifies the effects of respirable crystalline silica exposure, increasing the risk of emphysema. MSHA reviewed the studies cited by OSHA and agrees with its conclusion. The studies reviewed are summarized below.

Becklake *et al*. (1987) determined that a miner who had worked in a high dust environment for 20 years had a greater chance of developing emphysema than a miner who had never worked in a high dust environment. In a retrospective cohort study, Hnizdo *et al.* (1991a) used autopsy lung specimens from 1,553 white gold miners to investigate the types of emphysema caused by respirable crystalline silica and found that the occurrence of emphysema was related to both smoking and dust exposure. This study also found a significant association

between emphysema (both panacinar and centriacinar emphysema types) and length of employment for miners working in high dust occupations. A separate study by Hnizdo *et al*. (1994) on life-long non-smoking South African gold miners found that the degree of emphysema was significantly associated with the degree of hilar gland nodules, which the authors suggested might serve as a surrogate for respirable crystalline silica exposure. While Hnizdo *et al.* (2000) conversely found that emphysema prevalence was decreased in relation to dust exposure, the authors suggested that selection bias was responsible for this finding.

The findings of several cross-sectional and case-control studies discussed in the OSHA (2013b) Health Effects Literature were more mixed. For example, de Beer *et al*. (1992) found an increased risk for emphysema; however, the reported odds ratio (OR) was smaller than previously reported by Becklake *et al*. (1987).

The OSHA (2013b) Health Effects Literature also recognized that several of the referenced studies (Becklake *et al.*, 1987 Hnizdo *et al.*, 1994) found that emphysema might occur in respirable crystalline silica-exposed workers who did not have silicosis and suggested a causal relationship between respirable crystalline silica exposure and emphysema. Experimental (animal) studies found that emphysema occurred at lower respirable crystalline silica exposure concentrations than fibrosis in the airways or the appearance of early silicotic nodules (Wright *et al.*, 1988). These findings tended to support human studies that respirable crystalline silica-induced emphysema can occur absent signs of silicosis.

Green and Vallyathan (1996) reviewed several studies of emphysema in workers exposed to silica and found an association between cumulative dust exposure and death from emphysema. The IARC (1997) also reviewed several studies and concluded that exposure to respirable crystalline silica increases the risk of emphysema. Finally, NIOSH (2002b) concluded in its Hazard Review that occupational exposure to respirable crystalline silica is associated with emphysema. However, some epidemiological studies suggested that this effect might be less frequent or absent in non-smokers.

Overall, MSHA agrees with OSHA that exposure to respirable crystalline silica causes emphysema even in the absence of silicosis.

b. Chronic Bronchitis

Chronic bronchitis is long-term inflammation of the bronchi, increasing the risk of lung infections. This condition develops slowly by small increments and "exists" when it reaches a certain stage (i.e., the presence of a productive cough sputum production for at least 3 months of the year for at least 2 consecutive years) (ATS, 2010b).

OSHA considered many studies that examined the association between respirable crystalline silica exposure and chronic bronchitis, concluding the following: (1) exposure to respirable crystalline silica causes chronic bronchitis regardless of whether silicosis is present; (2) an exposure-response relationship may exist; and (3) smokers may be at an increased risk of chronic bronchitis compared to non-smokers. MSHA has reviewed the literature and agrees with OSHA's conclusions.

Miller *et al.* (1997) reported a 20 percent increased risk of chronic bronchitis in a British mining cohort compared to the disease occurrence in the general population. Using British pneumoconiosis field research data, Hurley *et al.* (2002) calculated estimates of mixed-RCMD-related disease in British coal miners at exposure levels that were common in the late 1980s and related their lung function and development of chronic bronchitis with their cumulative dust exposure. The authors estimated that by the age of 58, 5.8 percent of these men would report breathlessness for every 100 gram-hour/m^3 dust exposure. The authors also estimated the prevalence of chronic bronchitis at age 58 would be 4 percent per 100 gram-hour/m^3 of dust exposure. These miners averaged over 35 years of tenure in mining and a cumulative respirable dust exposure of 132 gram-hour/m^3.

Cowie and Mabena (1991) found that chronic bronchitis was present in 742 of 1,197 (62 percent) black South African gold miners, and Ng *et al*. (1992b) found a higher prevalence of respiratory symptoms, independent of smoking and age, in Singaporean granite quarry workers

exposed to high levels of dust (rock drilling and crushing) compared to those exposed to low levels of dust (maintenance and transport workers). However, Irwig and Rocks (1978) compared symptoms of chronic bronchitis in silicotic and non-silicotic South African gold miners and did not find as clear a relationship as did the above studies, concluding that the symptoms were not statistically more prevalent in the silicotic miners, although prevalence was slightly higher.

Sluis-Cremer *et al*. (1967) found that dust-exposed male smokers had a higher prevalence of chronic bronchitis than non-dust exposed smokers in a gold mining town in South Africa. Similarly, Wiles and Faure (1977) found that the prevalence of chronic bronchitis rose significantly with increasing dust concentration and cumulative dust exposure in South African gold miners of smokers, nonsmokers, and ex-smokers. Rastogi *et al.* (1991) found that female grinders of agate stones in India had a significantly higher prevalence of acute bronchitis, but they had no increase in the prevalence of chronic bronchitis compared to controls matched by socioeconomic status, age, and smoking. However, the study noted that respirable crystalline silica exposure durations were very short, and control workers may also have been exposed to respirable crystalline silica.

Studies examining the effect of years of mining on chronic bronchitis risk were mixed. Samet *et al*. (1984) found that prevalence of symptoms of chronic bronchitis was not associated with years of mining in a population of underground uranium miners, even after adjusting for smoking. However, Holman *et al*. (1987) studied gold miners in West Australia and found that the prevalence of chronic bronchitis, as indicated by ORs (controlled for age and smoking), was significantly increased in those that had worked in the mines for over 1 year, compared to lifetime non-miners. In addition, while other studies found no effect of years of mining on chronic bronchitis risk, those studies often qualified this result with possible confounding factors. For example, Kreiss *et al*. (1989) studied 281 hard-rock (molybdenum) miners and 108 non-miner residents of Leadville, Colorado. They did not find an association between the prevalence of chronic bronchitis and work in the mining industry (Kreiss *et al*., 1989); however, it is

important to note that the mine had been temporarily closed for 5 months when the study began, so miners were not exposed at the time of the study.

The American Thoracic Society (ATS) (1997) published a review finding chronic bronchitis to be common among worker groups exposed to dusty environments contaminated with respirable crystalline silica. NIOSH (2002b) also published a review finding that occupational exposure to respirable crystalline silica has been associated with bronchitis; however, some epidemiological studies suggested this effect might be less frequent or absent in non-smokers.

Finally, Hnizdo *et al.* (1990) found an independent exposure-response relationship between respirable crystalline silica exposure and impaired lung function. For miners with less severe impairment, the effects of smoking and dust together were additive. However, for miners with the most severe impairment, the effects of smoking and dust were synergistic (i.e., more than additive).

Overall, MSHA agrees with OSHA's conclusion that exposure to respirable crystalline silica causes chronic bronchitis regardless of whether silicosis is present and that an exposure-response relationship may exist.

c. Pulmonary Function Impairment

Pulmonary function impairment, generally defined as reduction below the lower limit of normal predicted by reference equations (and in older literature as less than 80 percent predicted) of diffusion capacity for carbon monoxide (DLCOcSB), total lung capacity (TLC), FVC, or FEV_1 is also a common condition of NMRD. Based on its review of the evidence in numerous longitudinal and cross-sectional studies and reviews, OSHA concluded that there is an exposure-response relationship between respirable crystalline silica and the development of impaired lung function. OSHA also concluded that the effect of tobacco smoking on this relationship may be additive or synergistic, and workers who were exposed to respirable crystalline silica but did not

show signs of silicosis may also have pulmonary function impairment. MSHA has reviewed the studies cited by OSHA and agrees with their conclusions.

OSHA reviewed several longitudinal studies regarding the relationship between respirable crystalline silica exposure and pulmonary function impairment. To evaluate whether exposure to silica affects pulmonary function in the absence of silicosis, the studies focused on workers who did not exhibit progressive silicosis.

Among both active and retired Vermont granite workers exposed to an average quartz dust exposure level of 60 $\mu g/m^3$, researchers found no exposure-related decreases in pulmonary function (Graham *et al*., 1981, 1994). However, Eisen *et al.* (1995) found significant pulmonary decrements among a subset of granite workers who left work and consequently did not voluntarily participate in the last of a series of annual pulmonary function tests (termed "dropouts"). This group experienced steeper declines in lung function compared to the subset of workers who remained at work and participated in all tests (termed "survivors"), and these declines were significantly related to dust exposure. Exposure-related changes in lung function were also reported in a 12-year study of granite workers (Malmberg *et al.*, 1993), in two 5-year studies of South African miners (Hnizdo, 1992; Cowie, 1998), and in a study of foundry workers whose lung function was assessed between 1978 and 1992 (Hertzberg *et al*., 2002). Similar reductions in FEV_1 (indicating an airway obstruction) were linked to respirable crystalline silica exposure.

Each of these studies reported their findings in terms of rates of decline in any of several pulmonary function measures (e.g., FEV_1, FVC, FEV_1/FVC). To put these declines in perspective, Eisen *et al*. (1995) reported that the rate of decline in FEV_1 seen among the dropout subgroup of Vermont granite workers was 4 ml per 1,000 $\mu g/m^3$-year (4 ml per mg/m^3-year) of exposure to respirable granite dust. By comparison, FEV_1 declines at a rate of 10 ml/year from smoking one pack of cigarettes daily. From their study of foundry workers, Hertzberg *et al.* (2002) reported a 1.1 ml/year decline in FEV_1 and a 1.6 ml/year decline in FVC for each 1,000

$\mu g/m^3$-year (1 mg/m^3-year) of respirable crystalline silica exposure after controlling for ethnicity and smoking. From these rates of decline, they estimated that exposure to 100 $\mu g/m^3$ of respirable crystalline silica for 40 years would result in a total loss of FEV_1 and FVC that was less than, but still comparable to, smoking a pack of cigarettes daily for 40 years. Hertzberg *et al.* (2002) also estimated that exposure to the existing MSHA standard (100 $\mu g/m^3$) for 40 years would increase the risk of developing abnormal FEV_1 or FVC by factors of 1.68 and 1.42, respectively.

OSHA reviewed cross-sectional studies that described relationships between lung function loss and respirable crystalline silica exposure or exposure measurement surrogates (e.g., tenure). The results of these studies were similar to those longitudinal studies already discussed. In several studies, respirable crystalline silica exposure was found to reduce lung function of:

- White South African gold miners (Hnizdo *et al*., 1990),
- Black South African gold miners (Cowie and Mabena, 1991; Irwig and Rocks, 1978),
- Respirable crystalline silica-exposed workers in Quebec (Bégin *et al*., 1995),
- Rock drilling and crushing workers in Singapore (Ng *et al*., 1992b),
- Granite shed workers in Vermont (Theriault *et al*., 1974a, 1974b),
- Aggregate quarry workers and coal miners in Spain (Montes *et al*., 2004a, 2004b),
- Concrete workers in the Netherlands (Meijer *et al*., 2001),
- Chinese refractory brick manufacturing workers in an iron-steel plant (Wang *et al*., 1997),
- Chinese gemstone workers (Ng *et al*., 1987b),
- Hard-rock miners in Manitoba, Canada (Manfreda *et al.*, 1982) and in Colorado (Kreiss *et al*., 1989),
- Pottery workers in France (Neukirch *et al*., 1994),
- Potato sorters in the Netherlands (Jorna *et al*., 1994),
- Slate workers in Norway (Suhr *et al*., 2003), and

- Men in a Norwegian community with years of occupational exposure to respirable crystalline silica (quartz) (Humerfelt *et al*., 1998).

The OSHA (2013b) Health Effects Literature recognized that many of these studies found that pulmonary function impairment: (1) can occur in respirable crystalline silica-exposed workers without silicosis, (2) was still observable when controlling for silicosis in the analysis, and (3) was related to the magnitude and duration of respirable crystalline silica exposure, rather than to the presence or severity of silicosis. Many other studies in the OSHA (2013b) Health Effects Literature have also found a relationship between respirable crystalline silica exposure and lung function impairment, including IARC (1997), the ATS (1997), and Hnizdo and Vallyathan (2003).

MSHA reviewed the studies and agrees with OSHA's finding that there is an exposure-response relationship between respirable crystalline silica and the impairment of lung function. MSHA also agrees with OSHA's finding that the effect of tobacco smoking on this relationship may be additive or synergistic, and that workers who were exposed to respirable crystalline silica, but did not show signs of silicosis, may also have pulmonary function impairment.

3. Carcinogenic Effects

a. Lung Cancer

Lung cancer, an irreversible and usually fatal disease, is a type of cancer that forms in lung tissue. Agreeing with the conclusion of other government and public health organizations that respirable crystalline silica is a "known human carcinogen," MSHA has preliminarily found that the scientific literature supports that respirable crystalline silica exposure significantly increases the risk of lung cancer mortality among miners. This determination is consistent with the conclusions of other government and public health organizations, including the IARC (1997b, 2012), the NTP (2000, 2016), NIOSH (2002b), the ATS (1997), and the American Conference of Governmental Industrial Hygienists (ACGIH®, (2010)). The Agency's determination is supported by epidemiological literature, encompassing more than 85 studies of

occupational cohorts from more than a dozen industrial sectors including: granite/stone quarrying and processing (Carta *et al.*, 2001; Attfield and Costello, 2004; Costello *et al.*, 1995; Guénel *et al.*, 1989a,b), industrial sand (Sanderson *et al.*, 2000; Hughes *et al.*, 2001; McDonald *et al.*, 2001, 2005; Rando *et al.*, 2001; Steenland and Sanderson, 2001), MNM mining (Steenland and Brown, 1995a; deKlerk and Musk, 1998; Roscoe *et al.*, 1995; Hessel *et al.*, 1986, 1990; Hnizdo and Sluis-Cremer, 1991; Reid and Sluis-Cremer, 1996; Hnizdo *et al*., 1997; Chen *et al.*, 1992; McLaughlin *et al*., 1992; Chen and Chen, 2002; Chen *et al.*, 2006; Schubauer-Berigan *et al*., 2009; Hua *et al.*, 1994; Meijers *et al*., 1991; Finkelstein 1998; Chen *et al.*, 2012; Liu *et al.*, 2017a; Wang *et al.*, 2020a,b; Wang *et al.*, 2021), coal mining (Meijers *et al*., 1988; Miller *et al.*, 2007; Miller and MacCalman, 2010; Miyazaki and Une, 2001; Graber *et al.*, 2014a,b; Tomaskova *et al*., 2012, 2017, 2020, 2022; Kurth *et al.*, 2020), pottery (Winter *et al.*, 1990; McLaughlin *et al.*, 1992; McDonald *et al.*, 1995), ceramic industries (Starzynski *et al*., 1996), diatomaceous earth (Checkoway *et al*., 1993, 1996, 1997, 1999; Seixas *et al*., 1997; Rice *et al.*, 2001), and refractory brick industries (cristobalite exposures) (Dong *et al.*, 1995).

The strongest evidence comes from the worldwide cohort and case-control studies reporting excess lung cancer mortality among workers exposed to respirable crystalline silica in various industrial sectors, confirmed by the 10-cohort pooled case-control analysis by Steenland *et al.* (2001a), the more recent pooled case-control analysis of seven European countries by Cassidy *et al.* (2007), and two national death certificate registry studies (Calvert *et al.*, 2003 in the United States; Pukkala *et al*., 2005 in Finland).

Recent studies examined lung cancer mortality among coal and non-coal miners (Meijers *et al*., 1988, 1991; Starzynski *et al.*, 1996; Miyazaki and Une, 2001; Tomaskova *et al*., 2012, 2017, 2020, 2022; Attfield and Kuempel, 2008; Graber *et al*., 2014a, 2014b; Kurth *et al*., 2020; NIOSH, 2019a). These studies also discuss the associations between RCMD and respirable crystalline silica exposures with lung cancer in coal mining populations. Furthermore, these newer studies are consistent with the conclusion of OSHA's final Quantitative Risk Assessment

(QRA) (2016a) that respirable crystalline silica is a human carcinogen. MSHA preliminarily concludes that miners, both MNM and coal miners, are at risk of developing lung cancer due to their occupational exposure to respirable crystalline silica.

In addition, based on its review of the literature, MSHA has preliminarily determined that radiographic silicosis is a marker for lung cancer risk. Reducing exposure to levels that lower the silicosis risk would reduce the lung cancer risk to exposed miners (Finkelstein, 1995, 2000; Brown, 2009). MSHA has also found that, based on the available epidemiological and animal data, respirable crystalline silica causes lung cancer (IARC, 2012; RTECS, 2016; ATSDR, 2019). Miners who inhale respirable crystalline silica over time are at increased risk of developing silicosis and lung cancer (Greaves, 2000; Erren *et al*., 2009; Tomaskova *et al.*, 2017, 2020, 2022).

Toxicity studies provide additional evidence of the carcinogenic potential of respirable crystalline silica. Studies using DNA exposed directly to freshly fractured respirable crystalline silica demonstrate the direct effect respirable crystalline silica had on DNA breakage. Cell culture research has investigated the processes by which respirable crystalline silica disrupt normal gene expression and replication. Studies have demonstrated that chronic inflammatory and fibrotic processes resulting in oxidative and cellular damage may lead to neoplastic changes in the lung (Goldsmith, 1997). In addition, the biologically damaging physical characteristics of respirable crystalline silica and its direct and indirect genotoxicity (Schins *et al.*, 2002; Borm and Driscoll, 1996) support MSHA's preliminary determination that respirable crystalline silica is an occupational carcinogen.

b. Cancers of Other Sites

In addition to lung cancer, OSHA reviewed studies examining the relationship between silica exposure and cancers at other sites. MSHA notes that OSHA reviewed these mortality studies (e.g., cancer of the larynx and the digestive system, including the stomach and esophagus) and found that studies suggesting a dose-response relationship were too limited in

terms of size, study design, or potential for confounding variables to be conclusive. OSHA also pointed to the NIOSH (2002b) silica (respirable crystalline silica) hazard review, which concluded that no association has been established between respirable crystalline silica exposure and excess mortality from cancer at other sites. MSHA has reviewed these studies and agrees with OSHA's conclusion. The following summarizes the studies reviewed with inconclusive findings.

1) Laryngeal Cancer

Three lung cancer studies (Checkoway *et al.*, 1997; Davis *et al*., 1983; McDonald *et al*., 2001) included in OSHA's health literature review suggest an association between respirable crystalline silica exposure and increased mortality from laryngeal cancer. However, a small number of cases were reported and researchers were unable to determine a statistically significant effect. Therefore, there is little evidence of an association based on these studies.

2) Gastric (Stomach) Cancer

OSHA reviewed several studies in its 2013b health literature review to assess a potential relationship between respirable crystalline silica exposures and stomach cancers. OSHA's literature review noted observations made previously by Cocco *et al.* (1996) and in the NIOSH respirable crystalline silica hazard review (2002b), which found that most epidemiological studies of respirable crystalline silica and stomach cancer did not sufficiently adjust for the effects of confounding factors. In addition, some of these studies were not properly designed to assess a dose-response relationship (e.g.*,* Finkelstein and Verma, 2005; Moshammer and Neuberger, 2004; Selikoff, 1978; Stern *et al.*, 2001) or did not demonstrate a statistically significant dose-response relationship (e.g.*,* Calvert *et al.*, 2003; Tsuda *et al.*, 2001). For these reasons, MSHA determined these studies were inconclusive in the context of this rulemaking.

3) Esophageal Cancer

OSHA considered several studies that examined the relationship between respirable crystalline silica exposures and esophageal cancer and found that the studies were limited in

terms of size, study design, or potential for confounding variables. Three nested case-control studies of Chinese workers demonstrated a dose-response association between increased risk of esophageal cancer mortality and respirable crystalline silica exposure (Pan *et al*., 1999; Wernli *et al*., 2006; Yu *et al.*, 2005). Other studies (Tsuda *et al*., 2001; Xu *et al.*, 1996a) also indicated elevated rates of esophageal cancer mortality with respirable crystalline silica exposure. However, OSHA noted that confounding factors due to other occupational exposures was possible. Additionally, two large national mortality studies in Finland and the United States did not show a positive association between respirable crystalline silica exposure and esophageal cancer mortality (Calvert *et al*., 2003; Weiderpass *et al*., 2003). MSHA agrees with OSHA's conclusion that the literature does not support attributing increased esophageal cancer mortality to exposure to respirable crystalline silica.

4) Other Sites

NIOSH (2002b) conducted a health literature review of the health effects potentially associated with respirable crystalline silica exposure, which identified only infrequent reports of statistically significant excesses of deaths for other cancers. Cancer studies have been reported in the following organs/systems: salivary gland, liver, bone, pancreas, skin, lymphopoietic or hematopoietic, brain, and bladder (see NIOSH, 2002b for full bibliographic references). However, the findings were not observed consistently among epidemiological studies, and NIOSH (2002b) concluded that no association has been established between these cancers and respirable crystalline silica exposure. OSHA concurred with NIOSH that these isolated reports of excess cancer mortality were insufficient to determine the role of respirable crystalline silica exposure.

Overall, OSHA concluded that evidence of an association between silica exposure and cancer at sites other than the lungs is not sufficient. MSHA agrees with OSHA's conclusion.

4. Renal Disease

Renal disease is characterized by the loss of kidney function, and in the case of ESRD, the need for a regular course of long-term dialysis or a kidney transplant. MSHA reviewed a wide variety of longitudinal and mortality epidemiological studies, including case series, case-control, and cohort studies, as well as case reports, and preliminarily concludes that respirable crystalline silica exposure increases the risk of morbidity and/or mortality related to ESRD. However, MSHA notes that the available literature on respirable crystalline silica exposures and renal disease in coal miners is less conclusive than the literature related to MNM miners.

Epidemiological studies have found statistically significant associations between occupational exposure to respirable crystalline silica and chronic renal disease (e.g., Calvert *et al.*, 1997), sub-clinical renal changes, including proteinuria and elevated serum creatinine (e.g., Ng *et al*., 1992a; Hotz *et al*., 1995; Rosenman *et al.*, 2000), ESRD morbidity (e.g., Steenland *et al*., 1990), ESRD mortality (Steenland *et al.*, 2001b, 2002a), and Wegener's granulomatosis (Nuyts *et al.*, 1995) (severe injury to the glomeruli that, if untreated, rapidly leads to renal failure). The pooled analysis conducted by Steenland *et al.* (2002a) is particularly convincing because it involved a large number of workers from three combined cohorts and had well-documented, validated job exposure matrices. Steenland *et al.* (2002a) found a positive and monotonic exposure-response trend for both multiple-cause mortality and underlying cause data. MSHA has preliminarily determined that the underlying data from Steenland *et al.* (2002a) are sufficient to provide useful estimates of risk.

Possible mechanisms suggested for respirable crystalline silica-induced renal disease include: (1) a direct toxic effect on the kidney, (2) a deposition in the kidney of immune complexes (e.g., Immunoglobulin A (IgA), an antibody blood protein) in the kidney following respirable crystalline silica-related pulmonary inflammation, and (3) an autoimmune mechanism (Gregorini *et al.*, 1993; Calvert *et al.*, 1997). Steenland *et al.* (2002a) demonstrated a positive exposure-response relationship between respirable crystalline silica exposure and ESRD mortality.

Overall, MSHA preliminarily determines that respirable crystalline silica exposure in mining increases the risk of renal disease.

5. Autoimmune Disease

Autoimmune diseases occur when the immune system mistakenly attacks healthy tissues within the body, causing inflammation, swelling, pain, and tissue damage. Examples include rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), scleroderma, and systemic sclerosis (SSc). Based on its literature review, MSHA preliminarily concludes that there is a causal association between occupational exposure to respirable crystalline silica and the development of systemic autoimmune diseases in miners. However, no studies are available to date that can be used to model respirable crystalline silica-exposure risk in a formal quantitative risk analysis.

Wallden *et al*. (2020) found that respirable crystalline silica exposure is correlated with an increased risk of developing ulcerative colitis, which increases with duration of exposure (work tenure) and the level of exposure. This effect was especially significant in men. Schmajuk *et al*. (2019) found that RA was significantly associated with coal mining and other non-coal occupations exposed to respirable crystalline silica. Finally, Vihlborg *et al.* (2017) found a significant increased risk of seropositive RA with high exposure (> 0.048 mg/m^3) to respirable crystalline silica dust when compared to individuals with no or lower exposure by examining detailed exposure-response relationships across four different respirable crystalline silica dose groups (quartiles): <23 $\mu g/m^3$, 24 to 35 $\mu g/m^3$, 36 to 47 $\mu g/m^3$, and >48 $\mu g/m^3$. However, these researchers did not report the risk of sarcoidosis and seropositive RA in relation to respirable crystalline silica exposure using logistic regressions resulting in models that could be used in the risk assessment. In addition, the meta-analysis of 19 published case-control and cohort studies on scleroderma by Rubio-Rivas *et al.* (2017) found statistically significant risks among individuals exposed to respirable crystalline silica, solvents, silicone, breast implants,

epoxy resins, pesticides, and welding fumes, but did not provide detailed quantitative exposure information.

C. Conclusion

MSHA preliminarily concludes that occupational exposure to respirable crystalline silica causes silicosis (acute silicosis, accelerated silicosis, simple chronic silicosis, and PMF), NMRD (including COPD), lung cancer, and kidney disease. Each of these effects is exposure-dependent, chronic, irreversible, potentially disabling, and can be fatal. MSHA suspects that respirable crystalline silica exposure is also linked to the development of some autoimmune disorders through inflammation pathways.

The scientific literature (including peer-reviewed medical, toxicological, public health, and other related disciplinary publications) is robust and compelling. It shows that miners exposed to the existing respirable crystalline silica limit of 100 $\mu g/m^3$ still have an unacceptable amount of excess risk for developing and dying from diseases related to occupational respirable crystalline silica exposures and still suffer material impairments of health or functional capacity.

VI. Preliminary Risk Analysis Summary

MSHA's preliminary risk analysis (PRA) quantifies risks associated with five specific health outcomes identified in the separate, standalone Health Effects document: silicosis morbidity and mortality, and mortality from NMRD, lung cancer, and ESRD. The standalone document, entitled *Preliminary Risk Analysis* (PRA document), has been placed into the rulemaking docket for the MSHA respirable crystalline silica rulemaking (RIN 1219-AB36, Docket ID no. MSHA–2023–0001) and is available on MSHA's website.

MSHA developed a PRA to support the risk determinations required to set an exposure limit for a toxic substance under the Mine Act. MSHA's PRA quantifies the health risk to miners exposed to respirable crystalline silica under the existing exposure limits for MNM and coal miners, at the proposed PEL of 50 $\mu g/m^3$, and at the proposed action level of 25 $\mu g/m^3$.

This analysis addresses three questions related to the proposed rule:

(1) whether potential health effects associated with existing exposure conditions constitute material impairment to any miner's health or functional capacity;

(2) whether existing exposure conditions place miners at risk of incurring any material impairment if regularly exposed for the period of their working life; and

(3) whether the proposed rule would reduce those risks.

To answer these questions, MSHA relied on the large body of research on the health effects of respirable crystalline silica and several published, peer-reviewed, quantitative risk assessments that describe the risk of exposed workers to silicosis mortality and morbidity, NMRD mortality, lung cancer mortality, and ESRD mortality. These assessments are based on several studies of occupational cohorts in a variety of industrial sectors. The underlying studies are described in the Health Effects document and are summarized in Section V. Health Effects Summary of this preamble.

This summary highlights the main findings from the PRA, briefly describes how they were derived, and directs readers interested in more detailed information to corresponding sections of the standalone PRA document.

A. Summary of MSHA's Preliminary Risk Analysis Process and Methods

MSHA evaluated the literature and selected an exposure-response model for each of the five health endpoints—silicosis morbidity, silicosis mortality, NMRD mortality, lung cancer mortality, and ESRD mortality. The selected exposure-response models were used to estimate lifetime excess risks and lifetime excess cases among the current population of MNM and coal miners based on real exposure conditions, as indicated by the samples in the compliance sampling datasets.

MSHA's PRA is largely based on the methodology and findings from a peer-reviewed January 2013 OSHA preliminary quantitative risk assessment (PQRA) and associated analysis of health effects in connection with OSHA's promulgation of a rule setting PELs for workplace exposure to respirable crystalline silica. OSHA's PQRA presented quantitative relationships

between respirable crystalline silica exposure and multiple health endpoints. Following multiple legal challenges, the U.S. Court of Appeals for the D.C. Circuit rejected challenges to OSHA's risk assessment methodology and its findings on different health risks. *N. Am.'s Bldg. Trades Unions* v. *OSHA*, 878 F.3d 271, 283-89 (D.C. Cir. 2017).

MSHA's PRA presents detailed quantitative analyses of health risks over a range of exposure concentrations that have been observed in MNM and coal mines. MSHA applied exposure-response models to estimate the respirable crystalline silica-related risk of material impairment of health or functional capacity of miners exposed to respirable crystalline silica at three levels – (1) the existing standards, (2) the proposed PEL, and (3) the proposed action level. As in past MSHA rulemakings, MSHA estimated and compared lifetime excess risks associated with exposures at the existing and proposed PEL (and at the proposed action level) over a miner's full working life of 45 years.

MSHA's PRA is also based on a compilation of miner exposure data to respirable crystalline silica. For the MNM sector, MSHA evaluated 57,769 valid respirable dust samples collected between January 2005 and December 2019; and for the coal sector, MSHA evaluated 63,127 valid respirable dust samples collected between August 2016 and July 2021. The compiled data set characterizes miners' exposures to respirable crystalline silica in various locations (e.g., underground, surface), occupations (e.g., drillers, underground miners, equipment operators), and commodities (e.g., metal, nonmetal, stone, crushed limestone, sand and gravel, and coal). MSHA enforcement sampling indicates a wide range of exposure concentrations. These include exposures from below the proposed action level (25 $\mu g/m^3$) to above the existing standards (100 $\mu g/m^3$ in MNM standards, 100 $\mu g/m^3$ MRE in coal standards, which is approximately 85.7 $\mu g/m^3$ ISO).[18]

[18] As discussed in the PRA, the existing PEL for coal is 100 $\mu g/m^3$ MRE, measured as a full-shift time-weighted average (TWA). To calculate risks consistently for both coal and MNM miners, the PRA converts the MRE full-

The primary results of the PRA are the calculated number of deaths and illnesses avoided assuming full compliance after implementation of MSHA's proposed rule. These calculations were performed for non-fatal silicosis illnesses (morbidity) and for deaths (mortality) due to silicosis, lung cancer, NMRD, and ESRD. For each health outcome, the reduced number of illnesses or deaths is calculated as the difference between (a) the number of illnesses and deaths currently occurring in the industry, assuming mines fully comply with the existing standards (100 $\mu g/m^3$ for MNM and 85.7 $\mu g/m^3$ ISO for coal) and (b) the number of deaths and illnesses expected to occur following implementation of the proposed rule, which includes a proposed PEL of 50 $\mu g/m^3$ for a full shift exposure, calculated as an 8-hour TWA.

Risks and cases were estimated under two scenarios: (a) a Baseline scenario where all exposures were capped at 100 $\mu g/m^3$ for MNM miners and at 85.7 $\mu g/m^3$ for coal miners, and (b) a proposed 50 $\mu g/m^3$ scenario where all risks were capped at the proposed PEL of 50 $\mu g/m^3$ for both MNM and coal miners. The difference between the two scenarios yields the estimated reduction in lifetime excess risks and in lifetime excess cases due to the proposed PEL.

To calculate risks, MSHA grouped MNM miners into the following exposure intervals: $\leq$25, >25 to $\leq$50, >50 to $\leq$100, >100 to $\leq$250, >250 to $\leq$500, and >500 $\mu g/m^3$. MSHA grouped

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shift TWA concentrations experienced by coal miners to ISO 8-hour TWA concentrations. (See Section 4 of the PRA document for a full explanation.) The equation used to convert MRE full-shift TWA concentrations into ISO 8-hour TWA concentrations is:

ISO 8-hour TWA concentration = (MRE TWA) x (original sampling time)/(480 minutes) x 0.857

Exposures at TWA 100 $\mu g/m^3$ MRE and SWA 85.7 $\mu g/m^3$ ISO are only equivalent when the sampling duration is 480 minutes (eight hours). However, for the sake of simplicity and for comparison purposes, the risk analysis approximates exposures at the existing coal exposure limit of 100 MRE $\mu g/m^3$ as 85.7 $\mu g/m^3$ ISO. Thus, ISO concentration values (measured as an 8-hour TWA) were used as the exposure metric when (a) calculating risk under the assumption of full compliance with the existing standards and (b) calculating risk under the assumption that no exposure exceeds the proposed PEL of 50 $\mu g/m^3$. To simulate compliance among coal miners at the existing exposure limit, exposures were capped at 85.7 $\mu g/m^3$ measured as an ISO 8-hour TWA.

coal miners into the following exposure intervals: ≤25, >25 to ≤50, >50 to ≤85.7, >85.7 to ≤100, >100 to ≤250, >250 to ≤500, and >500 μg/m^3. MSHA calculated the median of all exposure samples in each exposure interval and assumed the population of miners is distributed across the exposure intervals in proportion to the number of exposure samples from the compliance dataset in each interval. Then, miners were assumed to encounter constant exposure at the median value of their assigned exposure interval. MSHA adjusted the annual cumulative exposure by a full-time equivalency (FTE) factor to account for the fact that miners may experience more or less than 2,000 hours of exposure per year. MSHA calculated the FTE adjustment factor as the weighted average of the production employee FTE ratio (0.99 for MNM and 1.14 for coal) and the contract miner FTE ratio (0.59 for MNM and 0.64 for coal), where the weights are the number of miners (150,928 for MNM production employees, 60,275 for MNM contract miners, 51,1573 for coal production employees, and 22,003 for coal contract miners). For example, the weighted average FTE ratio for MNM is (0.987×150,928 + 0.591×60,275)/(150,928 + 60,275) = 0.87 and is (1.139×51,573 + 0.636×22,003)/(51, 573 + 22,003) = 0.99 for coal.

MSHA calculated excess risk, which refers to the additional risk of disease and death attributable to exposure to respirable crystalline silica. For silicosis morbidity, MSHA used an exposure-response model that directly yields the accumulated or lifetime excess risk of silicosis morbidity, assuming there is no background rate[19] of silicosis in an unexposed (i.e., non-miner) group. For the four mortality endpoints (silicosis mortality, lung cancer mortality, NMRD mortality, and ESRD mortality), MSHA used cohort life tables to calculate excess risks, assuming all miners begin working at age 21, retire at the end of age 65, and do not live past age 80. From the life tables, MSHA acquired the lifetime mortality risk by summing the miner

[19] Here, the "background" risk (or rate) refers to the risk of disease that the exposed person would have experienced in the absence of exposure to respirable crystalline silica. These background morbidity and mortality rates are measured using the disease-specific rates among the general population, which is not exposed to respirable crystalline silica.

cohort's mortality risks in each year from age 21 through age 80. Life tables were also constructed for unexposed (i.e., non-miner) groups assumed to die from a given disease at typical rates for the U.S. male population. MSHA used 2018 data for all males in the U.S. (published by the National Center for Health Statistics, 2020b) to estimate (a) the disease-specific mortality rates among unexposed males and (b) the all-cause mortality rates among both groups (exposed miners and unexposed non-miners).

For a given scenario (either Baseline or Proposed 50 $\mu g/m^3$), MSHA constructed life tables in the manner described above, both for a miner cohort exposed to respirable crystalline silica and for an unexposed non-miner cohort. MSHA calculated excess risk of the disease as the difference between the two cohorts' disease-specific mortality risk (due to silicosis, lung cancer, NMRD, or ESRD). MSHA determined the lifetime excess cases by multiplying the lifetime excess risk by the number of exposed miner FTEs (including both production employee FTEs and contract miner FTEs). Risks and cases were calculated separately for each exposure interval listed above. Then, the lifetime excess cases were aggregated across all exposure intervals. MSHA calculated the final lifetime excess risks per 1,000 miners in the full population by dividing the total number of lifetime excess cases by the total number of miners in the population (exposed at any interval). Finally, to estimate the risk reductions and avoided cases of illness due to the proposed PEL, MSHA compared the lifetime excess risks and lifetime excess cases across the two scenarios (Baseline and Proposed 50 $\mu g/m^3$).

B. Overview of Epidemiologic Studies

MSHA reviewed extensive research on the health effects of respirable crystalline silica and several quantitative risk assessments published in the peer-reviewed scientific literature regarding occupational exposure risks of illness and death from silicosis, NMRD, lung cancer, and ESRD. The Health Effects document describes the specific studies reviewed by MSHA. Of the many studies evaluated, MSHA believes that the 13 studies used by OSHA (2013b) to

estimate risks provide reliable estimates of the disease risk posed by miners' exposure to respirable crystalline silica. These studies are summarized in Table VI-1.

Table VI-1. Epidemiologic Studies of Miner Exposures to Respirable Crystalline Silica Reviewed in MSHA's PRA

Study	Population Studied	Exposure Measure	Health Risks Modeled					
			Morbidity		Mortality			
			Silicosis	RPP[a]	Silicosis	NMRD	Lung Cancer	ESRD
1. Attfield and Costello (2004)	Vermont granite workers	Job/exposure matrix					X	
2. Buchanan *et al.* (2003)	Scottish coal miners	Cumulative dust and respirable crystalline silica exposure	X	X				
3. Chen *et al.* (2001)	Chinese tin miners	Cumulative dust exposure, job/exposure matrix	X					
4. Chen *et al.* (2005)	Chinese tin, tungsten miners and pottery workers	Cumulative dust exposure, job/exposure matrix	X					
5. Hnizdo and Sluis-Cremer (1993b)	White South African gold miners	Job/exposure matrix, tenure	X					
6. Hughes *et al.* (2001)	North American industrial sand workers	Cumulative dust exposure, job/exposure matrix					X	
7. Mannetje *et al.* (2002b), ToxaChemica International Inc. (2004)	6 cohorts from U.S., Finnish, and Australian miners	Cumulative dust exposure/job/ exposure matrices			X			
8. Miller and MacCalman (2010)	British coal miners	Tenure, cumulative dust exposure					X	
9. Park *et al.* (2002)	California diatomaceous earth workers	Cumulative dust exposure; cristobalite			X	X		
10. Rice *et al.* (2001)	California diatomaceous earth workers	Cumulative dust exposure; cristobalite					X	
11. Steenland and Brown (1995b)	South Dakota gold miners	Median respirable crystalline silica exposure, job/exposure matrix	X					

Table VI-1. Epidemiologic Studies of Miner Exposures to Respirable Crystalline Silica Reviewed in MSHA's PRA								
Study	Population Studied	Exposure Measure	Health Risks Modeled					
			Morbidity		Mortality			
			Silicosis	RPP[a]	Silicosis	NMRD	Lung Cancer	ESRD
12. Steenland *et al.* (2001a), ToxaChemica, International Inc. (2004)	10 cohorts: U.S. Diatomaceous earth workers, Finnish and U.S. granite, U.S. industrial sand, Chinese pottery, tin, and tungsten miners, South African, U.S., and Australian gold miners	Cumulative dust exposure					X	
13. Steenland *et al.* (2002a)	3 cohorts: U.S. gold miners, industrial sand workers, and granite workers	Cumulative dust exposure, job/exposure matrix						X

a. MSHA used the Buchanan *et al* study to assess exposure rate effects on the risks of accelerated silicosis (more common in MNM miners) and rapidly progressive pneumoconiosis (RPP, primarily seen in coal miners, but also reported in silica flour packers). Miners exposed to respirable crystalline silica at variable intensities (i.e., high concentrations and low concentrations) may develop rapid progression of disease, referred to as RPP. It is defined as the development of PMF and/or an increase in small opacity profusion greater than one subcategory over a 5-year period (Antao *et al*., 2005).

Of these 13 studies, OSHA selected one per health endpoint for final modeling and estimation of lifetime excess risk and cases. Combining the five selected studies with the observed exposure data yields estimates of actual lifetime excess risks and lifetime excess cases among worker populations based on real exposure conditions. Table VI-2 presents the 13 studies from OSHA's PQRA, which MSHA has also considered. MSHA evaluated the evidence of OSHA's analysis of the 13 studies and the accompanying risks associated with exposure at 25, 50, 100, 250, and 500 $\mu g/m^3$. Thorough evaluation has led MSHA to determine that the studies OSHA selected still provide the best available epidemiological models. However, MSHA utilized the Miller and MacCalman (2010) study to estimate risks. This study was published after OSHA completed much of its modeling for their 2013 PRA (OSHA, 2013b). The study was included in OSHA's health effects assessment and its PQRA. The following lists the study used by MSHA for each health endpoint:

Silicosis morbidity: Buchanan *et al.* (2003);

Silicosis mortality: Mannetje *et al*. (2002b);

NMRD mortality: Park *et al.* (2002);

Lung cancer mortality: Miller and MacCalman (2010); and

ESRD mortality: Steenland *et al.* (2002a).

MSHA developed its risk estimates based on recent mortality data and using certain assumptions that differed from those used by OSHA, as explained in the standalone PRA document. Examples of these MSHA assumptions include a lifetime that ends at age 80, updated background mortality data and all-cause mortality, miner population sizes, and miner-specific full-time equivalents (FTEs).[20]

MSHA's modeling has been done using life tables, in a manner consistent with OSHA's PQRA. In general, the life table is a technique that allows estimation of excess risk of disease-specific mortality while factoring in the probability of surviving to a particular age assuming no exposure to respirable crystalline silica. This analysis accounts for competing causes of death, background mortality rates of the disease, and the effect of the accumulation of risk due to elevated mortality rates in each year of a working life. For each cause of mortality, the selected study was used in the life table analysis to compute the increase in miners' disease-specific mortality rates attributable to respirable crystalline silica exposure.

MSHA uses cumulative exposure (i.e., cumulative dose) to characterize the total exposure over a 45-year working life. Cumulative exposure is defined as the product of exposure duration and exposure intensity (i.e., exposure level). Cumulative exposure is the predictor variable in the selected exposure-response models.

[20] FTEs were used to adjust the cumulative exposure over a year based on the average number of hours that miners work.

Table VI-2. Summary of Exposure Response Models in Studies Considered in MSHA's PRA, Based on OSHA's 13 PQRA Models*				
	Study	**Cohort**	**Exposure Lag (years)[a]**	**Model Parameter (Standard Error (SE))**
Morbidity				
Silicosis	Chest X-ray category of 2/1 or greater (Buchanan *et al.*, 2003)*	British coal miners	No lag	Prob(2/1+) = 1/ (1+exp-(-4.83 + 0.443*Cum. Quartz$_{<2}$ + 01.323 * Cum.Exp$_{>2\ mg/cubic\ m}$).[b]
	Silicosis mortality and/or X-ray of 1/1 or greater (Steenland and Brown, 1995b)	U.S. gold miners	No lag	Life table approach to estimate silicosis risk based on the silicosis rates that are age- and calendar-time-adjusted, from Table 2 (page 1374) of Steenland and Brown (1995b). Exposure to crystalline silica is assumed to begin at age 20 through age 65.[c]
	Chest X-ray category of 1/1 or greater (Hnizdo and Sluis-Cremer, 1993b)	South African gold miners	No lag	Cumulative Risk (CR) = 1 – {1/[1 + exp(2.439/.2199)*CDE$^{1/.2199}$]}.[d]
	Chest X-ray category of 1 or greater (Chen *et al.*, 2001)	Chinese tin miners	No lag	CR = 1-exp(-0.0076*E)$^{2.23}$ where E is cumulative exposure to total dust.[e]
	Chest X-ray category of 1 or greater (Chen *et al.*, 2005)	Chinese tin miners	No lag	Estimated from Figure 2B in Chen *et al.* (2005) showing cumulative risk vs. cumulative exposure to respirable crystalline silica. Average age at onset was 47.9 years for tin miners.
	Chest X-ray category of 1 or greater (Chen *et al.*, 2005)	Chinese tungsten miners	No lag	Estimated from Figure 2B in Chen *et al.* (2005) showing cumulative risk vs. cumulative exposure to respirable crystalline silica. Average age at onset was 41.8 years for tungsten miners.
	Chest X-ray category of 1 or greater (Chen *et al.*, 2005)	Chinese pottery workers	No lag	Estimated from Figure 2B in Chen *et al.* (2005) showing cumulative risk vs. cumulative exposure to respirable crystalline silica. Average age at onset was 52.5 years for pottery workers.
Mortality				
Silicosis	Mannetje *et al.* 2002b; ToxaChemica International, Inc. 2004*	Pooled analysis for silicosis	No lag	Estimates derived from rate ratios based on the categorical model after accounting for exposure measurement uncertainty, from Table 7, page 40 of ToxaChemica, International Inc. (2004). Absolute risk calculated as 1 – exp(-Σtime*rate), where rate is the rate ratio for a given cumulative exposure times a base rate of 4.7E-5. (OSHA, 2013b, page 352).
NMRD	Park *et al.*, 2002*	California diatomaceous earth workers	No lag	Linear relative rate model: RR=1+(0.5469*E) where E is cumulative respirable crystalline silica exposure in mg/m^3.[f]
Lung Cancer				
	Steenland *et al.*, 2001a; ToxaChemica, Inc. 2004	Ten pooled cohorts[g]	15	Range based on three models log-linear model with log cumulative exposure (mg/m^3-years; see Table II-2, OSHA 2013b, page 290):

Table VI-2. Summary of Exposure Response Models in Studies Considered in MSHA's PRA, Based on OSHA's 13 PQRA Models*

	Study	Cohort	Exposure Lag (years)[a]	Model Parameter (Standard Error (SE))
				1) Log-linear model: $\beta = 0.60$ (0.015) (Model with log cumulative exposure (mg/m^3-days + 1)); 2) Linear model: $\beta = 0.074950$ (0.024121) (Model with log cumulative exposure (mg/m^3-days + 1)); and 3) Linear spline model: $\beta_1 = 0.16498$ (0.0653) and $\beta_2 = -0.1493$ (0.0657) Model with cumulative exposure (mg/m^3-years) and 95% confidence interval calculated as follows (where CE = cumulative exposure in mg/m^3-years and SE is standard error of the parameter estimate in parentheses): For $CE \leq 2.19$: $1 + [(\beta_1 \pm (1.96*SE_1)) *CE]$ For $CE > 2.19$: $1 + [(\beta_1 * CE) + (\beta_2 * (CE-2.19))] \pm 1.96 * SQRT[(CE^2 * SE_1^2) + ((CE-2.19)^2 *SE_2^2) + (2*CE*(CE-3.29)*-0.00429)]$.[h]
	Rice *et al.*, 2001	California diatomaceous earth workers	10	Linear relative risk model: $\beta = 0.1441*E$ Model with cumulative respirable crystalline silica exposure E =mg/m^3-years (Table II-2, OSHA 2013b, page 290).[i]
	Attfield and Costello, 2004	U.S. granite workers	15	Log-linear relative risk model: $\beta = \exp(0.19*E)$ where E is cumulative respirable crystalline silica exposure in mg/m^3-years Table II-2 (OSHA 2013b, page 290).[j]
	Hughes *et al.,* 2001	North American industrial sand workers	15	Log-linear relative risk model: $\beta = 0.13 *E$, SE = 0.074; where E is cumulative respirable crystalline silica exposure in mg/m^3-years (Table II-2, OSHA 2013b, page 290).[k]
	Miller and MacCalman, 2010*	British coal miners	15	Log-linear relative risk model: B = 0.0524 * E, where E is cumulative respirable crystalline silica exposure in mg/m^3-years, SE = 0.0188, life table analysis (Table II-2, OSHA 2013b, page 290).[h]
ESRD	Steenland *et al.*, 2002a*	Three cohorts	No lag	Log-linear model: R = exp(0.269(lnE)) where E is cumulative respirable crystalline silica exposure in mg/m^3-days, life table analysis.[l]

Notes:

* Indicates the study MSHA selected for modeling.

a. The exposure-response models may include an exposure lag period that accounts for disease latency (NIOSH 2019a). Researchers will typically model different lag periods to determine a model's best fit. An exposure lag could potentially improve the model as there is often a delay in the development of disease, such as silicosis and lung cancer, following exposure (OSHA 2013b).

b. Quartz is cumulative respirable silica exposure in ghm^{-3} (i.e., gram-hours/m^3) with one year of work = 2000 hours (250 days per year x 8 hours per day). Exposure to crystalline silica is assumed to begin at age 20 through age 65. Age of cohort at follow-up was between 50 and 74 years (OSHA 2013b, page 335).

c. Was used by OSHA in its life table approach.

d. CDE = cumulative respirable dust exposure in mg/m^3-years, assumed quartz content of respirable dust in 30%. Average age of cohort at onset was 55.9 years (range 38-74 years).

Table VI-2. Summary of Exposure Response Models in Studies Considered in MSHA's PRA, Based on OSHA's 13 PQRA Models*				
	Study	**Cohort**	**Exposure Lag (years)[a]**	**Model Parameter (Standard Error (SE))**

e. Respirable crystalline silica reported by Chen *et al.* (2001) to be 3.6 % of total dust. Average age at onset was 48.3 years.
f. Was used by OSHA in its life table approach.
g. 10 Cohort studies: US diatomaceous earth (Checkoway *et al.*, 1997), South Africa gold (Hnizdo and Sluis-Cremer, 1991; Hnizdo *et al.*, 1997), US gold (Steenland and Brown, 1995a), Australian gold (de Klerk and Musk, 1998), US granite (Costello and Graham, 1988), Finnish granite (Koskela *et al.*, 1994), US industrial sand (Steenland *et al.*, 2001b), Chinese tungsten (Chen *et al.*, 1992), Chinese pottery (Chen *et al.*, 1992), Chinese tin (Chen *et al.*, 1992).
h. Was used by OSHA in its life table approach.
i. Was used by OSHA in its life table approach. Standard error not reported; upper and lower confidence limit on beta estimated from confidence interval of risk estimate reported in Rice e*t al*., 2001. (OSHA 2013b, Table II-2, page 290).
j. Was used by OSHA in its life table approach. Standard error not reported, upper and lower confidence limit on beta estimated from confidence interval of risk estimate reported in Attfield and Costello, 2004 (OSHA 2013b, Table II-2, page 290).
k. Was used by OSHA in its life table approach. Standard error of the coefficient was estimated from the p-value for trend (Rice *et al*., 2001).
l. Was used by OSHA in its life table approach.

For each health endpoint, MSHA generated two sets of risk estimates—one representing a scenario of full compliance with the existing standards (herein referred to as the "Baseline" scenario) and another representing a scenario wherein no samples exceed the proposed PEL (herein referred to as the "Proposed 50 μg/m^3" scenario). In the Baseline scenario, MNM miners in the >100-250, >250-500, and >500 μg/m^3 groups were assigned exposure intensities of 100 μg/m^3 ISO. Coal miners in the 85.7-100, >100-250, >250-500, and >500 μg/m^3 groups were assigned exposure intensities of 85.7 μg/m^3 ISO, calculated as an 8-hour TWA. Exposure intensities were not changed for miners with lower exposure concentrations, because their exposures were considered compliant with the existing standards. A similar procedure was used for the Proposed 50 μg/m^3 scenario, except that each miner group whose exposure exceeded the proposed PEL was assigned a new exposure of 50 μg/m^3 ISO (for both MNM and coal). This process—of creating an exposure profile based on actual exposure data and modifying it based on the existing standards or the proposed PEL—allowed MSHA to estimate real exposure conditions that miners would encounter under each scenario, thereby enabling estimates of the actual excess risks the current population of miners would experience under each scenario (Baseline and Proposed 50 μg/m^3).

For purposes of calculating risk in the PRA, both for MNM and coal miners, MSHA estimated excess risks by using the concentration collected over the full shift and calculating it as a full-shift, 8-hour TWA expressed in ISO standards. This metric of exposure intensity—the 8-hour TWA concentration of respirable crystalline silica in ISO standards—was used consistently across all sets of estimates (both MNM and coal sectors, and both the Baseline and Proposed 50 $\mu g/m^3$ scenarios), thereby facilitating meaningful comparison. MSHA acknowledges that this metric does not correspond to the manner in which coal exposure concentrations are calculated for purposes of evaluating compliance under the existing standard. Nonetheless, MSHA believes that a full-shift, 8-hour TWA concentration accurately represents risks to miners and thus is the most appropriate cumulative exposure metric for computing risk given that FTEs were used to scale exposure durations relative to the assumption of 250 8-hour workdays per year.

C. Summary of Studies Selected for Modeling

1. Silicosis Morbidity

Due to the long latency periods associated with chronic silicosis, OSHA's respirable crystalline silica standard relied on the subset of studies that were able to contact and evaluate many workers through retirement. MSHA agrees that relying on studies that included retired workers comes closest to characterizing lifetime risk of silicosis morbidity.

The health endpoint of interest in these studies was the appearance of opacities on chest radiographs indicative of pulmonary pneumoconiosis (a group of lung diseases caused by the lung's reaction to inhaled dusts). The most reliable estimates of silicosis morbidity, as detected by chest X-rays, come from the studies that evaluated those X-rays over time, included radiographic evaluation of workers after they left employment, and derived cumulative or lifetime estimates of silicosis disease risk.

To describe the presence and severity of pneumoconiosis, including silicosis, the International Labour Organization (ILO) developed a standardized system to classify lung opacities identified on chest radiographs (X-rays) (ILO, 1980, 2002, 2011, 2022). The ILO

system grades the size, shape, and profusion of opacities. Although silicosis is defined and categorized based on chest X-ray, the X-ray is an imprecise tool for detecting pulmonary pneumoconiosis (Craighead and Vallyathan, 1980; Hnizdo *et al.*, 1993; Rosenman *et al.*, 1997; Cohen and Velho, 2002). Hnizdo *et al.* (1993) recommended that an ILO category 0/1 (or greater) should be considered indicative of silicosis among workers exposed to high respirable crystalline silica concentrations. They noted that the sensitivity of the chest X-ray as a screening test increases with disease severity and to maintain high specificity, category 1/0 (or 1/1) chest X-rays should be considered as a positive diagnosis of silicosis for miners who work in low dust occupations (Hnizdo *et al.*, 1993). MSHA, consistent with NIOSH's use of chest X-rays in their occupational respiratory disease surveillance program (NIOSH 2014b), agrees that a small opacity profusion score of 1/0 is consistent with chronic silicosis stage 1. Most of the studies reviewed by MSHA considered a finding consistent with an ILO category of 1/1 or greater to be a positive diagnosis of silicosis, although some also considered an X-ray classification of 1/0 or 0/1 to be positive. The low sensitivity of chest radiography to detect minimal silicosis suggests that risk estimates derived from radiographic evidence likely underestimate the true risk of this disease (Craighead and Vallyathan, 1980; Hnizdo *et al*., 1993; Rosenman *et al*., 1997; Cohen and Velho, 2002).

OSHA summarized the Miller *et al.* (1995, 1998) and Buchanan *et al.* (2003) papers in their final respirable crystalline silica standard in 2016 (OSHA 2016a, 81 FR 16286, 16316). These researchers reported on a 1991 follow-up study of 547 survivors of a 1,416-member cohort of Scottish coal workers from a single mine. These men had all worked in the mine during the period between early 1971 and mid-1976, during which time they had experienced "unusually high concentrations of freshly cut quartz in mixed coal mine dust." The population's exposures to quartz dust had been measured in unique detail for a considerable proportion of the men's working lives (OSHA 2013b, page 333).

The 1,416 men had previous chest X-rays dating from before, during, or just after this high respirable crystalline silica exposure period. Of these 1,416 men, 384 were identified as having died by 1990/1991. Of the 1,032 remaining men, 156 were untraced, and, of the 876 who were traced and replied, 711 agreed to participate in the study. Of these, the total number of miners who were surveyed was 551. Four of these were omitted, two because of a lack of an available chest X-ray. The 547 surviving miners (age range: 29-85 years, average=59 years) were interviewed and received their follow-up chest X-rays between November 1990 and April 1991. The interviews consisted of questions on current and past smoking habits and occupational history since leaving the coal mine, which closed in 1981. They were also asked about respiratory symptoms and were given a spirometry test (OSHA 2013b, pages 333-334).

Exposure characterization was based on extensive respirable dust sampling; samples were analyzed for quartz content by IR spectroscopy. Between 1969 and 1977, two coal seams were mined. One had produced quarterly average concentrations of respirable crystalline silica much less than 1,000 $\mu g/m^3$ (only 10 percent exceeded 300 $\mu g/m^3$). The other more unusual seam (mined between 1971 and 1976) lay in sandstone strata and generated respirable crystalline silica levels such that quarterly average exposures exceeded 1,000 $\mu g/m^3$ (10 percent of the quarterly measurements were over 10,000 $\mu g/m^3$). Thus, this cohort study allowed evaluation of the effects of both higher and lower respirable crystalline silica concentrations and exposure-rate effects on the development of silicosis (OSHA 2013b, page 334).

Three physicians read each chest film taken during the current survey as well as films from the surveys conducted in 1974 and 1978. Films from an earlier 1970 survey were read only if no films were available from the subsequent two surveys. Silicosis cases were identified if the median classification of the three readers indicated an ILO category of 1/1 or greater (Miller *et al*, 1995, page 24), plus a progression from the earlier reading. Of the 547 men, 203 (38 percent) showed progression of at least 1 ILO category from the 1970s' surveys to the 1990-91 survey; in 128 of these (24 percent) there was progression of 2 or more ILO categories. In the 1970s'

surveys, 504 men had normal chest X-rays; of these 120 (24 percent) acquired an abnormal X-ray consistent with ILO category 1/0 or greater at the follow-up. Of the 36 men whose X-rays were consistent with ILO category 1/0 or greater in the 1970s' surveys, 27 (75 percent) exhibited further progression at the 1990/1991 follow-up. Only one subject showed a regression from any earlier reading, and that was slight, from 1/0 to 0/1. The earlier Miller *et al.* (1995) report presented results for cases classified as having X-ray films consistent with either 1/0+ and 2/1+ degree of profusion; the Miller *et al.* (1998) analysis and the Buchanan *et al.* (2003) re-analyses emphasized the results from cases having X-rays classified as 2/1+ (OSHA 2013b, page 334).

MSHA modeled the exposure-response relationship by using cumulative exposure expressed as gram/m^3-hours, assuming 2,000 work hours per year and a 45-year working life (after adjusting for full-time equivalents, including production employees and contract workers). MSHA estimated risk at the existing standard assuming cumulative exposure to 100 µg/m^3 ISO for MNM miners and 85.7 µg/m^3 ISO (100 µg/m^3 MRE) for coal miners. Respirable crystalline silica exposures were calculated by commodity, and median exposure values were used within a variety of exposure intervals. Risks were computed using a life table methodology which iteratively updated the survival, risk, and mortality rates each year based on the results of the preceding year. Covariates in the regression included smoking, age, amount of coal dust, and percent of quartz in the coal dust during various previous survey periods.

Both Miller *et al.* papers (1995, 1998) presented the results of numerous regression models, and they compared the results of the partial regression coefficients using Z statistics of the coefficient divided by the standard error. Also presented were the residual deviances of the models and the residual degrees of freedom. In the introduction to the results section, Miller *et al.* (1995) stated that, "in none of the models fitted was there a significant effect of smoking habit (current, ex-smoker, and never smoker), nor was there any evidence of any difference between smoking groups in their relationship of response with age." They therefore presented the results of the regression analyses without terms for smoking effects (i.e., without including

smoking effects as a variable in the final regression analysis, because they found that smoking did not affect the modeling results). The logistic regression models developed by Miller *et al.* (1995) included terms for cumulative exposure and age. In their later publication, Miller *et al.* (1998) presented models similar to their 1995 report, but without the age variable. Their logistic regression model A from Table 7 of their report (page 56) included only an intercept (-4.32) and the respirable crystalline silica (quartz) cumulative exposure variable (0.416). They estimated that respirable crystalline silica exposure at an average concentration of 100 $\mu g/m^3$ for 15 years (2.6 $gram/m^3$-hr assuming 1,750 hours worked per year) would result in an increased risk of silicosis (ILO>2/1) of 5 percent (OSHA 2013b, page 334).

OSHA had a high degree of confidence in the estimates of silicosis morbidity risk from this Scotland coal mine study. This was mainly because of highly detailed and extensive exposure measurements, radiographic records, and detailed analyses of high exposure-rate effects. However, in another paper, Soutar *et al.* (2004) noted that: "If the effects of silica vary according to the conditions of exposure, these risks are probably towards the high end of the risk spectrum, since the silica was freshly fractured from massive sandstone, and not derived from dirt bands where the quartz grains are aged and accompanied by clay minerals" (OSHA 2013b, page 336). MSHA has reviewed and agrees with OSHA's conclusion.

Buchanan *et al.* (2003) provided an analysis and risk estimates only for cases having X-ray films consistent with ILO category 2/1+ extent of profusion of opacities, after adjusting for the disproportionately severe effect of exposure to high respirable crystalline silica concentrations. Estimating the risk of 1/0+ profusions from the Buchanan *et al.* (2003) or the earlier Miller *et al.* (1995, 1998) publications can only be roughly approximated because of the summary information included. Table 4 of Miller *et al.* (1998) (page 55) presents a cross-tabulation of radiograph progression, using the 12-point ILO scale, from the last baseline exam to the 1990/1991 follow-up visit for the 547 men at the Scottish coal mine. From this table, among miners having both early X-ray films and follow-up films, 44 men had progressed to 2/1+

by the last follow-up and an additional 105 men had experienced the onset of silicosis (i.e., X-ray films were classified as 1/0, 1/1, or 1/2). Thus, by the time of the follow-up, there were three times more miners with silicosis consistent with ILO category 1 than there were miners with a category 2+ level of severity ((105 + 44)/44 = 3.38). This suggests that the Buchanan *et al.* (2003) model, which reflects the risk of progressing to ILO category 2+, underestimates the risk of acquiring radiological silicosis by about three-fold in this population (OSHA 2013b, page 336). This type of analysis shows that the risk of developing silicosis estimated from the Buchanan *et al.* (2003) and Miller *et al.* (1998) studies is of the same magnitude as the risks reported by Hnizdo and Sluis-Cremer (1993b) (OSHA 2013b, page 338).

MSHA estimated silicosis risk by using the Buchanan *et al.* (2003) model that predicted the lifetime probability of developing silicosis at the 2/1+ category based on cumulative respirable crystalline silica exposures. As discussed previously, MSHA applied the Buchanan *et al*. (2003) model, assuming that miners are exposed for 45 years of working life extending from age 21 through age 65, using a life table approach. Buchanan *et al.* provides an exposure-response model using cumulative exposure in mg/m^3-hours as the predictor variable and lifetime risk of silicosis as the outcome variable. MSHA assumed 45 years of exposure, each such year having a duration of 2,000 work hours, scaled by a weighted average FTE ratio that accounts for the average annual hours worked by production employees and contract miners.

2. Accelerated Silicosis and Rapidly Progressive Pneumoconiosis (RPP) Study

OSHA concluded in their risk assessment, and MSHA agrees, that there is little evidence of a dose-rate effect at respirable crystalline silica concentrations in the exposure range of 25 $\mu g/m^3$ to 500 $\mu g/m^3$ (81 FR 16286, 16396). OSHA noted that the risk estimates derived from the Buchanan *et al.* (2003) study were not appreciably different from those derived from the other studies of silicosis morbidity (see OSHA 2016a, 81 FR 16286, 16386; Table VI-1. *Summary of Lifetime or Cumulative Risk Estimates for Crystalline Silica*). However, OSHA also concluded that some uncertainty related to dose-rate effects exists at concentrations far higher than the

exposure range of interest. OSHA stated that it is possible for such a dose-rate effect to impact the results if not properly addressed in study populations with high concentration exposures. OSHA used the model from the Buchanan *et al.* (2003) study in its silicosis morbidity risk assessment to account for possible dose-rate effects at high average concentrations (OSHA 2016a, 81 FR 16286, 16396 OSHA 2013b, pages 335–342). MSHA has reviewed and agrees with OSHA's conclusions.

NIOSH stated in its post-hearing brief to OSHA, that a "detailed examination of dose rate would require extensive and real time exposure history which does not exist for silica (or almost any other agent)" (81 FR 16285, 16375). Similarly, Dr. Kenneth Crump, a researcher from Louisiana Tech University Foundation who served on OSHA's peer review panel for the Review of Health Effects Literature and Preliminary Quantitative Risk Assessment, wrote to OSHA that, "[h]aving noted that there is evidence for a dose rate effect for silicosis, it may be difficult to account for it quantitatively. The data are likely to be limited by uncertainty in exposures at earlier times, which were likely to be higher" (OSHA 2016a, 81 FR 16286, 16375). OSHA agreed with the conclusions of NIOSH and Dr. Crump. OSHA believed that it used the best available evidence to estimate risks of silicosis morbidity and sufficiently accounted for any dose rate effect at high silica average concentrations by using the Buchanan *et al.* (2003) study as part of their final Quantitative Risk Analysis (QRA) (OSHA 2016a, 81 FR 16286, 16396). MSHA has reviewed and agrees with OSHA's conclusions.

MSHA is using the Buchanan *et al.* (2003) study to explain, in part, the observed cases of progressive lung disease in miners, known as RPP in coal miners (Laney and Attfield, 2010; Wade *et al*., 2010; Laney *et al.*, 2012b; 2017; Blackley *et al*., 2016b, 2018b; Reynolds *et al*., 2018b; Halldin *et al.*, 2019; Halldin *et al.*, 2020; Almberg *et al.*, 2018a; Cohen *et al.*, 2022) and accelerated silicosis in MNM miners (Dumavibhat *et al.*, 2013; Hessel *et al*., 1988; Mohebbi and Zubeyri 2007). The inclusion of this discussion in the risk analysis is to describe research that explains, in part, the progressive disease observed in shorter-tenured miners. MSHA believes

that the risks estimated by the Buchanan *et al*. model can be applied to all mining populations that have similar respirable crystalline silica exposure exceedances. MSHA estimated the increase of silicosis risk in miners exposed to extreme respirable crystalline silica exposures for varying periods of time ranging from 0 hours to 348 hours per year (i.e., 0.0 percent to 20.0 percent of time at extreme exposures). This information is important because MSHA data indicate that many miners' respirable crystalline silica exposure samples over the years have exceeded the existing exposure limit(s) of 100 $\mu g/m^3$. MSHA data also indicate that a smaller number of MSHA samples showed respirable crystalline silica concentrations well above the existing MSHA standard of 100 $\mu g/m^3$. Over the last 15 years of MNM compliance data, 188 samples (0.3 percent) were over 500 $\mu g/m^3$; the upper range of exposure was 4,289 $\mu g/m^3$ ISO (see PRA Table 4 of the PRA document). Over the last 5 years of coal compliance data, eight samples (<0.1 percent) were over 500 $\mu g/m^3$; the upper range of exposure was 791.4 $\mu g/m^3$ MRE (see PRA Table 7 of the PRA document).

Analysis provided by Buchanan *et al.* (2003) provides strong evidence of an exposure-rate effect for silicosis in a British Pneumoconiosis Field Research (PFR) coal mining cohort exposed to high levels of respirable crystalline silica over short periods of time (OSHA 2013b, page 335). Exposure was categorized as pre- and post-1964, the latter period being that of generally higher quartz concentrations used to estimate exposure-rate effects. For the purpose of this analysis, the results were presented for the 371 men (out of the original 547) who were between the ages of 50 and 74 at the time of the 1990/1991 follow-up, "since they had experienced the widest range of quartz concentrations and showed the strongest exposure-response relations." Thus, combined with their exposure history, which went back to pre-1954, many of these men had 30 to 40+ years of highly detailed occupational exposure histories available for analysis. Of these 371 miners, there were 35 men (9.4 percent) who had X-ray films consistent with ILO category 2/1+, with at least 29 of them having progressed from less

severe silicosis since the previous follow-up during the 1970s (from Miller *et al.*, 1998) (OSHA 2013b, page 335).

The Buchanan *et al.* (2003) re-analysis presented logistic regression models in stages. In the final stage of modeling, using only the statistically significant post-1964 cumulative exposures, the authors separated these exposures into, "two quartz concentration bands, defined by the cut-point 2.0 mg/m^3." This yielded the final simplified equation, adapted from Buchanan *et al*., 2003, page 162:

$$\log\left(\frac{p_2}{1-p_2}\right) = -4.83 + 0.443 * E_{<2} + 1.323 * E_{>2})$$

where p_2 is the probability of profusion category 2/1 or higher (2/1+) at follow-up and E is the cumulative exposure.

In this model, both the cumulative exposure concentration variables were "highly statistically significant in the presence of the other" (Buchanan *et al*., 2003, page 162). Since these variables were in the same units, mg/m^3-hr, the authors noted that the coefficient for exposure concentrations >2,000 µg/m^3 (>2.0 mg/m^3) was three times that for the concentrations <2,000 µg/m^3 (<2.0 mg/m^3). They concluded that their latest analysis showed that "the risk of silicosis over a working lifetime can rise dramatically with exposure to such high concentrations over a timescale of merely a few months" (Buchanan *et al.*, 2003, page 163, OSHA 2013b, page 336).

Buchanan *et al.* (2003) also used these models to estimate the risk of acquiring a chest X-ray classified as ILO category 2/1+, 15 years after exposure ends, as a function of low <2,000 µg/m^3 (<2.0 mg/m^3) and high >2,000 µg/m^3 (>2.0 mg/m^3) quartz concentrations. OSHA chose to use this model to estimate the risk of radiological silicosis consistent with an ILO category 2/1+ chest X-ray for several exposure scenarios. They assumed 45 years of exposure, 2,000 hours/year of exposure, and no exposure above a concentration of 2,000 µg/m^3 (2.0 mg/m^3) (OSHA 2013b, page 336).

Buchanan *et al.* (2003) used these models to estimate the combined effect on the predicted risk of low quartz exposures (e.g., 100 μg/m^3, equal to 0.1 mg/m^3) and short-term exposures to high quartz concentrations (e.g., 2,000 μg/m^3, equal to 2 mg/m^3). Predicted risks were estimated for miners who progressed to silicosis level 2/1+ 15 years after exposure ended. This analysis showed the increase in predicted risk with relatively short periods of quartz exceedance exposures, over 4, 8, and 12 months. Buchanan *et al.* predicted a risk of 2.5 percent for 15 years quartz exposure to 100 μg/m^3 (0.1 mg/m^3). This risk increased to 10.6 percent with the addition of only 4 months of exposure at the higher concentration. The risk increased further to 72 percent with 12 months at the higher exposure of 2,000 μg/m^3 (2.0 mg/m^3).

The results indicate miners exposed to exceedances above MSHA's existing standard could develop progression of silicosis at an exaggerated rate. The results of Buchanan *et al.* also indicated that miners' exposure to exceedances at MSHA's proposed standard will also suffer increased risk of developing progressive disease, though at a reduced rate (see Buchanan *et al.* (2003), Table 4, page 163).

MSHA used a life table approach to estimate the lifetime excess silicosis morbidity from age 21 to age 80, assuming exposure from age 21 through age 65 (45 years of working life) and an additional 15 years of potential illness progress thereafter. MSHA used the Buchanan *et al.* (2003) model to estimate the effect of respirable crystalline silica exposure exceedances as seen in MSHA's compliance data on miners' silicosis risk at the existing and proposed standard. The model predicted the probability of developing silicosis at the 2/1+ category based on cumulative respirable crystalline silica exposures. Age-specific cumulative risk was estimated as 1/(1+EXP(-(-4.83+0.443*cumulative exposure))). The model determined that even at 17.4 hours on average per year at an exposure of 1,500 μg/m^3 (1.50 mg/m^3), miners' risk of developing 2/1+ silicosis increased from a baseline of 24.8/1,000 to 29.0/1,000 at the existing standard and 14/1,000 to 16.6/1,000 at the proposed standard. Of course, the more hours exposed to these levels of respirable crystalline silica resulted in even higher increased risk. It is important to note

that NIOSH's X-ray classification of the lowest case of pneumoconiosis is 1/0 profusion of small opacities (NIOSH 2008c, page A-2). Using a case definition of level 2/1+, the miners studied by Buchanan *et al.* (2003) would be more likely to show clinical signs of disease. MSHA emphasizes the importance of maintaining miner exposure to respirable crystalline silica at or below the proposed standard to minimize these health risks as much as possible.

3. Silicosis and NMRD Mortality

Silicosis mortality was ascertained in the studies included in the pooled analysis by Mannetje *et al.* (2002b). These studies included cohorts of U.S. diatomaceous earth workers (Checkoway *et al.*, 1997), Finnish granite workers (Koskela *et al*., 1994), U.S. granite workers (Costello and Graham, 1988), U.S. industrial sand workers (Steenland and Sanderson, 2001), U.S. gold miners (Steenland and Brown (1995a), and Australian gold miners (de Klerk *et al.*, 1998). The researchers analyzed death certificates across all cohorts for cause of death. OSHA relied upon the published, peer-reviewed, pooled analysis of six epidemiological studies first published by Mannetje *et al.* (2002b) and a sensitivity analysis of the data conducted by ToxaChemica, International, Inc. (2004). OSHA used the model described by Mannetje *et al.* (2002b) and the rate ratios that were estimated from the ToxaChemica, International Inc. sensitivity analysis to estimate the risks of silicosis mortality. This process better controlled for age and exposure measurement uncertainty (OSHA 2013b, page 295). MSHA has reviewed and agrees with OSHA's conclusions. These studies are summarized below, including detailed discussion and analysis of uncertainty in the studies and associated risk estimates.

OSHA found that the estimates from Mannetje *et al.* (2002b) and ToxaChemica Inc. probably understated the actual risk because silicosis is underreported as a cause of death since there is no nationwide system for collecting silicosis morbidity case data (OSHA 2016a, 81 FR 16286, 16325). To help address this uncertainty, OSHA also included an exposure-response analysis of diatomaceous earth workers (Park *et al.*, 2002). This analysis better recognized the totality of respirable crystalline silica-related respiratory disease than the datasets of Mannetje *et*

al. (2002b) and ToxaChemica International Inc. (2004). Information from the Park *et al.* (2002) study (described in the next subsection) was used to quantify the relationship between cristobalite exposure and mortality caused by NMRD, which includes silicosis, pneumoconiosis, emphysema, and chronic bronchitis. The category of NMRD captures much of the silicosis misclassification that results in underestimation of the disease. NMRD also includes risks from other lung diseases associated with respirable crystalline silica exposures. OSHA found the risk estimates derived from Park *et al.* (2002) were important to include in their range of estimates of the risk of death from respirable crystalline silica-related respiratory diseases, including silicosis (OSHA 2013b, pages 297–298). OSHA concluded that the ToxaChemica International Inc. (2004) re-analysis of Mannetje *et al.*'s (2002b) silicosis mortality data and Park *et al.*'s (2002) study of NMRD mortality provided a credible range of estimates of mortality risk from silicosis and NMRD across many workplaces. The upper end of this range, based on the Park *et al.* (2002) study, is less likely to underestimate risk because of underreporting of silicosis mortality. However, risk estimates from studies focusing on cohorts of workers from different industries cannot be directly compared (OSHA 2016a, 81 FR 16286, 16397).

a. Silicosis Mortality: Mannetje et al. (2002b); ToxaChemica, International, Inc. (2004)

Mannetje *et al.* (2002b) relied upon the epidemiological studies contained within the Steenland *et al.* (2001a) pooled analysis of lung cancer mortality that also included extensive data on silicosis. The six cohorts included:

1) U.S. diatomaceous earth workers (Checkoway *et al.*, 1997),
2) Finnish granite workers (Koskela *et al.*, 1994),
3) U.S. granite workers (Costello and Graham, 1988),
4) U.S. industrial sand workers (Steenland and Sanderson, 2001),
5) U.S. gold miners (Steenland and Brown, 1995b), and
6) Australian gold miners (de Klerk and Musk, 1998).

These six cohorts contained 18,364 workers and 170 silicosis deaths, where silicosis mortality was defined as death from silicosis (ICD–9 502, n = 150) or from unspecified pneumoconiosis (ICD–9 505, n = 20). Table VI-3 provides information on each cohort, including size, time period studied, overall number of deaths, and number of deaths identified as silicosis for the pooled analysis conducted by Mannetje *et al.* (2002b). The authors believed this definition to err on the side of caution in that some cases of death from silicosis in the cohorts may have been misclassified as other causes (e.g., tuberculosis or COPD without mention of pneumoconiosis). Four cohorts were not included in the silicosis mortality study. The three Chinese studies did not use the ICD to code cause of death. In the South African gold miner study, silicosis was not generally recognized as an underlying cause of death. Thus, it did not appear on death certificates (OSHA 2013b, page 292).

Table VI-3. Summary of Cohort Studies Used in the Pooled Analysis for Silicosis Mortality

Author	Cohort	Size of cohort	Time period of study	Number of deaths	Number of silicosis deaths
Checkoway *et al.*, 1997	U.S. diatomaceous earth	2,342	1942-1994	749	15 ("other" NMRD, including silicosis)
Koskela *et al.*, 1994	Finnish granite	1,026	1940-1993	418	14
Costello and Graham, 1988	U.S. granite	5,408	1950-1982	1,762	43
Steenland *et al.*, 2001b	U.S. industrial sand	4,027	1974-1996	860	15
Steenland and Brown, 1995b	U.S. gold miners	3,348	1940-1996	1,925	39
de Klerk and Musk, 1998	Australian surface and underground gold miners	2,213	1961-1993	1,351	44
	Total	18,364		7,065	170

Adapted from Mannetje *et al.* (2002b)
Source: OSHA 2013b, page 293.

Mannetje *et al.* (2002a) described the exposure assessments developed for the pooled analysis. Exposure information from each of the 10 cohort studies varied and included dust measurements representing particle counts, mass of total dust, and respirable dust mass. Measurement methods also changed over time for each of the cohort studies. Generally, sampling was performed using impingers in earlier decades, and gravimetric techniques later.

Exposure data based on analysis for respirable crystalline silica by XRD (the current method of choice) were available only from the study of U.S. industrial sand workers. To develop cumulative exposure estimates for all cohort members and to pool the cohort data, all exposure data were converted to units of $\mu g/m^3$ (mg/m^3) respirable crystalline silica. Cohort-specific conversion factors were generated based on the silica content of the dust to which workers were exposed. In some instances, results of side-by-side comparison sampling were available. Within each cohort, available job- or process-specific information on the silica composition or nature of the dust was used to reconstruct respirable crystalline silica exposures. Most of the studies did not have exposure measurements prior to the 1950s. Exposures occurring prior to that time were estimated either by assuming such exposures were the same as the earliest recorded for the cohort or by modeling that accounted for documented changes in dust control measures.

To evaluate the reasonableness of the exposure assessment for the lung cancer pooled study, Mannetje *et al.* (2002a) investigated the relationship between silicosis mortality and cumulative exposure. They performed a nested case-control analysis for silicosis or unspecified pneumoconiosis using conditional logistic regression. Since exposure to respirable crystalline silica is the sole cause of silicosis, any finding for which cumulative exposure was unrelated to silicosis mortality risk would suggest that serious misclassification of the exposures assigned to cohort members occurred. Cases and controls were matched for race, sex, age (within 5 years), and 100 controls were matched to each case. Each cohort was stratified into quartiles by cumulative exposure. Standardized rate ratios (SRRs) were calculated using the lowest-exposure quartile as the baseline. Odds ratios (ORs) were also calculated for the pooled data set overall, which was stratified into quintiles based on cumulative exposure. For the pooled data set, the relationship between the ORs for silicosis mortality and cumulative exposure, along with each of the 95 percent confidence intervals (95% CI), were as follows:

1) 4,450 $\mu g/m^3$-years (4.45 mg/m^3-years), OR=3.1 (95% CI: 2.5-4.0);

2) 9,080 $\mu g/m^3$-years (9.08 mg/m^3-years), OR=4.6 (95% CI: 3.6-5.9);

3) 16,260 µg/m^3-years (16.26 mg/m^3-years), OR=4.5 (95% CI: 3.5-5.8); and

4) 42,330 µg/m^3-years (42.33 mg/m^3-years), OR=4.8 (95% CI: 3.7-6.2).

In addition, in seven of the cohorts, there was a statistically significant trend between silicosis mortality and cumulative exposure. For two of the cohorts (U.S. granite workers and U.S. gold miners), the trend test was not statistically significant (p=0.10). An analysis could not be performed on the South African gold miner cohort because silicosis was never coded as an underlying cause of death, apparently due to coding practices in that country.

Based on this analysis, Mannetje *et al.* (2002a) concluded that the exposure-response relationship for the pooled data set was "positive and reasonably monotonic." That is, the response increased with increasing exposure. The results also indicated that the exposure assessments provided reasonable estimates of cumulative exposures. In addition, despite some large differences in the range of cumulative exposures between cohorts, a clear positive exposure-response trend was evident in seven of the cohorts (OSHA 2013b, page 271).

Furthermore, in their pooled analysis of silicosis mortality for six of the cohorts, Mannetje *et al.* (2002b) found a clear and consistently positive response with increasing decile of cumulative exposure, although there was an anomaly in the 9th decile. Overall, these data supported a monotonic exposure-response relationship for silicosis. Thus, although some exposure misclassification almost certainly existed in the pooled data set, the authors concluded that exposure estimates did not appear to have been sufficiently misclassified to obscure an exposure-response relationship (OSHA 2013b, page 271).

As part of an uncertainty analysis conducted for OSHA, Drs. Steenland and Bartell (ToxaChemica International, Inc. 2004) examined the quality of the original data set and analysis to identify and correct any data entry, programming, or reporting errors (ToxaChemica International, Inc. 2004). This quality assurance process revealed a small number of errors in exposure calculations for the originally reported results. Primarily, these errors resulted from rounding of job class exposures when converting the original data file for use with a different

statistical program. Although the corrections affected some of the exposure-response models for individual cohorts, ToxaChemica International, Inc. (2004) reported that models based on the pooled dataset were not impacted by the correction of these errors (OSHA 2013b, pages 271-272).

Silicosis mortality was evaluated using standard life table analysis in Mannetje *et al.* (2002b). Poisson regression, using 10 categories of cumulative exposure and adjusting for age, calendar time, and cohort, was conducted to derive silicosis mortality rate ratios using the lowest exposure group of 0-100 μg/m^3-years (0-0.1 mg/m^3-year) as the referent group. More detailed exploration of the exposure-response relationship using a variety of exposure metrics, including cumulative exposure, duration of exposure, average exposure (calculated as cumulative exposure/duration), and the log transformations of these variables, was conducted via nested case-control analyses (conditional logistic regression). Each case was matched to 100 controls selected from among those who had survived to at least the age of the case, with additional matching on cohort, race, sex, and date of birth within 5 years. The authors explored lags of 0, 5, 10, 15, and 20 years, noting that there is no *a priori* reason to apply an exposure lag, as silicosis can develop within a short period after exposure. However, a lag could potentially improve the model, as there is often a considerable delay in the development of silicosis following exposure. In addition to the parametric conditional logistic regression models, the authors performed some analyses using a cubic-spline model, with knots at 5, 25, 50, 75, and 95 percent of the distribution of exposure. Models with cohort-exposure interaction terms were fit to assess heterogeneity between cohorts (OSHA 2013b, page 294).

The categorical analysis found a nearly monotonic increase in silicosis rates with cumulative exposure, from 4.7 per 100,000 person-years in the lowest exposure category (0-990 μg/m^3-years [0-0.99 mg/m^3-years]) to 299 per 100,000 person-years in the highest exposure category (>28,000 μg/m^3-years [>28 mg/m^3-years]). Nested case-control analyses showed a significant association between silicosis mortality and cumulative exposure, average exposure,

and duration of exposure. The best-fitting conditional logistic regression model used log-transformed cumulative exposure with no exposure lag, with a model χ^2 of 73.2 versus χ^2 values ranging from 19.9 to 30.9 for average exposure, duration of exposure, and untransformed cumulative exposure (1 degree of freedom). No significant heterogeneity was found between individual cohorts for the model based on log-cumulative exposure. The cubic-spline model did not improve the model fit for the parametric logistic regression model using the log-cumulative exposure (OSHA 2013b, page 294).

Mannetje *et al.* (2002b) developed estimates of silicosis mortality risk through age 65 for two levels of exposure (50 and 100 µg/m^3 respirable crystalline silica), assuming a working life of occupational exposure from age 20 to 65. Risk estimates were calculated based on the silicosis mortality rate ratios derived from the categorical analysis described above. The period of time over which workers' exposures and risks were calculated (age 20 to 65) was divided into one-year intervals. The mortality rate used to calculate risk in any given interval was dependent on the worker's cumulative exposure at that time. The equation used to calculate risk is as follows:

$$\text{Risk} = 1 - \exp\left(- \sum_{i=20}^{65} \text{time}_i * \text{rate}_i \right)$$

Where time$_i$ is equal to one for every age *i*, and rate$_i$ is the age-, calendar time-, and cohort adjusted silicosis mortality rate associated with the level of cumulative exposure acquired at age *i*, as presented in Mannetje *et al.* (2002b, Table 2, page 725). The calculated absolute risks equal the excess risks since there is no background rate of silicosis in the exposed population. Mannetje *et al.* (2002b) estimated the lifetime risk of death from silicosis, assuming 45 years of exposure to 100 µg/m^3, to be 13 deaths per 1,000 workers; at an exposure of 50 µg/m^3, the estimated lifetime risk was 6 per 1,000. Confidence intervals (CIs) were not reported (OSHA 2013b, page 295).

In summary, OSHA's estimates of silicosis morbidity risks were based on studies of active and retired workers for which exposure histories could be constructed and chest X-ray films could be evaluated for signs of silicosis. There is evidence in the record that chest X-ray films are relatively insensitive to detecting lung fibrosis (OSHA 2016a, 81 FR 16286, 16397). MSHA agrees with OSHA's estimate of silicosis morbidity risks.

Hnizdo *et al.* (1993a) found chest X-ray films to have low sensitivity for detecting lung fibrosis related to initial cases of silicosis, compared to pathological examination at autopsy. To address the low sensitivity of chest X-rays for detecting silicosis, Hnizdo *et al.* (1993a) recommended that radiographs consistent with an ILO category of 0/1 or greater be considered indicative of silicosis among workers exposed to a high concentration of respirable crystalline silica-containing dust. In like manner, to maintain high specificity, chest X-rays classified as category 1/0 or 1/1 should be considered as a positive diagnosis of silicosis in miners who work in low dust (0.2 mg/m^3) occupations. The studies on which OSHA relied in its risk assessment typically used an ILO category of 1/0 or greater to identify cases of silicosis. According to Hnizdo *et al.* (1993), they were unlikely to have included many false positives (i.e., assumed diagnosis of silicosis in a miner without the disease), but may have included false negatives (i.e., failure to identify cases of silicosis). Thus, in OSHA's risk assessment, the use of chest X-rays to ascertain silicosis cases in the morbidity studies may have underestimated risk given the X-rays' low sensitivity to detect disease. MSHA agrees with OSHA's assessment.

To estimate the risk of silicosis mortality at the existing and proposed exposure limits, OSHA used the categorical model described by Mannetje *et al.* (2002b) but did not rely upon the Poisson regression in their study. Instead, OSHA used rate ratios estimated from a nested case-control design implemented as part of a sensitivity analysis (ToxaChemica, International, Inc. 2004). The case-control design was selected because it was expected to better control for age. In addition, the rate ratios derived from the case control study were derived from a Monte Carlo analysis to reflect exposure measurement uncertainty (See ToxaChemica, International, Inc.

(2004), Table 7, page 40). The rate ratio for each interval of cumulative exposure was multiplied by the annual silicosis rate assumed to be associated with the lowest exposure interval, 4.7 per 100,000 for exposures of 990 $\mu g/m^3$-years (0.99 mg/m^3-years), to estimate the silicosis rate for each interval of exposure. The lifetime silicosis mortality risk is the sum of the silicosis rate for each year of life through age 85 and assuming exposure from age 20 to 65. From this analysis, OSHA estimated the silicosis mortality risk for exposure to the then existing general industry exposure limit (100 $\mu g/m^3$) and proposed exposure limit (50 $\mu g/m^3$) to be 11 (95% CI 5-37) and 7 (95% CI 3-21) deaths per 1,000 workers, respectively. For exposure to 250$\mu g/m^3$ (0.25 mg/m^3) and 500 $\mu g/m^3$ (0.5 mg/m^3), the range approximating the then existing construction/shipyard exposure limit, OSHA estimated the risk to range from 17 (95% CI 5-66) to 22 (95% CI 6-85) deaths per 1,000 workers (OSHA 2013b, page 294-295).

In view of the foregoing discussion, MSHA agrees with OSHA's analysis, and MSHA also selected the Mannetje *et al*. (2002b) study for estimating silicosis mortality risks and cases. MSHA used a life table analysis to estimate the lifetime excess silicosis mortality through age 80. To estimate the age-specific risk of silicosis mortality at the existing standards, the proposed PEL, and the proposed action level, MSHA used the same categorical model that OSHA used in their PQRA (as described above from Mannetje *et al.,* 2002b; ToxaChemica International, Inc. 2004) to estimate lifetime risk following cumulative exposure of 45 years. MSHA used the 2018 all-cause mortality rates (NCHS, Underlying Cause of Death, 2018 on CDC WONDER Online Database, released in 2020b) as all-cause mortality rates. As stated previously, the general (unexposed) population is assumed to have silicosis mortality rates equal to zero.

b. NMRD Mortality: Park et al. (2002)

In addition to causing silicosis, exposure to respirable crystalline silica causes increased risks of other NMRD. These include chronic obstructive pulmonary disease (COPD), which includes chronic bronchitis, emphysema, and combinations of the two and is a cause of chronic airways obstruction. COPD is characterized by airflow limitation that is usually progressive and

not fully reversible. OSHA reviewed several studies of NMRD morbidity and used a study by Park *et al.* (2002) to assess NMRD risk. Checkoway *et al.* (1997) originally studied a California diatomaceous earth cohort for which Park *et al.* (2002) then analyzed the effect of respirable crystalline silica exposures on the development of NMRD. The authors quantified the relationship between exposure to cristobalite and mortality from NMRD (OSHA 2013b, page 295).

The California diatomaceous earth cohort consisted of 2,570 diatomaceous earth workers employed for 12 months or more from 1942 to 1994. As noted above, Park *et al.* (2002) was interested in the relationship between cristobalite exposure and mortality from chronic lung disease other than cancer (LDOC). LDOC included chronic diseases such as pneumoconiosis (which included silicosis), chronic bronchitis, and emphysema, but excluded pneumonia and other infectious diseases. The investigators selected LDOC as the health endpoint for three reasons. First, increased mortality from LDOC had been documented among respirable crystalline silica-exposed workers in several industry sectors, including gold mining, pottery, granite, and foundry industries. Second, the authors pointed to the likelihood that silicosis as a cause of death is often misclassified as emphysema or chronic bronchitis. Third, the number of deaths from the diatomaceous earth worker cohort that were attributed to silicosis was too small (10) for analysis. Industrial hygiene data for the cohort were available from the employer for total dust, respirable crystalline silica (mostly cristobalite), and asbestos. Smoking information was available for about 50 percent of the cohort and for 22 of the 67 LDOC deaths available for analysis, permitting Park *et al.* (2002) to partially adjust for smoking (OSHA 2013b, pages 295-296).

Park *et al.* (2002) used the exposure assessment previously reported by Seixas *et al.* (1997) and used by Rice *et al.* (2001) to estimate cumulative respirable crystalline silica exposures for each worker in the cohort based on detailed work history files. The average respirable crystalline silica concentration for the cohort was 290 $\mu g/m^3$ (0.29 mg/m^3) over the

period of employment (Seixas *et al.*, 1997). The total respirable dust concentration in the diatomaceous earth plant was 3,550 µg/m^3 (3.55 mg/m^3) before 1949 and declined by more than 10-fold after 1973, to 290 µg/m^3 (0.29 mg/m^3) (Seixas *et al.*, 1997). The concentration of respirable crystalline silica in the dust ranged from one to 25 percent and was dependent on the location within the worksite. It was lowest at the mine and greatest in the plant where the raw ore was calcined into final product. The average cumulative exposure values for total respirable dust and respirable crystalline silica were 7,310 µg/m^3-year (7.31 mg/m^3-year) and 2,160 µg/m^3-year (2.16 mg/m^3-year), respectively. The authors also estimated cumulative exposure to asbestos (OSHA 2013b, page 296).

Using Poisson regression models and Cox's proportional hazards models, the authors fit the same series of relative rate exposure-response models that were evaluated by Rice *et al.* (2001) for lung cancer (i.e., log-linear, log-square root, log-quadratic, linear relative rate, a power function, and a shape function). In general form, the relative rate model was:

$$\text{Rate} = \exp(a_0) \times f(E),$$

where $\exp(a_0)$ is the background rate and E is the cumulative respirable crystalline silica exposure. Park *et al.* (2002) also employed an additive excess rate model of the form:

$$\text{Rate} = \exp(a_0) + \exp(a_E).$$

Relative or excess rates were modeled using internal controls and adjusting for age, calendar time, ethnicity, and time since first entry into the cohort. In addition, relative rate models were evaluated using age- and calendar time-adjusted external standardization to U.S. population mortality rates for 1940 to 1994 (OSHA 2013b, page 296).

There were no LDOC deaths recorded among workers having cumulative exposures above 32,000 µg/m^3-years (32 mg/m^3-years), causing the response to level off or decline in the highest exposure range. The authors believed the most likely explanation for this observation (which was also observed in their analysis of silicosis morbidity in this cohort) was some form of survivor selection, possibly smokers or others with compromised respiratory function leaving

work involving extremely high dust concentrations. These authors suggested several alternative explanations. First, there may have been a greater depletion of susceptible populations in high dust areas. Second, there may have been greater misclassification of exposures in the earlier years where exposure data were lacking (and when exposures were presumably the highest) (OSHA 2013b, pages 296-297).

Therefore, Park *et al.* (2002) performed exposure-response analyses that restricted the dataset to observations where cumulative exposures were below 10,000 $\mu g/m^3$-years (10 mg/m^3-years). This is a level more than four times higher than that resulting from 45 years of exposure to the former OSHA PEL for cristobalite (which was 50 $\mu g/m^3$ (0.05 mg/m^3) when cristobalite was the only polymorph present). These investigators also conducted analyses using the full dataset (OSHA 2013b, page 297).

Model fit was assessed by evaluating the decrease in deviance resulting from addition of the exposure term, and cubic-spline models were used to test for smooth departures from each of the model forms described. Park *et al.* (2002) found that both lagged and unlagged models fit well, but unlagged models provided a better fit. In addition, they believed that unlagged models were biologically plausible in that recent exposure could contribute to LDOC mortality. The Cox proportional hazards models yielded results that were similar to those from the Poisson analysis. Consequently, only the results from the Poisson analysis were reported. In general, the use of external adjustments for age and calendar time yielded considerably improved fit over models using internal adjustments. The additive excess rate model also proved to be clearly inferior compared to the relative rate models. With one exception, the use of cumulative exposure as the exposure metric consistently provided better fits to the data than did intensity of exposure (i.e., cumulative exposure divided by duration of exposure). As to the exception, when the highest-exposure cohort members were included in the analysis, the log-linear model produced a significantly improved fit with exposure intensity as the exposure metric, but a poor fit with cumulative exposure as the metric (OSHA 2013b, page 297).

Among the models based on the restricted dataset (excluding observations with cumulative exposures greater than 10,000 μg/m^3-years (10 mg/m^3-years)), the best-fitting model with a single exposure term was the linear relative rate model using external adjustment. Most of the other single-term models using external adjustment fit almost as well. Of the models with more than one exposure term, the shape model provided no improvement in fit compared with the linear relative rate model. The log-quadratic model fit slightly better than the linear relative rate model, but Park *et al.* (2002) did not consider the gain in fit sufficient to justify an additional exposure term in the model (OSHA 2013b, page 297).

Based on its superior fit to the cohort data, Park *et al.* (2002) selected the linear relative rate model with external adjustment and use of cumulative exposure as the basis for estimating LDOC mortality risks among exposed workers. Competing mortality was accounted for using U.S. death rates published by the National Center for Health Statistics (1996). The authors estimated the lifetime excess risk for white men exposed to respirable crystalline silica (mainly cristobalite) for 45 years at 50 μg/m^3 (0.05 mg/m^3) to be 54 deaths per 1,000 workers (95% CI: 17-150) using the restricted dataset, and 50 deaths per 1,000 using the full dataset. For exposure to 100 μg/m^3 (0.1 mg/m^3), they estimated 100 deaths per 1,000 using the restricted dataset, and 86 deaths per 1,000 using the full dataset. The CIs were not reported (OSHA 2013b, page 297).

The estimates of Park *et al.* (2002) were about eight to nine times higher than those that were calculated for the pooled analysis of silicosis mortality (Mannetje *et al.*, 2002b). Also, these estimates are not directly comparable to those from Mannetje *et al.* (2002b) because the mortality endpoint for the Park *et al.* (2002) analysis was death from all non-cancer lung diseases beyond silicosis (including pneumoconiosis, emphysema, and chronic bronchitis). In the pooled analysis by Mannetje *et al.* (2002b), only deaths coded as silicosis or other pneumoconiosis were included (OSHA 2013b, pages 297-298).

Less than 25 percent of the LDOC deaths in the Park *et al.* (2002) analysis were coded as silicosis or other pneumoconiosis (15 of 67). As noted by Park *et al.* (2002), it is likely that

silicosis as a cause of death is often misclassified as emphysema or chronic bronchitis (although COPD is part of the spectrum of disease caused by respirable crystalline silica exposure and can occur in the absence of silicosis). Thus, the selection of deaths by Mannetje *et al.* (2002b) may have underestimated the true risk of silicosis mortality. The analysis by Park *et al.* (2002) would have more fairly captured the total respiratory mortality risk from all non-malignant causes, including silicosis and chronic obstructive pulmonary disease. Furthermore, Park *et al.* (2002) used untransformed cumulative exposure in a linear model compared to the log-transformed cumulative exposure metric used by Mannetje *et al.* (2002b). This would have caused the exposure-response relationship to flatten in the higher exposure ranges (OSHA 2013b, page 298).

It is also possible that some of the difference between Mannetje *et al.*'s (2002b) and Park *et al.*'s (2002) risk estimates reflected factors specific to the nature of exposure among diatomaceous earth workers (e.g., exposure to cristobalite vs. quartz). However, neither the cancer risk assessments nor assessments of silicosis morbidity supported the hypothesis that cristobalite is more hazardous than quartz (OSHA 2013b, page 298).

Based on the available risk assessments for silicosis mortality, OSHA believed that the estimates from the pooled study by Mannetje *et al.*'s (2002b) represented those least likely to overestimate mortality risk. It was unlikely to have overstated silicosis mortality risks given that the estimates reflected only those deaths where silicosis was specifically identified on death certificates. Therefore, there was most likely an underestimate of the true silicosis mortality risk. In contrast, the risk estimates provided by Park *et al.* (2002) for the diatomaceous earth cohort would have captured some of this misclassification and included risks from other lung diseases (e.g., emphysema, chronic bronchitis) that have been associated with respirable crystalline silica exposure. Therefore, OSHA believed that the Park *et al.* (2002) study provided a better basis for estimating the respirable crystalline silica-related risk of NMRD mortality, including that from silicosis. Based on Park *et al.*'s (2002) linear relative rate model [$RR = 1 + \beta x$, where $\beta = 0.5469$

(no standard error reported) and x = cumulative exposure], OSHA used a life table analysis to estimate the lifetime excess NMRD mortality through age 85. For this analysis, OSHA used all-cause and cause-specific background mortality rates for all males (National Center for Health Statistics, 2009). Background rates for NMRD mortality were based on rates for ICD-10 codes J40-J47 (chronic lower respiratory disease) and J60-J66 (pneumoconiosis). OSHA believed that these corresponded closely to the ICD-9 disease classes (ICD 490-519) used by the original investigators. According to CDC (2001), background rates for chronic lower respiratory diseases were increased by less than five percent because of the reclassification to ICD-10. From the life table analysis, OSHA estimated that the excess NMRD risk due to respirable crystalline silica exposure at the former general industry PEL (100 $\mu g/m^3$) and at OSHA's final PEL (50 $\mu g/m^3$) for 45 years are 83 and 43 deaths per 1,000, respectively. For exposure at the former construction/shipyard exposure limit, OSHA estimated that the excess NMRD risk ranged from 188 to 321 deaths per 1,000 (OSHA 2013b, page 298).

Following its own independent review, MSHA agrees with and has followed the rationale presented by OSHA in its selection of the Park *et al.* (2002) model to estimate NMRD mortality risk in miners. Coal miners were not included in the NMRD mortality analysis because the endpoint was included in the *Quantitative Risk Assessment in Support of the Final Respirable Coal Mine Dust Rule* (Dec. 2013).

MSHA used a life table analysis to estimate the lifetime excess NMRD mortality through age 80. MSHA used the Park *et al.* (2002) model to estimate age-specific NMRD mortality risk as 1 + 0.5469 * cumulative exposure. MSHA used all-cause and cause-specific background mortality rates for all males for 2018 (National Center for Health Statistics, Underlying Cause of Death 2018 on CDC WONDER Online Database, released in 2020b). Background rates for NMRD mortality were based on rates for ICD-10 codes J40-J47 (chronic lower respiratory disease) and J60-J66 (pneumoconiosis).

4. Lung Cancer Mortality

Since the publication of OSHA's final rule in 2016, NIOSH has published two documents concerning occupational carcinogens, *Chemical Carcinogen Policy* (2017b) and *Practices in Occupational Risk Assessment* (2019a). NIOSH will no longer set recommended exposure levels for occupational carcinogens. Instead, NIOSH intends to develop risk management limits for carcinogens (RML-Cas) to acknowledge that, for most carcinogens, there is no known safe level of exposure. An RML-CA is a reasonable starting place for controlling exposures. An RML-CA limit is based on a daily maximum 8-hour TWA concentration of a carcinogen above which a worker should not be exposed (NIOSH 2017b, page vi). RML-Cas for occupational carcinogens are established at the estimated 95% lower confidence limit on the concentration (e.g., dose) corresponding to 1 in 10,000 (10^{-4}) lifetime excess risk (when analytically possible to measure) (NIOSH 2019a). NIOSH stated that in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-Cas that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4} (NIOSH 2017b, page vi).

MSHA used the Miller *et al.* (2007) and Miller and MacCalman (2010) studies to estimate lung cancer mortality risk in miners. In British coal miners, excess lung cancer mortality was studied through the end of 2005 in a cohort of 17,800 miners (Miller *et al.*, 2007; Miller and MacCalman, 2010). By that time, the cohort had accumulated 516,431 person-years of observation (an average of 29 years per miner), with 10,698 deaths from all causes. Overall lung cancer mortality was elevated (Standard Mortality Ratio (SMR)=115.7, 95% CI: 104.8–127.7), and a positive exposure-response relationship with respirable crystalline silica exposure was determined from Cox regression after adjusting for smoking history. Three strengths of this study were: 1) the detailed time-exposure measurements of quartz and total mine dust, 2) detailed individual work histories, and 3) individual smoking histories. For lung cancer, analyses

based on Cox regression provided strong evidence that, for these coal miners, although quartz exposures were associated with increased lung cancer risk, simultaneous exposures to coal dust did not cause increased lung cancer risk (OSHA 2016a, 81 FR 16286, 16308).

Miller *et al.* (2007) and Miller and MacCalman (2010) conducted a follow-up study of cohort mortality, begun in 1970. Their previous report on mortality presented a follow-up analysis on 18,166 coal miners from 10 British coal mines followed through the end of 1992 (Miller *et al.*, 1997). The two reports from 2007 and 2010 analyzed the mortality experience of 17,800 of these miners (18,166 minus 346 men whose vital status could not be determined) and extended the analysis through the end of 2005. Causes of deaths that were of particular interest included pneumoconiosis, other NMRD, lung cancer, stomach cancer, and tuberculosis. The researchers noted that no additional exposure measurements were included in the updated analysis, since all the mines had closed by the mid-1980s. However, some of these men might have had additional exposure at other mines or facilities not reported in this study (OSHA 2013b, page 287).

This cohort mortality study included analyses using both external and internal controls. The external controls used British administrative regional age-, time-, and cause-specific mortality rates from which to calculate SMRs. The internal controls from the mines used Cox proportional hazards regression methods, which considered each miner's age, smoking status, and detailed dust and respirable crystalline silica (quartz) time-dependent exposure measurements. Cox regression analyses were done in stages, with the initial analyses used to establish what factors were required for baseline adjustment (OSHA 2013b, page 287).

For the analysis using external mortality rates, the all-cause mortality SMR from 1959 through 2005 was 100.9 (95% CI: 99.0-102.8), based on all 10,698 deaths. However, these SMRs were not uniform over time. For the period from 1990-2005, the SMR was 109.6 (95% CI:106.5-112.8), while the ratios for previous periods were less than 100. This pattern of increasing SMRs in the recent past was also seen for cause-specific deaths from chronic

bronchitis, SMR=330.0 (95% CI:268.1-406.2); tuberculosis, SMR=193.4 (95% CI: 86.9-430.5); cardiovascular disease, SMR=106.6 (95% CI: 102.0-111.5); all cancers, SMR=107.1 (95% CI:101.3-113.2); and lung cancer, SMR=115.7 (95% CI: 104.8-127.7). The SMR for NMRD was 142.1 (95% CI: 132.9-152.0) in this recent period and remained highly statistically significant. In their previous analysis on mortality from lung cancer, reflecting follow-up through 1995, Miller *et al.* (1997) had not found any increase in the risk of lung cancer mortality (OSHA 2013b, page 287).

OSHA reported that Miller and MacCalman (2010) used these analyses to estimate relative risks for a lifetime exposure of 5 gram-hours/m^3 (ghm^{-3}) to quartz (OSHA 2013b, page 288). This is equivalent to approximately 55 $\mu g/m^3$ (0.055 mg/m^3) for 45 years, assuming 2,000 hours per year of exposure and/or 100 ghm^{-3} total dust. The authors estimated relative risks (see Miller and MacCalman (2010), Table 4, page 9) for various causes of death including pneumoconiosis, COPD, ischemic heart disease, lung cancer, and stomach cancer. Their results were based on models with single exposures to dust or respirable crystalline silica (quartz) or simultaneous exposures to both, with and without 15-year lag periods. Generally, the risk estimates were slightly greater using a 15-year lag period.

For the models using only quartz exposures with a 15-year lag, pneumoconiosis, RR=1.21 (95% CI: 1.12-1.31); COPD, RR=1.11 (95% CI: 1.05-1.16); and lung cancer, RR=1.07 (95% CI: 1.01-1.13) showed statistically significant increased risks.

For lung cancer, analyses based on these Cox regression methods provided strong evidence that, for these coal miners, quartz exposures were associated with increased lung cancer risk, but simultaneous exposures to coal dust were not associated with increased lung cancer risk. The relative risk (RR) estimate for lung cancer deaths using coal dust with a 15-year lag in the single exposure model was 1.03 (95% CI: 0.96 to 1.10). In the model using both quartz and coal mine dust exposures, the RR based on coal dust decreased to 0.91, while that for quartz exposure remained statistically significant, increasing to a RR=1.14 (95% CI: 1.04 to 1.25). According to

Miller and MacCalman (2010), other analyses have shown that exposure to radon or diesel fumes was not associated with an increased cancer risk among British coal miners (OSHA 2013b, page 288).

The RRs in the Miller and MacCalman (2010) report were used to estimate excess lung cancer risk for OSHA's purposes. Life table analyses were done as in the other studies above. Based on the RR of 1.14 (95% CI: 1.04-1.25) for a cumulative exposure of 5 ghm^{-3}, the regression slope was recalculated as $\beta = 0.0524$ per 1,000 µg-years (per mg/m^3-years) and used in the life table program. Similarly, the 95-percent CI on the slope was 0.0157–0.08926. From this study, the lifetime (to age 85) risk estimates for 45 years of exposure to 50 $\mu g/m^3$ (0.05 mg/m^3) and 100 $\mu g/m^3$ (0.100 mg/m^3) respirable crystalline silica were 6 and 13 excess lung cancer deaths per 1,000 workers, respectively. These lung cancer risk estimates were less by about 2- to 4-fold than those estimated from the other cohort studies described above.

However, three factors might explain these differences. First, these estimates were adjusted for individual smoking histories so any smoking-related lung cancer risk (or smoking–respirable crystalline silica interaction) that might possibly be attributed to respirable crystalline silica exposure in the other studies were not reflected in the risk estimates derived from the study of these coal miners. Second, these coal miners had significantly increased risks of death from other lung diseases, which may have decreased the lung cancer-susceptible population. Of note, for example, were the higher increased SMRs for NMRD during the years 1959-2005 for this cohort (Miller and MacCalman, 2010, Table 2, Page 7). Third, the difference in risk seen in these coal miners may have been the result of differences in the toxicity of quartz present in the coal mines as compared to the work environments of the other cohorts. One Scottish mine (Miller *et al.*, 1998) in this 10-mine study had been cited as having presented "unusually high exposures to [freshly fractured] quartz." However, this was also described as an atypical exposure among miners working in the 10 mines. Miller and MacCalman (2010) stated that increased quartz-related lung cancer risk in their cohort was not confined to that Scottish mine

alone. They also stated, "The general nature of some quartz exposures in later years… may have been different from earlier periods when coal extraction was largely manual…" (OSHA 2013b, page 288).

All these factors in this mortality analysis for the British coal miner cohort could have combined to yield lower lung cancer risk estimates. However, OSHA believed that these coal miner-derived estimates were credible because of the quality of several study factors relating to both study design and conduct. In terms of design, the cohort was based on union rolls with very good participation rates and good reporting. The study group also included over 17,000 miners, with an average of nearly 30 years of follow-up, and about 60 percent of the cohort had died. Just as important was the high quality and detail of the exposure measurements, both of total dust and quartz. However, one exposure factor that may have biased the estimates upward was the lack of exposure information available for the cohort after the mines closed in the mid-1980s. Since the death ratio for lung cancer was higher during the last study period, 1990–2005, this period contributed to the increased lung cancer risk. It is possible that any quartz exposure experienced by the cohort after the mines had closed could have accelerated either death or malignant tumor (lung cancer) growth. By not accounting for this exposure, if there were any, the risk estimates would have been biased upwards. Although the 15-year lag period for quartz exposure used in the analyses provided slightly higher risk estimates than use of no lag period, the better fit seen with the lag may have been artificial. This may have occurred since there appeared to have been no exposures during the recent period when risks were seen to have increased (OSHA 2013b, page 289).

OSHA believed, as does MSHA, that this study of a large British coal mining cohort provided convincing evidence of the carcinogenicity of respirable crystalline silica. This large cohort study, with almost 30 years of follow-up, demonstrated a positive exposure-response after adjusting for smoking histories. Additionally, the authors state that there was no evidence that exposure to potential confounders such as radon and diesel exhaust were associated with excess

lung cancer risk (Miller and MacCalman (2010), page 270). MSHA is relying on the British studies conducted by Miller *et al.* (2007) as well as Miller and MacCalman (2010) to estimate the lung cancer risk in all miners.

MSHA found these two studies suitable for use in the quantitative characterization of health risks to exposed miners for several reasons. First, their study populations were of sufficient size to provide adequate statistical power to detect low levels of risk. Second, sufficient quantitative exposure data were available over a sufficient span of time to characterize cumulative respirable crystalline silica exposures of cohort members. Third, the studies either adjusted for or otherwise adequately addressed confounders such as smoking and exposure to other carcinogens. Finally, these investigators developed quantitative assessments of exposure-response relationships using appropriate statistical models or otherwise provided sufficient information that permits MSHA to do so.

MSHA implemented the risk model in its life table analysis so that the use of background rates of lung cancer and assumptions regarding length of exposure and lifetime were consistent across models. Thus, MSHA was able to estimate lung cancer risks associated with exposure to specific levels of respirable crystalline silica of interest to the Agency. MSHA used the Miller *et al.* (2007) and Miller and MacCalman (2010) model to estimate age-specific cumulative lung cancer mortality risk as EXP(0.0524*cumulative exposure), lagged 15 years.

MSHA's PRA uses risk estimates derived from 10 coal mines in the U.K. (Miller *et al.*, 2007; Miller and MacCalman, 2010). These investigators developed regression analyses for time-dependent estimates of individual exposures to respirable dust. Their analyses were based on the detailed individual exposure estimates of the PFR programme. To estimate mortality risk for lung cancer from the pooled cohort analysis, MSHA used the same life table approach as OSHA. However, for this life table analysis, MSHA used 2018 mortality rates for U.S. males (i.e., all-cause and background lung cancer). The 2018 lung cancer death rates were based on the ICD-10 classification of diseases, C34.0, C34.2, C34.1, C34.3, C34.8, and C34.9. Lifetime risk

estimates reflected excess risk through age 80. To estimate lung cancer risks, MSHA used the log-linear relative risk model, exp(0.0524×cumulative exposure), lagged 15 years. The coefficient for this model was 0.0524 (OSHA 2013b, page 290).

5. ESRD Mortality

Several epidemiological studies have found statistically significant associations between occupational exposure to respirable crystalline silica and renal disease, although others have failed to find a statistically significant association. These studies are discussed in the Health Effects document. Possible mechanisms suggested for respirable crystalline silica-induced renal disease included a direct toxic effect on the kidney, deposition of immune complexes (IgA) in the kidney following respirable crystalline silica-related pulmonary inflammation, and an autoimmune mechanism (Gregorini *et al.*, 1993; Calvert *et al.*, 1997; Parks *et al*., 1999; Steenland 2005b) (OSHA 2016a, 81 FR 16286, 16310).

MSHA, like OSHA, chose the Steenland *et al*. (2002a) study to include in the PRA. In a pooled cohort analysis, Steenland *et al.* (2002a) combined the industrial sand cohort from Steenland *et al.* (2001b), the gold mining cohort from Steenland and Brown (1995a), and the Vermont granite cohort studies by Costello and Graham (1988). All three were included in portions of OSHA's PQRA for other health endpoints: under lung cancer mortality in Steenland *et al.* (2001a) and under silicosis mortality in the related work of Mannetje *et al.* (2002b). In all, the combined cohort consisted of 13,382 workers with exposure information available for 12,783. The analysis demonstrated statistically significant exposure-response trends for acute and chronic renal disease mortality with quartiles of cumulative respirable crystalline silica exposure (OSHA 2016a, 81 FR 16286, 16310).

The average duration of exposure, cumulative exposure, and concentration of respirable crystalline silica for the pooled cohort were 13.6 years, 1,200 $\mu g/m^3$-years (1.2 mg/m^3-years), and 70 $\mu g/m^3$ (0.07 mg/m^3), respectively. Renal disease risk was most prevalent among workers with cumulative exposures of 500 $\mu g/m^3$ or more (Steenland *et al.*, 2002a). SMRs (compared to

the U.S. population) for renal disease (acute and chronic glomerulonephritis, nephrotic syndrome, acute and chronic renal failure, renal sclerosis, and nephritis/nephropathy) were statistically significant and elevated based on multiple cause of death data (SMR 1.28, 95% CI: 1.10-1.47, 194 deaths) and underlying cause of death data (SMR 1.41, 95% CI: 1.05-1.85, 51 observed deaths) (OSHA 2013b, page 315).

A nested case-control analysis was also performed which allowed for more detailed examination of exposure-response. This analysis included 95 percent of the cohort for which there were adequate work history and quartz exposure data. This analysis included 50 cases for underlying cause mortality and 194 cases for multiple-cause mortality. Each case was matched by race, sex, and age within 5 years to 100 controls from the cohort. Exposure-response trends were examined in a categorical analysis where renal disease mortality of the cohort divided by exposure quartile was compared to U.S. rates (OSHA 2013b, page 315).

In this analysis, statistically significant exposure-response trends for SMRs were observed for multiple-cause ($p < 0.000001$) and underlying cause ($p = 0.0007$) mortality (Steenland *et al.*, 2002a; Table 1; Page 7).

With the lowest exposure quartile group serving as a referent, the case-control analysis showed monotonic trends in mortality with increasing cumulative exposure. Conditional regression models using log-cumulative exposure fit the data better than cumulative exposure (with or without a 15-year lag) or average exposure. Odds ratios by quartile of cumulative exposure were 1.00, 1.24, 1.77, and 2.86 ($p = 0.0002$) for multiple cause analyses and 1.00, 1.99, 1.96, and 3.93 for underlying cause analyses ($p=0.03$) (Steenland *et al.*, 2002a; Table 2; Page 7). For multiple-cause mortality, the exposure-response trend was statistically significant for cumulative exposure ($p=0.004$) and log-cumulative exposure ($p=0.0002$), whereas for underlying cause mortality, the trend was statistically significant only for log-cumulative exposure ($p=0.03$). The exposure-response trend was homogeneous across the three cohorts and interaction terms did not improve model fit (OSHA 2013b, pages 216, 315).

Based on the exposure-response coefficient for the model with the log of cumulative exposure, Steenland (2005) estimated lifetime excess risks of death (age 75) over a working life (age 20 to 65). At 100 µg/m^3 (0.1 mg/m^3) respirable crystalline silica, this risk was 5.1 percent (95% CI 3.3-7.3) for ESRD based on 23 cases (Steenland *et al.*, 2001b). It was 1.8 percent (95% CI 0.8-9.7) for kidney disease mortality (underlying), based on 51 deaths (Steenland *et al.*, 2002a) above a background risk of 0.3 percent (OSHA 2013b, page 216).

MSHA notes that these studies added to the evidence that renal disease is associated with respirable crystalline silica exposure. Statistically significant increases in odds ratios and SMRs were seen primarily for cumulative exposures of >500 µg/m^3-years (0.5 mg/m^3-years). Steenland (2005b) noted that this could have occurred from working for 5 years at an exposure level of 100 µg/m^3 (0.1 mg/m^3) or 10 years at 50 µg/m^3 (0.05 mg/m^3).

OSHA had a large body of evidence, particularly from the three-cohort pooled analysis (Steenland *et al.*, 2002a), on which to conclude that respirable crystalline silica exposure increased the risk of renal disease mortality and morbidity. The pooled analysis by Steenland *et al.* (2002a) involved a large number of workers from three cohorts with well-documented, validated job-exposure matrices. These investigators found a positive, monotonic increase in renal disease risk with increasing exposure for underlying and multiple cause data. Thus, the exposure and work history data were unlikely to have been seriously misclassified. However, there are considerably less data available for renal disease than there are for silicosis mortality and lung cancer mortality. Nevertheless, OSHA concluded that the underlying data were sufficient to provide useful estimates of risk and included the Steenland *et al.* (2002a) analysis in its PQRA (OSHA 2013b, pages 229, 316).

To estimate renal disease mortality risk from the pooled cohort analysis, OSHA implemented the same life table approach as was done for the assessments on lung cancer and NMRD. However, for this life table analysis, OSHA used 1998 all-cause and background renal mortality rates for U.S. males, rather than the 2006 rates used for lung cancer and NMRD. The

1998 rates were based on the ICD-9 classification of diseases, which was the same as used by Steenland *et al.* (2002a) to ascertain the cause of death of workers in their study. However, U.S. cause-of-death data from 1999 to present are based on the ICD-10, in which there were considerable changes in the classification system for renal diseases. According to CDC (2001), the change in the classification from ICD-9 to ICD-10 increased death rates for nephritis, nephritic syndrome, and nephrosis by 23 percent, in large part due to reclassifying ESRD. The change from ICD-9 to ICD-10 did not materially affect background rates for those diseases grouped as lung cancer or NMRD. Consequently, OSHA conducted its analysis of excess renal disease mortality associated with respirable crystalline silica exposure using background mortality rates for 1998. As before, lifetime risk estimates reflected excess risk through age 85. To estimate renal mortality risks, OSHA used the log-linear model with log-cumulative exposure that provided the best fit to the pooled cohort data (Steenland *et al.*, 2002a). The coefficient for this model was 0.269 (SE = 0.120) (OSHA 2013b, page 316). Based on the life table analysis, OSHA estimated that exposure to the former general industry exposure limit of 100 $\mu g/m^3$ and to the final exposure limit of 50 $\mu g/m^3$ over a working life would result in a lifetime excess renal disease risk of 39 (95% CI: 2-200) and 32 (95% CI: 1.7-147) deaths per 1,000, respectively. OSHA also estimated lifetime risks associated with the former construction and shipyard exposure limits of 250 and 500 $\mu g/m^3$. These lifetime excess risks ranged from 52 (95% CI 2.2-289) to 63 (95% CI 2.5-368) deaths per 1,000 workers (OSHA 2013b, page 316).

MSHA concludes that the evidence supporting causality regarding renal risk outweighs the evidence casting doubt on that conclusion. However, MSHA acknowledges the uncertainty associated with the divergent findings in the renal disease literature. To estimate renal disease mortality risk from the pooled cohort analysis, MSHA implemented the same life table approach as OSHA. However, MSHA's life table analysis used 2018 all-cause and 1998 background renal mortality rates for U.S. males. The 1998 renal death rates were based on the ICD-9 classification of diseases, 580-589. This is the same classification used by Steenland *et al.* (2002a) to ascertain

the cause of death of workers in their study. Consequently, MSHA conducted its analysis of excess ESRD mortality associated with exposure to respirable crystalline silica using background mortality rates for 1998. The U.S. cause-of-death data from 2018 were used as well. Lifetime risk estimates reflect excess risk through age 85. To estimate ESRD mortality risks, MSHA used the log-linear model with log-cumulative exposure that provided the best fit to the pooled cohort data (Steenland *et al.*, 2002a), as EXP(0.269*ln(cumulative exposure)). The coefficient for this model was 0.269 (SE = 0.120) (OSHA 2013b, page 316).

6. Coal Workers' Pneumoconiosis (CWP)

Exposure to respirable coal mine dust causes lung diseases including CWP, emphysema, silicosis, and chronic bronchitis, known collectively as "black lung." These diseases are debilitating, incurable, and can result in disability and premature death. There are no specific treatments to cure CWP or COPD. These chronic effects may progress even after miners are no longer exposed to coal dust.

MSHA's 2014 coal dust rule quantified benefits among coal miners related to reduced cases of CWP due to lower exposure limits for respirable coal mine dust. In this PRA, MSHA has not quantified the reduction in risk associated with CWP among coal miners. Nonetheless, MSHA believes that the proposed rule would reduce the excess risk of this disease. Many coal miners work extended shifts, thus increasing their potential exposure to respirable crystalline silica. The result of calculating exposures based on a full-shift 8-hour TWA would be more protective. Thus, the proposed rule is expected to provide additional reductions in CWP risk beyond those ascribed in the 2014 coal dust rule. However, exposure-response relationships based on respirable crystalline silica exposure are not available for CWP, so the reductions in this disease due to reductions in silica exposure cannot be quantified.

D. Overview of Results

Table VI-4 summarizes the PRA's main results: once it is fully effective (and all miners have been exposed only under the proposed PEL), the proposed rule is expected to result in at

least 799 avoided deaths and 2,809 avoided cases of silicosis morbidity among the working miner population. These numbers represent the lifetime health outcomes expected to occur after both 45 years of employment under the proposed PEL (from 21 through 65 years of age) and 15 years of retirement (up to 80 years of age). These estimates of the avoided lifetime excess mortality and morbidity represent the final calculations based on the 5 selected models and the observed exposure data. The first group of miners that would experience the avoided lifetime fatalities and illnesses shown in Table VI-4 is the population living 60 years after promulgation of the proposed rule. In other words, this group would only contain miners exposed under the proposed rule. To calculate benefits associated with the proposed rulemaking, the economic analysis monetizes avoided deaths and illnesses while accounting for the fact that, during the first 60 years following promulgation, miners would have fewer avoided lifetime fatalities and illnesses because they would be exposed under both the existing standards and the proposed PEL.

Table VI-4. Lifetime Excess Cases of Death and Illness Avoided Due to Implementation of Proposed Exposure Limit

	Avoided Cases of Death (Mortality) or Illness (Morbidity) by Sector		
Health Outcome	**MNM**	**Coal**	**Total**
Morbidity			
Silicosis (excluding deaths)	2,566	244	2,809
Total	2,566	244	2,809
Mortality			
Silicosis	174	12	186
Lung cancer	56	5	61
NMRD (excluding silicosis deaths)	366	35	402
ESRD	139	12	150
Total	736	63	799

Notes:
Due to rounding, some totals do not exactly equal the sum of the corresponding individual entries.

Table VI-5 summarizes miners' expected percentage reductions in lifetime excess risk of developing or dying from certain diseases due to their reduced respirable crystalline silica exposure expected to result from implementation of the proposed rule. The lifetime excess risk reflects the probability of developing or dying from diseases over a maximum lifetime of 45 years of exposure during employment and 15 years of retirement. The excess risk reduction

compares (a) miners' excess health risks associated with respirable crystalline silica exposure at the limits included in MSHA's existing standards to (b) miners' excess health risks associated with exposure at this standard's proposed PEL. MSHA expects full-scale implementation to reduce lifetime excess mortality risk by 9.5 percent and to reduce lifetime excess silicosis morbidity risk by 41.9 percent. Excess mortality risk includes the excess risk of death due to silicosis, NMRD, lung cancer, and ESRD.

Table VI-5. Lifetime Excess Risk Reduction Due to Implementation of Proposed Exposure Limit

	Percentage Reduction in Lifetime Excess Risk of Death (Mortality) or Illness (Morbidity) by Sector		
Health Outcome	**MNM**	**Coal**	**Total**
Morbidity			
Silicosis (excluding deaths)	47.2%	19.2%	41.9%
Total	47.2%	19.2%	41.9%
Mortality			
Silicosis	21.2%	4.9%	17.6%
NMRD (excluding silicosis deaths)	20.8%	5.8%	17.0%
Lung cancer	23.0%	6.3%	19.0%
ESRD	4.2%	0.9%	3.2%
Total	12.0%	1.7%	9.5%

Notes:
Due to rounding, some totals do not exactly equal the sum of the corresponding individual entries.

Table VI-6 presents MSHA's estimates of lifetime excess risk per 1,000 miners at exposure levels equal to the existing standards, the proposed PEL, and the proposed action level. These estimates are adjusted for FTE ratios and thus utilize cumulative exposures that more closely reflect the average hours worked per year.[21] For an MNM miner who is presently exposed at the existing PEL of 100 $\mu g/m^3$ (and given the weighted average FTE ratio of 0.87), implementing the proposed PEL would lower the miner's lifetime excess risk of death by 58.8 percent for silicosis, 45.6 percent for NMRD (not including silicosis), 52.0 percent for lung cancer, and 19.9 percent for ESRD. The MNM miner's risk of acquiring a non-fatal case of silicosis (would decrease by 80.4 percent).

[21] The FTE ratios used in these calculations are a weighted average of the FTE ratio for production employees and the FTE ratio for contract miners.

For a coal miner who is currently exposed at the existing exposure limit of 85.7 μg/m^3 (and given the weighted average FTE ratio of 0.99), implementing the proposed PEL would lower the miner's lifetime excess risk of death by 42.3 percent for silicosis mortality, 40.2 percent for NMRD mortality (not including silicosis), 43.5 percent for lung cancer mortality, and 15.8 percent for ESRD mortality. The coal miner's lifetime excess risk of acquiring non-fatal silicosis would decrease by 73.8 percent. While even greater reductions would be achieved at exposures equal to the proposed action level (25 μg/m^3), some residual risks do remain at exposures of 25 μg/m^3. Notably, at the proposed action level, ESRD risk is still 20.7 per 1,000 MNM miners and 21.6 per 1,000 coal miners. At the proposed action level, risk of non-fatal silicosis is 16.3 per 1,000 MNM miners and 16.9 per 1,000 coal miners.

Table VI-6. Lifetime Excess Risk (per 1,000 Miners) for Selected Health Endpoints at Respirable Crystalline Silica Exposure Levels Equal to the Existing Standards, Proposed PEL, and Proposed Action Level

Health Outcome (Study)	MNM			Coal		
	100 μg/m^3	50 μg/m^3	25 μg/m^3	85.7 μg/m^3	50 μg/m^3	25 μg/m^3
Silicosis Morbidity (Buchanan *et al*., 2003)	206.7	43.6	18.7	189.9	54.2	21.0
Silicosis Morbidity (Net of Silicosis Mortality)[a]	192.4	37.7	16.3	175.9	46.2	16.9
Silicosis Mortality (Mannetje *et al*., 2002b)	14.3	5.9	2.5	14.0	8.1	4.0
NMRD Mortality (Park *et al*., 2002)	54.7	27.9	14.1	53.1	31.5	15.9
NMRD Mortality (Net of Silicosis Mortality)[b]	40.4	22.0	11.6	39.1	23.4	11.8
Lung Cancer Mortality (Miller and MacCalman, 2010)	5.5	2.6	1.3	5.3	3.0	1.5
ESRD Mortality (Steenland *et al*., 2002a)	32.5	26.1	20.7	32.2	27.1	21.6

Notes:

a. The lifetime excess silicosis morbidity risk (net of silicosis mortality) is the difference between (a) the lifetime excess silicosis risk computed from the Buchanan *et al*. model and (b) the lifetime excess risk of silicosis mortality computed from the Mannetje *et al*. model.
b. NMRD (net) mortality risk is the difference between projected total NMRD mortality risk and projected silicosis mortality risk.
c. Values may not sum to total due to rounding.
d. Lifetime excess risk values are based on annual exposure durations that are scaled by a weighted average FTE ratio for contract miners and production employees. For MNM miners, this ratio is 0.87. For coal miners, this ratio is 0.99.

E. Healthy Worker Bias

MSHA accounted for "healthy worker survivor bias" in estimating the risks for coal and MNM miners. The healthy worker survivor bias causes epidemiological studies to underestimate excess risks associated with occupational exposures. As with most worker populations, miners are composed of heterogeneous groups that possess varying levels of background health. Over the course of miners' careers, illness tends to remove the most at-risk workers from the workforce prematurely, thus causing the highest cumulative exposures to be experienced by the healthiest workers who are most immune to risk. Failing to account for this imbalance of cumulative exposure across workers negatively biases risk estimates, thereby underestimating true risks in the population. Keil *et al*. (2018) analyzed a type of healthy worker bias referred to as the healthy worker survivor bias in the context of OSHA's 2016 life table estimates for risk associated with respirable crystalline silica exposure. After analyzing data from 65,999 workers pooled across multiple countries and industries, Keil *et al*. found that the "healthy worker survivor bias results in a 28% underestimate of risk for lung cancer and a 50% underestimate for other causes of death," with risk being defined as "cumulative incidence of mortality [at age 80]."

Given that MSHA has calculated risks using the same underlying epidemiological studies OSHA used in 2016, the healthy worker survivor bias is likely impacting the estimates in Table VI-6 of lifetime excess risk and lifetime excess cases avoided. Accordingly, as part of a sensitivity analysis, MSHA re-estimated risks for MNM and coal miners to account for the healthy worker survivor bias. MSHA adjusted for this effect by increasing the risk estimates of lung cancer risk by 28 percent and increasing the risk of each other disease by 50 percent. This produced larger estimates of lifetime excess risk reductions and lifetime excess cases avoided, which are presented in PRA Table 23 through PRA Table 26 of the PRA document. As these tables show, when adjusting for the healthy worker survivor bias, the proposed PEL would decrease lifetime silicosis morbidity risk by 20.8 cases per 1,000 MNM miners (compared to the

unadjusted estimate of 13.9 cases per 1,000 MNM miners, see PRA Table 15 of the PRA document) and 5.0 cases per 1,000 coal miners (compared to 3.3 cases per 1,000 coal miners, see PRA Table 16 of the PRA document). Still accounting for the healthy worker survivor bias, the proposed PEL would decrease total morbidity by 3,848 lifetime cases among MNM miners (compared to 2,566 cases, see PRA Table 17 of the PRA document) and by 366 lifetime cases among coal miners (compared to 244 cases, see PRA Table 18 of the PRA document). Among the current MNM and coal mining populations, implementation of the proposed PEL during their full lives would have prevented 1,091 deaths and 94 deaths, respectively, over their lifetimes (compared to unadjusted estimates of 736 deaths and 63 deaths, respectively).

MSHA believes adjusted estimates for the healthy worker survivor bias are more reliable than unadjusted estimates. However, given that the literature does not support specific scaling factors for each of the health endpoints analyzed, these adjustments for the healthy worker survivor bias have not been incorporated into the final lifetime excess risk estimates that served as the basis for monetizing benefits. Because the monetized benefits do not account for the healthy worker bias, MSHA believes the reductions in lifetime excess risks and lifetime excess cases, as well as the monetized benefits, likely underestimate the true reductions and benefits attributable to the proposed rule.

F. Uncertainty Analysis

MSHA conducted extensive uncertainty analyses to assess the impact on risk estimates of factors including treatment of data in excess of the proposed PEL, sampling error, and use of average rather than median point estimates for risk. The impact of excluding insufficient mass (weight) samples was also examined.

1. Alternate Treatment of Exposure Samples in Excess of the Proposed Exposure Limit

To estimate excess risks and excess cases under the proposed PEL, MSHA assumed that no exposures would exceed the proposed limit, which effectively reduced any exposures exceeding 50 $\mu g/m^3$ to 50 $\mu g/m^3$. However, if mines implement controls with the goal of

reducing exposures to 50 μg/m^3 on every shift, then some exposure currently in excess of 50 μg/m^3 would likely decrease below the proposed PEL. For this reason, the estimation method of capping all exposure data at 50 μg/m^3 represents a "lowball" estimate of risk reductions due to the proposed PEL. In this section, MSHA presents estimates using an alternate "highball" method wherein exposures exceeding 50 μg/m^3 are set equal to the median exposure value for the 25-50 μg/m^3 exposure group. Because this highball method attributes larger reductions in exposure to the proposed PEL, it estimates higher lifetime excess risk reductions and more avoided lifetime excess cases.

As with lifetime excess risks, the highball method also yields larger reductions in lifetime excess cases. Using the highball method, MNM miners are expected to experience 3,111 fewer cases of non-fatal silicosis and coal miners are expected to experience 344 fewer cases of non-fatal silicosis over their lifetimes. MNM miners would experience 1,137 fewer deaths and coal miners would experience 123 fewer deaths over their lifetimes. Compared to the lowball method—which estimates that the proposed PEL would prevent a total of 2,809 lifetime cases of non-fatal silicosis and 799 lifetime excess deaths (among both MNM and coal miners)—the highball method estimates totals of 3,445 avoided lifetime cases of non-fatal silicosis and 1,260 avoided lifetime excess deaths.

2. Sampling Error in Exposure Data

To quantify the impact of sampling uncertainty on the risk estimates, 1,000 bootstrap resamples of the original exposure data were generated (sampling with replacement). The resamples were stratified by commodity to preserve the relative sampling frequencies of coal, metal, non-metal, sand and gravel, crushed limestone, and stone observations in the original dataset. Risk calculations were repeated on each of the 1,000 bootstrap samples, thereby generating empirical distributions for all risk estimates. From these empirical distributions, 95 percent confidence intervals were calculated. These confidence intervals characterize the uncertainty in the risk estimates arising from sampling error in the exposure data. All lifetime

excess risk estimates had narrow confidence intervals, indicating that the estimates of lifetime excess morbidity and mortality risks have a high degree of precision.

In regard to use of average, rather than median, point estimates of risk, the estimates acquired from average exposures are similar to the estimates from median exposures, with 95 percent confidence intervals having similar widths. However, the 95 percent confidence intervals are not always overlapping, and average exposures tended to yield higher estimates of reduced morbidity and mortality. Among MNM miners, MSHA expects the proposed PEL to produce lifetime risk reductions of silicosis morbidity of 2,546 - 2,777 using average exposures (see PRA Table 41 of the PRA document), compared to 2,453 - 2,683 using median exposures (see PRA Table 37 of the PRA document). Among coal miners, this reduction is expected to be 246 - 279 using average exposures (see PRA Table 42 of the PRA document), compared to 229 - 265 using median exposures (see PRA Table 38 of the PRA document). The proposed PEL is estimated to reduce lifetime excess mortality by 735 - 791 MNM miner deaths and 65 - 73 coal miner deaths using average exposures (see PRA Tables 41 and 42 of the PRA document), compared to 708 - 764 MNM miner deaths and 60 - 69 coal miner deaths using median exposures (see PRA Tables 37 and 38 of the PRA document).

3. Samples with Insufficient Mass

The MNM exposure data gathered by enforcement from January 1, 2005, through December 31, 2019, contain samples that were analyzed using the P-2 method. As discussed, the P-2 method specifies that filters are only analyzed for quartz if they achieve a net mass gain of 0.100 mg or more. If cristobalite is requested, a mass gain of 0.050 mg or more is required for a filter to be analyzed (MSHA 2022a). During the 15-year sample period for MNM exposure data, 40,618 MNM samples were not analyzed because the filter failed to meet the P-2 minimum net mass (weight) gain requirements.

Similarly, the coal exposure data gathered by enforcement from August 1, 2016, through July 31, 2021, contains samples that were analyzed using the P-7 method. The P-7 method

requires a minimum sample mass of 0.100 mg[22] of dust for the sample to be analyzed for quartz. During the five-year sample period for coal exposure data, 63,127 coal samples were not analyzed because the P-7 method's minimum mass requirement was not met.

For samples that do not meet a minimum threshold for total respirable dust mass, the MSHA lab does not analyze these samples for respirable crystalline silica. These samples were excluded from the risk analysis because their concentrations of respirable crystalline silica are not known. Nonetheless, the unanalyzed samples all had very low total respirable dust mass, making it unlikely that many would have exceeded the existing standards or the proposed PEL. Excluding these unanalyzed samples from the exposure datasets thus may introduce bias, potentially causing the Agency to overestimate the proportion of high-intensity exposure values.

As a sensitivity analysis, MSHA used imputation techniques to estimate the respirable crystalline silica mass for each sample based on the sample weight and the median percent silica content for each commodity and occupation. All the unanalyzed samples with imputed concentrations were estimated to be < 25 $\mu g/m^3$, and thus including these unanalyzed samples in the analysis leads to lower estimates of estimated lifetime excess cases for both MNM and coal miners.

When including the imputed values for the unanalyzed samples, the proposed PEL would result in 1,642 fewer cases of non-fatal silicosis among MNM miners and 128 fewer cases among coal miners, over their lifetimes. The proposed PEL would also result in 469 fewer deaths (due to all 4 diseases) among MNM miners and 34 fewer deaths among coal miners, over their lifetimes. This yields a total reduction of 1,770 in lifetime excess morbidity and of 503 in lifetime excess mortality, respectively. While these estimates are lower than those presented in Table VI-4 (of 2,809 avoided lifetime cases of non-fatal silicosis and 799 avoided lifetime excess

[22] Often the threshold for analyzing Coal samples is ≥0.1 mg. There are, however, some exceptions based on Sample Type and Occupation Code. For samples with Sample Type 4 or 8, if the sample's Occupation Code is not 307, 368, 382, 383, 384, or 386, then the threshold is ≥0.2 mg.

fatalities), MSHA nonetheless believes that—even including these unanalyzed samples—the proposed PEL would still reduce the risk of material impairment of health or functional capacity in miners exposed to respirable crystalline silica. Moreover, the possible positive bias that may arise when excluding these samples would be offset by other negative biases discussed herein (e.g., the healthy worker survivor bias and the assumption that full compliance with the proposed PEL would not produce any reductions in exposure below 50 $\mu g/m^3$).

It should be noted that the imputation method has some limitations. For example, the method assumes that, if the insufficient mass samples had been analyzed, every sample would have possessed a percentage of quartz, by mass, equal to the median percentage for that sample's associated commodity and occupation. (See Section 17.1 of the PRA document for a full discussion of the imputation method.) However, within a given occupation, this percentage varies substantially and is positively correlated with exposure concentration. Suppressing the variation in this percentage quartz, by mass, produces less variation in the resulting imputed concentrations. Consequently, the imputation method may underestimate the number of unanalyzed samples that would truly exceed 50 $\mu g/m^3$.

VII. Section-by-Section Analysis

MSHA proposes to add a new part 60, titled *Respirable Crystalline Silica*, to title 30 CFR, chapter I, subchapter M – Uniform Mine Health Regulations. Proposed part 60, which would apply to all MNM and coal mines, contains health standards to protect all miners from adverse health risks caused by occupational exposure to respirable crystalline silica (as discussed in the standalone document entitled *Effects of Occupational Exposure to Respirable Crystalline Silica on the Health of Miners* and as summarized in Section V. Health Effects Summary of this preamble). This proposed part establishes a new PEL for respirable crystalline silica for all mines and includes other ancillary provisions to improve methods of compliance, exposure monitoring, corrective actions, respiratory protection, medical surveillance for MNM miners, and recordkeeping. In addition to the new part 60, MSHA proposes to incorporate by reference ASTM F3387-19, *Standard Practice for Respiratory Protection*, to replace its respiratory protection standards under 30 CFR parts 56, 57, and 72 to better protect all miners from airborne contaminants. This section-by-section analysis discusses each provision under the proposed part 60, the conforming amendments related to the proposed part, and the updated respiratory protection standard.

A. Part 60 – Respirable Crystalline Silica

MSHA has preliminarily determined that occupational exposure to respirable crystalline silica causes adverse health effects, including silicosis (acute silicosis, accelerated silicosis, simple chronic silicosis, and PMF), NMRD (e.g., emphysema and chronic bronchitis), lung cancer, and renal diseases. MSHA has also preliminarily determined that under the existing standards, miners remain at risk of suffering material impairment of health or functional capacity from these adverse health effects. Each of these effects is exposure-dependent, chronic, irreversible, and potentially disabling or fatal. MSHA has preliminarily concluded that lowering the PEL for respirable crystalline silica to 50 $\mu g/m^3$ would substantially reduce the health risks to miners.

MSHA proposes to replace its existing standards for respirable crystalline silica or respirable dust containing quartz with a single, uniform health standard for all miners. The proposed uniform standard would establish consistent, industry-wide requirements that directly address the adverse health effects of overexposure to respirable crystalline silica. This proposal would also facilitate mining-industry compliance and help MSHA and other stakeholders provide consistent compliance assistance. MSHA believes this unified regulatory framework for controlling miner exposure to respirable crystalline silica would improve protection for all miners and help the Agency fulfill its obligations under the Mine Act to prevent occupational diseases.

Proposed part 60 includes: Scope and effective date; Definitions; Permissible exposure limit (PEL); Methods of compliance; Exposure monitoring; Corrective actions; Respiratory protection; Medical surveillance for metal and nonmetal miners; Recordkeeping requirements; and Severability.

Detailed discussions of the proposed sections are followed by discussions on conforming amendments and discussions of the proposed update to the respiratory protection standard in parts 56, 57, and 72.

1. Section 60.1 – Scope; effective date.

This section provides that proposed part 60 would take effect 120 days after the final rule is published in the *Federal Register*. Mine operators would be required to comply with the requirements in this part starting on the proposed effective date.

MSHA believes that the proposed 120-day period gives operators the necessary time to plan and prepare for effective compliance with the new standards, while also ensuring that improved protections for miners from the hazards of respirable crystalline silica take effect as soon as practically possible. MSHA believes that it is important to reduce miner exposure to respirable crystalline silica promptly because every exposure at levels above the proposed PEL imposes adverse health risks on miners. However, for implementation to be successful, mine

operators need enough time to understand the standard and to prepare for compliance (e.g., by purchasing gravimetric ISO-conforming samplers and/or selecting a commercial laboratory for respirable crystalline silica analysis, if necessary). MSHA believes that the proposed effective date of 120 days would provide enough time for mine operators to take necessary steps to achieve successful compliance. Under the existing standards, both MNM and coal operators have had many years of experience with monitoring and controlling airborne contaminants, including respirable crystalline silica, and this experience should facilitate implementation of the proposed standard.

2. Section 60.2 – Definitions.

This section includes the proposed definitions of four terms: "action level," "objective data," "respirable crystalline silica," and "specialist."

The term "action level" would mean an airborne concentration of respirable silica of 25 micrograms per cubic meter of air ($\mu g/m^3$) for a full-shift exposure, calculated as an 8-hour time-weighted average (TWA). The action level sets the level of respirable crystalline silica concentration at or above which operators would be subject to periodic sampling requirements, which are explained in proposed § 60.12. This proposed action level is intended to support operator compliance with the proposed PEL of 50 $\mu g/m^3$ by initiating periodic sampling requirements.

The proposed action level of 25 $\mu g/m^3$, one-half of the proposed PEL, is consistent with NIOSH research findings and other MSHA standards. According to NIOSH research, wherever exposure measurements are above one-half the PEL, the employer cannot be reasonably confident that the employee is not exposed to levels above the PEL on days when no measurements are taken (NIOSH 1975). MSHA has experience with setting an action level equivalent to 50 percent of the PEL for occupational noise exposure (30 CFR 62.101), applicable to MNM and coal mines, and an action level of 50 percent of the exhaust gas monitoring standards for underground coal mines (30 CFR 70.1900). Based upon Agency experience,

MSHA believes these action levels have allowed mine operators to be more proactive in providing necessary protection.

The term "objective data" would mean information such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance that indicates the level of miner exposure to respirable crystalline silica associated with a particular product or material or a specific process, task, or activity. Such data must reflect mining conditions closely resembling, or with a higher exposure potential than, the processes, types of material, control methods, work practices, and environmental conditions in the operator's current operations. Some examples of information that would qualify as objective data under this definition include historical MSHA sampling data, NIOSH Health Hazard Evaluations and other published scientific reports, and industry-wide surveys compiled from mines with similar mining conditions, geological composition, work processes, miner tasks, and the same commodities.

"Respirable crystalline silica" would mean quartz, cristobalite, and/or tridymite contained in airborne particles that are determined to be respirable by a sampling device designed to meet the characteristics for respirable-particle-size-selective samplers that conform to the International Organization for Standardization (ISO) 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related Sampling. These characteristics are described further below.

First, the proposed definition would apply to airborne particles that contain collectively or individually, quartz, cristobalite, and/or tridymite, three polymorphs of respirable crystalline silica that may be encountered in mining and for which exposures are addressed in existing MSHA standards. Quartz is the most common polymorph and is present in varying amounts in almost every type of mineral, whereas naturally occurring cristobalite and tridymite are rare.

Second, airborne particles determined to be respirable are those particles capable of entering the gas-exchange region (alveolar region) of the lungs. MSHA's proposed definition would harmonize the Agency's existing practice with current aerosol science and be consistent with the nationally and internationally accepted ISO definition of "respirable particulate mass"

(i.e., the respirable mass fraction of total airborne particles that can be inhaled through the nose or mouth). ISO 7708:1995 defines conventions for the "inhalable," "thoracic," and "respirable" fractions of total airborne particles. The *inhalable* fraction represents the fraction of total airborne particles capable of being inhaled through the nose or mouth. The *thoracic* fraction is the portion of the inhalable particles that pass the larynx and into the airways (trachea) and the bronchial region of the lungs. The *respirable* fraction is the portion of inhalable particles that can enter the gas-exchange region (alveolar region) of the lungs. The ISO 7708:1995 definition of "respirable particulate mass" corresponds to particulate matter (respirable dust) that is inhaled and capable of entering the gas-exchange region (alveolar region) of the lungs. MSHA considers this definition to be biologically relevant because exposures to airborne contaminants that are respirable can lead to material impairment of health or functional capacity.[23]

Third, respirable particles are those particles which can be collected by a sampling device designed to meet the characteristics for respirable-particle-size-selective samplers that conform to the ISO 7708:1995 standard. While "respirable dust" generally refers to dust particles having an aerodynamic diameter of 10 micrometers (μm) or less, ISO 7708:1995 defines the term more precisely based on the respiratory system's efficiency at collecting different types and sizes of particles. Collection efficiency is represented by particle collection efficiency curves based on the aerodynamic diameter of particles.[24] The ISO 7708:1995 standard uses particle collection efficiency curves to approximate the fraction of respirable particles that can be deposited in the alveolar region of the human respiratory tract. A sampling device that conforms to the ISO

[23] The gas-exchange region of the human lung is the region where the exchange of carbon dioxide and oxygen occurs between the lung and blood and includes the alveoli and respiratory bronchioles.

[24] The ISO 7708:1995 standard defines aerodynamic diameter as the "diameter of a sphere of density 1 g/cm^3 with the same terminal velocity due to gravitational force in calm air as the particle, under the prevailing conditions of temperature, pressure, and relative humidity."

7708:1995 standard would ensure the collection of only respirable particles, including crystalline silica polymorphs.

MSHA believes that the proposed definition of respirable crystalline silica has two main advantages. First, because the ISO 7708:1995 definition of respirable particulate mass represents an international consensus, adoption of the ISO 7708:1995 criterion would allow harmonization with standards used by other occupational health and safety organizations in the U.S. and internationally, including ACGIH, OSHA (29 CFR 1910.1053 and 29 CFR 1926.1153), NIOSH (2003b, Manual of Analytical Methods), and the European Committee for Standardization (CEN) (ISO 7708:1995). Second, the proposed definition would eliminate inconsistencies in the existing standards for MNM and coal mines. Under the proposal, defining respirable crystalline silica to include quartz, cristobalite, and/or tridymite and establishing a PEL for exposure to respirable particles of any combination of these three polymorphs would provide consistency across the different mining sectors. Using samplers that conform to ISO 7708:1995 would allow for uniform collection for these three polymorphs. The proposed streamlined approach would facilitate compliance and provide consistency in the development of best practices and would allow mine operators and MSHA to better promote the health and safety of all miners.

"Specialist" would mean an American Board-Certified Specialist in Pulmonary Disease or an American Board-Certified Specialist in Occupational Medicine. The proposed definition is applicable to proposed § 60.15, which addresses medical surveillance for MNM miners. Under the proposed medical surveillance requirements, which will be discussed later, MNM mine operators would be required to provide miners with medical examinations performed by a specialist in pulmonary disease or occupational medicine or a PLHCP.

3. Section 60.10 – Permissible exposure limit (PEL).

This section establishes a single, uniform PEL of 50 $\mu g/m^3$ for respirable crystalline silica for all mines. Under this proposed provision, mine operators would be required to ensure that "no miner is exposed to an airborne concentration of respirable crystalline silica in excess of 50

μg/m^3 for a full-shift exposure, calculated as an 8-hour TWA." For coal mines, this proposal would establish a separate PEL for respirable crystalline silica. This proposed PEL would replace the Agency's existing exposure limits for respirable crystalline silica or respirable quartz in 30 CFR parts 56, 57, 70, 71, and 90.

The proposed PEL is consistent with NIOSH's recommended exposure limit for workers and with the PEL for respirable crystalline silica covering U.S. workplaces regulated by OSHA. NIOSH recommended in 1974 that occupational exposure to crystalline silica be controlled so that "no worker is exposed to a TWA of silica [respirable crystalline silica] greater than 50 μg/m^3 as determined by a full-shift sample for up to a 10-hour workday over a 40-hour workweek" (NIOSH 1974). In 2016, OSHA promulgated a rule establishing that for construction, general industry, and the maritime industry, workers' exposures to respirable crystalline silica must not exceed 50 μg/m^3, averaged over an 8-hour day (29 CFR 1910.1053(c); 29 CFR 1926.1153(d)(1)).[25] MSHA's 2014 rule on respirable coal mine dust established that the average concentration of respirable dust in the mine atmosphere during each shift to which each miner is exposed be at or below 1.5 mg/m^3, calculated as a TWA, and that coal miners' exposure to

[25] NIOSH conducted a literature review of studies containing environmental data on the harmful effects of exposure to respirable crystalline silica. Based on these studies, and especially fifty years' worth of studies on Vermont granite workers during which time dust controls improved, exposures fell, and silicosis diagnoses neared zero, NIOSH recommended an exposure limit of 50 μg/m^3 for all industries. OSHA's examination of health effects evidence and its risk assessment led to the conclusion that occupational exposure to respirable crystalline silica at the previous PELs, which were approximately equivalent to 100 μg/m^3 for general industry and 250 μg/m^3 for construction and maritime industries, resulted in a significant risk of material health impairment to exposed workers, and that compliance with the revised PEL would substantially reduce that risk. (81 FR at 16755). OSHA considered the level of risk remaining at the revised PEL to be significant but determined that a PEL of 50 μg/m^3 is appropriate because it is the lowest level feasible.

respirable crystalline silica be regulated through reductions in the overall respirable dust standard (30 CFR 70.100, 70.101, 71.100, 71.101, 90.100, and 90.101).[26]

As discussed in the Health Effects Summary of this preamble, occupational exposure to respirable crystalline silica is detrimental to an individual's health. Silicosis and other diseases caused by respirable crystalline silica exposure are irreversible, disabling, and potentially fatal. However, these diseases are exposure-dependent and are therefore preventable. The lower a miner's exposure to respirable crystalline silica, the less likely that miner is to suffer from adverse health effects.

As presented in the PRA, MSHA has preliminarily determined that: (1) under existing respirable crystalline silica or quartz standards, miners are exposed to respirable crystalline silica at concentrations that result in a risk of material impairment of health or functional capacity; and (2) that lowering the PEL to 50 $\mu g/m^3$ would substantially reduce this risk. According to the CDC, between 1999 and 2014, miners died from silicosis, COPD, lung cancer, and NMRD at substantially higher rates than did members of the general population; for silicosis, the proportionate mortality ratio for miners was 21 times as high.[27] Evidence in the standalone Health Effects document demonstrates that exposure to respirable crystalline silica at levels permitted under existing standards contributes to this excess mortality.

In the case of coal mines, the proposed rule would establish a separate PEL for respirable crystalline silica. Under the existing standard, miners' exposure to quartz is tied to exposure to respirable coal mine dust, making it more difficult to monitor coal miners' exposure to respirable

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[26] For Part 90 miners, MSHA lowered the exposure to respirable coal mine dust during a coal miner's shift to not exceed 0.5 mg/m^3.

[27] Data on occupational mortality by industry and occupation can be accessed by visiting the CDC website at https://www.cdc.gov/niosh/topics/noms/default.html. The NOMS database provides detailed mortality data for the 11-year period from 1999, 2003 to 2004, and 2007 to 2014. https://wwwn.cdc.gov/niosh-noms/industry2.aspx; accessed November 7, 2022.

crystalline silica. The proposed separate standard would be more transparent and make compliance easier to track, allowing more effective control of respirable crystalline silica.

The proposed PEL of 50 µg/m^3 applies to a miner's full-shift exposure, calculated as an 8-hour TWA. Under this proposal, a miner's work shift exposure would be calculated as follows:

$$\frac{\text{Total mass of respirable crystalline silica (µg) collected over a full shift}}{\text{Air flow rate (liters per minute) x 480 min x 0.001 m}^3\text{/L}}$$

Regardless of a miner's actual working hours (full shift), 480 minutes would be used in the denominator. This means that the respirable crystalline silica collected over an extended period (e.g., a 12-hour shift) would be calculated (or normalized) as if it were collected over 8 hours (480 minutes). For example, if a miner was sampled for 12 hours and 55 µg of respirable crystalline silica was collected on the sample, the miner's respirable crystalline silica 8-hour TWA exposure would be 67.4 µg/m^3, calculated as follows:

$$\frac{55\ (\mu g)}{1.7\ (\text{liters per minute}) \text{ x } 480 \text{ min x } 0.001\ \text{m}^3\text{/L}}$$

This proposed calculation method is the one that MSHA uses to calculate MNM miner exposures to respirable crystalline silica and other airborne contaminants; it differs from the existing method of calculating a coal miner's exposure to respirable coal mine dust. For coal miners, the existing calculation method uses the entire duration of a miner's work shift in both the denominator and numerator, resulting in the total mass of respirable coal mine dust collected over an entire work shift scaled by the sample's air volume over the same period.

MSHA's proposal to apply the existing method of calculating MNM miner exposure to all miners has two main advantages. First, the proposal would improve protection for coal miners who work longer shifts. The goal of the proposed respirable crystalline silica PEL is to prevent miners from suffering a body burden high enough to cause adverse health effects. If a miner works longer than 8 hours, the miner's body (lungs, in particular) may not have sufficient time to eliminate the respirable crystalline silica that enters the lungs or to reduce the body

burden.[28] Coal miners commonly work extended shifts, with many working 10-hour or longer shifts.[29] In such cases, a coal miner's recovery time would be reduced from 16 hours to 12 to 14 hours. To account for this increased risk, the proposed calculation (like the current MNM calculation method) normalizes to an 8-hour TWA. The concept of adjusting occupational exposure limits for "extended shifts" has been addressed by researchers (Brief and Scala, 1986; Elias, 2013).

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[28]The pulmonary uptake and clearance of respirable crystalline silica are dependent upon many factors, including a miner's breathing patterns, exposure duration, concentration (dose), particle size, and durability or bio-persistence of the particle. These factors will also affect the time to clear particles, even after exposure ceases. Of principal concern is the possibility that a continuous dust exposure over an extended period of time (or high dust level exposure during a short exposure period may excessively tax lung defense mechanisms (Industrial Minerals Association-North America and Mine Safety and Health Administration, 2008).

The ACGIH (2022), while not specifically addressing silica, has stated, "numerous mathematical models to adjust for unusual work schedules have been described. In terms of toxicologic principles, their general objective is to identify a dose that ensures that the daily peak body burden or weekly peak body burden does not exceed that which occurs during a normal 8-hours/day, 5-day/week shift." There are associated concerns with the body burden from an "unusual work schedule" such as a 10- or a 12- hour shift. As Elias (2013) stated, "if the length of the workday is increased, there is more time for the chemical to accumulate, and less time for it to be eliminated. It is assumed that the time away from work will be contamination free. The aim is to keep the chemical concentrations in the target organs from exceeding the levels determined by the TLVs® (8-hour day, 5-day week) regardless of the shift length. Ideally, the concentration of material remaining in the body should be zero at the start of the next day's work."

[29] Sampling hours of coal mine dust samples approximate the working hours of coal miners who were sampled. According to the coal mine dust samples for a 5-year period (August 2016 - July 2021), 90 percent of the samples by MSHA inspectors were from miners working 8 hours or longer and about 43 percent of the samples from miners working 10 hours or longer. The dust samples by coal mine operators show that over 98 percent of them were from miners working 8 hours or longer and over 26 percent from the miners working 10 hours or longer. The coal mine dust samples are available at Mine Data Retrieval System | Mine Safety and Health Administration (MSHA).

Second, applying the proposed calculation method for all miners would be more straightforward and easier to understand for mine operators, miners, and other stakeholders. The current calculation method for coal miners requires first determining the percentage of quartz in the sample of collected respirable dust, then dividing the result into the number 10 to calculate an exposure limit for respirable dust. The proposed calculation method requires only measuring the total mass of respirable crystalline silica collected and dividing it by the air volume over 480 minutes.

This proposal would establish a lower PEL and apply it to all miners using a consistent method for calculating exposures. These changes would improve the health and safety of miners while making compliance more straightforward and transparent. The 8-hour TWA is the "gold standard" for exposure assessments, except in scenarios involving chemical substances that are predominantly fast-acting (i.e., those evoking acute effects). NIOSH has also supported the use of the TWA and discussed this term since the publication of the NIOSH Pocket Guide to Chemical Hazards (First Edition, 1973) (the "White Book").

4. Section 60.11 – Methods of compliance.

This proposed section would require mine operators to install, use, and maintain feasible engineering and administrative controls to keep each miner's exposure to respirable crystalline silica at or below the proposed PEL. Mine operators would be required to use feasible engineering controls as the primary means of controlling respirable crystalline silica; administrative controls would be used, when necessary, as a supplementary control. However, under the proposal, rotation of miners – that is, assigning more than one miner to a high-exposure task or location, and rotating them to keep each miner's exposure below the PEL – would be prohibited. Under the proposal, respiratory protection equipment could be used in specific and limited situations, as discussed in § 60.14 – Respiratory Protection, but the use of respiratory protection equipment would not be acceptable as a method of compliance.

This proposed approach to controlling miners' exposures is consistent with MSHA's existing standards, NIOSH's recommendations, and generally accepted industrial hygiene principles. The proposal is consistent with MSHA's existing respirable dust standards, which require engineering controls as the primary means to protect miners. MSHA's experience and data show that engineering controls provide improved, more consistent, and more reliable protection for miners than administrative controls or respirators. In its recommendations, NIOSH also stressed the importance of using engineering controls to control miners' exposure to respirable crystalline silica. In 1995, NIOSH recommended that the dust standard state that "the mine operator shall use engineering controls and work practices [administrative controls] to keep worker exposures at or below the REL [recommended exposure limit]…" (NIOSH 1995a). In its public response to MSHA's 2019 Request for Information for Respirable Silica (Quartz) (84 FR 45452, Aug. 29, 2019), NIOSH also supported the use of engineering controls as the primary means of protecting miners from exposure to respirable crystalline silica, stating that "[r]espirators should only be used when engineering control systems are not feasible. Engineering control systems, such as adequate ventilation or scrubbing of contaminants, are the preferred control methods for reducing worker exposures."[30]

As discussed in the technological feasibility and preliminary regulatory impact analysis sections of the preamble, MSHA has preliminarily determined that engineering and administrative controls are technologically and economically feasible, and the use of these controls would be sufficient to achieve compliance with the proposed PEL. After reviewing the effectiveness of various exposure reduction controls which are currently available and have been successfully adopted in various combinations in mines, MSHA has concluded that all mine operators can ensure miners' exposures are below the proposed PEL through implementing some

[30] Comment from Paul Schulte, NIOSH (Oct. 23, 2019) to Docket No. MSHA 2016-0013.

combination of enhanced maintenance of existing engineering controls, new engineering controls, and improved administrative controls/work practices.

a. Engineering Controls

Proposed paragraph (a) would require mine operators to use feasible engineering controls as the primary means of controlling respirable crystalline silica; administrative controls would be used, when necessary, as a supplementary control.

This proposed paragraph would require engineering controls to be used as the primary means of controlling respirable crystalline silica. Engineering controls can include ventilation systems (i.e., main, auxiliary, local exhaust), dust suppression devices (i.e., wet dust suppression and airborne capture), and enclosed cabs or control booths with filtered breathing air, as well as changes in materials handling, equipment used in a process, ventilation, and dust capture mechanisms. Engineering controls generally suppress (e.g., using water sprays, wetting agents, foams, water infusion), dilute (e.g., ventilation), divert (e.g., water sprays, passive barriers, ventilation), or capture dust (e.g., dust collectors) to minimize the exposure of miners working in the surrounding areas. The use of automated ore-processing equipment and use of video cameras for remote scanning and monitoring can also help to reduce or eliminate miners' exposures to respirable crystalline silica.

Engineering controls are the most effective means of controlling the amount of dust to which miners are exposed. They have the advantage of addressing dust at its source, thus ensuring that all miners in an area are adequately protected from overexposure to respirable crystalline silica. Engineering controls provide more consistent and more reliable protection to miners than other interventions because the controls are not dependent on an individual's performance, supervision, or intervention to function as intended. In contrast to other controls and other interventions, engineering controls can also be continually evaluated and monitored relatively easily, allowing their effectiveness to be assessed regularly.

b. Administrative Controls

Under the proposed rule, mine operators would be permitted to supplement engineering controls with administrative controls as a means of controlling exposure to respirable crystalline silica. Administrative controls include practices that change the way tasks are performed to reduce a miner's exposure. These practices would include housekeeping procedures; proper work positions of miners; cleaning of spills; and measures to prevent or minimize contamination of clothing to help decrease miners' exposure to respirable crystalline silica.

Administrative controls require significant effort by mine operators to ensure that miners understand and follow the controls. If not properly implemented, understood, or followed, or if persons responsible for administrative controls do not properly supervise their implementation, they would not be effective in controlling miners' overexposure to respirable crystalline silica. Therefore, administrative controls would be permitted only as supplementary measures, with engineering controls required as the primary means of protection.

Proposed paragraph (b) would prohibit mine operators from using rotation of miners — that is, assigning more than one miner to a high-exposure task or location, and rotating them to keep each miner's exposure below the PEL—as an acceptable method of compliance. MSHA does not believe that rotation of miners is consistent with the Agency's regulatory framework or its mandate under the Mine Act. Based on MSHA's experience, rotation of miners may, if permitted, reduce the amount of time each miner is exposed to the hazard by rotating miners out of the task faster. However, it would increase the number of miners working in high-exposure tasks or areas and would lead to increased material impairment of health or functional capacity for the additional miners.

The concept of miner rotation, which may be an appropriate control to minimize musculoskeletal stress, is not acceptable for work involving carcinogens. Based on NIOSH's publication entitled "Current Intelligence Bulletin 68: NIOSH Chemical Carcinogen Policy," MSHA believes that the primary way to prevent occupational cancer is to reduce worker

exposure to chemical carcinogens as much as possible through elimination or substitution at the source and through engineering controls (NIOSH 2017b).

5. Section 60.12 – Exposure monitoring.

The proposed section addresses exposure monitoring, sampling method, and sample analysis methods. MSHA is proposing two types of exposure monitoring: quantitative, through sampling the air that miners breathe, and qualitative, through semi-annual evaluations of how changes in mining processes, production activities, and dust control systems affect exposures. For the quantitative monitoring, MSHA is proposing four types of sampling – baseline, periodic, corrective actions, and post-evaluation – together with methods for sampling and analyzing the samples.

The proposed exposure monitoring requirements, which include sampling miners' exposures, would facilitate operator compliance with the proposed PEL, harmonize MSHA's approach to monitoring and evaluating respirable crystalline silica exposures in both MNM and coal mines, and lead to better protection of miners' health. Monitoring miner exposures to airborne contaminants is an effective risk management tool. The sampling and evaluation requirements of proposed § 60.12 are designed to ensure maximum protection for miners and prevent them from suffering material impairment of health or functional capacity, while providing operators flexibility to tailor their sampling program to the miners' risk of exposure to respirable crystalline silica at their mines.

The first type of exposure monitoring under the proposed rule is quantitative sampling for miners' exposures to respirable crystalline silica. This sampling would help mine operators determine the extent and degree of exposures, identify sources of exposure and potential overexposure, maintain updated and accurate records of exposures, select the most appropriate control methods, and evaluate the effectiveness of those controls. The proposal would require operators to conduct sampling for a miner's regular full shift during typical mining activities. The second type of exposure monitoring under the proposed rule would be qualitative

evaluations, which would help operators identify changes in mining conditions and processes that affect the exposure risk to miners.

a. Section 60.12 (a) – Baseline sampling.

The first action mine operators would take to assess miners' exposures under the proposed rule would be to conduct baseline sampling. Baseline sampling would provide an initial measurement of respirable crystalline silica exposures that would be compared to the proposed action level and the proposed PEL to determine the effectiveness of existing controls and the need for additional controls.

Proposed paragraph (a)(1) would require mine operators to perform baseline sampling to assess the full-shift, 8-hour TWA exposure of respirable crystalline silica for each miner who is or may reasonably be expected to be exposed to respirable crystalline silica at any level. MSHA assumes that most mining occupations related to extraction and processing would meet the "reasonably be expected" threshold; however, MSHA recognizes that some miners may work in areas or perform tasks where exposures are not reasonably likely, and some miners may work in silica-free environments. Based on the Agency's experience, both MNM and coal mine operators generally know from their existing sampling data and MSHA's sampling data the occupations, work areas, and work activities where respirable crystalline silica exposures occur. The mine operator would be required to sample only those miners the operator knows or reasonably expects to be exposed to respirable crystalline silica.

The proposed provisions would require that, within the first 180 days after the effective date of the final rule, the mine operator perform the baseline sampling. During this 180-day period, mine operators would acquire necessary sampling devices or sampling services, sample occupations or areas of known or reasonably expected exposures, identify appropriate laboratories, and arrange for analysis of samples. Given that the mining industry has experience with sampling programs for other airborne contaminants, as well as respirable crystalline silica,

MSHA anticipates that the proposed 180 days would provide sufficient time for mine operators to comply with the proposed standard.

Under this proposed standard, mine operators would need to accurately characterize the exposure of each miner who is or may reasonably be expected to be exposed to respirable crystalline silica. As discussed later in detail, mine operators would be permitted to use representative sampling whenever sampling is required. In some cases, however, operators may have to sample all miners to obtain an accurate assessment of exposures.

This proposed requirement would ensure that mine operators have the quantitative information needed to evaluate miners' exposure risks, determine the adequacy of existing engineering and administrative controls, and make necessary changes to ensure miners are not overexposed. In addition, the results of the baseline sampling would determine further operator obligations for periodic sampling. A baseline sample result at or above the proposed action level but at or below the proposed PEL, would require operators to conduct periodic sampling under proposed § 60.12(b). However, if the baseline sample indicated that exposures were below the proposed action level and operators can confirm those results, mine operators would not be required to conduct periodic sampling. The results can be confirmed in three ways: (1) sample data, collected by the operator or the Secretary in the 12 months preceding the baseline sampling, that also shows exposures below the proposed action level; (2) objective data (as defined in the proposal) confirming that a miner's exposure to respirable crystalline silica would remain below the proposed action level; or (3) another sample taken within 3 months showing exposure below the proposed action level.

Proposed paragraph (a)(2) would allow mine operators to use objective data to confirm the baseline sample result. Under this proposal, objective data must demonstrate that respirable crystalline silica would not be released in airborne concentrations at or above the action level under any expected conditions. Objective data, as defined in proposed § 60.2, would include air monitoring data from industry-wide surveys that demonstrate miners' exposure to respirable

crystalline silica associated with a particular product or material or a specific process, task, or activity. Objective data must reflect mining conditions that closely resemble the processes, material, control methods, work practices, and environmental conditions in the mine operator's current operations. The mine operator would have the burden of showing that the objective data characterizes miner exposures to respirable crystalline silica with sufficient accuracy.

Also, proposed paragraph (a)(2) would permit mine operators to use sampling conducted by the Secretary or mine operator within the preceding 12 months of baseline sampling to confirm miner exposures below the proposed action level. The proposed rule would require mine operator sampling that was conducted in accordance with sampling requirements in paragraph (f) and analyzed according to paragraph (g) of this section. Under proposed paragraph (a)(2), any subsequent sampling conducted by the operator or by the Secretary, collected within 3 months of the baseline sample, could also be used to confirm a baseline sample result.

MSHA believes that before sampling is discontinued for miners previously determined to be exposed at or above the proposed action level, it is necessary to confirm any sample result that indicates miner exposures are below the proposed action level. When such a result is confirmed by a second measurement, an operator could reasonably expect exposures to remain below the action level if mining conditions and practices do not change. However, as discussed later, under proposed paragraph (d), if there is any change in conditions or practices that could be reasonably expected to result in exposures at or above the action level, sampling to assess these exposures would be required.

b. Section 60.12 (b) – Periodic sampling.

Periodic sampling under the proposed rule would provide mine operators and miners with regular information about miners' exposures. Changes in exposure levels can be caused by changes in the mine environment, inadequate engineering controls, or other changes in mining processes or procedures. Periodic sampling would inform mine operators about increases in exposures in a timely manner so they can prevent potential overexposures. In addition, periodic

sampling alerts operators and miners of the continued need to protect against the hazards associated with exposure to respirable crystalline silica. If a mine operator installs new engineering controls and/or starts new administrative control practices, periodic sampling would show whether those controls are working properly to achieve the anticipated health results and would document their effectiveness.

Proposed § 60.12(b) would require periodic sampling of miners' exposures to respirable crystalline silica whenever the most recent sampling indicates that exposures are at or above the proposed action level but at or below the proposed PEL. Whether a mine operator would have to conduct periodic sampling under the proposal would depend on the results of the most recent sample, which could include a baseline sample, a corrective actions sample, or a post-evaluation sample, as well as samples taken by MSHA during its inspections. If operators are required to conduct periodic sampling, and periodic sampling results indicate that miner exposures are below the action level, a mine operator would be permitted to discontinue periodic sampling for those miners whose exposures are represented by these samples. If the most recent sample shows exposures at or above the action level but at or below the proposed PEL, periodic sampling every 3 months would continue until two consecutive sample analyses showed miners' exposures below the action level. MSHA believes that two consecutive sample analyses showing exposures below the action level would indicate a low probability that prevailing mining conditions would result in overexposures.

MSHA believes that the proposed frequency for periodic sampling – repeating the sampling within 3 months – is practical for mine operators and protective of the health and safety of miners. MSHA has preliminarily concluded that the health risks caused by respirable crystalline silica overexposure warrant more regular sampling when exposure levels approach the proposed PEL, because this periodic sampling would provide a higher level of confidence that miners would not be overexposed. Due to the unique conditions of mining environments, where conditions change quickly and exposures to respirable crystalline silica can vary

frequently, MSHA is proposing a three-month periodic sampling schedule (NIOSH, 2014e). This three-month schedule would provide a meaningful degree of confidence that mine operators would recognize quickly when exposures are increasing and approaching the proposed PEL and would respond by implementing additional controls to prevent overexposure. Periodic sampling data would also provide information that operators could use to select, implement, and maintain controls. MSHA has structured the proposal to balance the costs of periodic sampling requirements, including when sampling can be stopped, and the benefits of additional health protection for miners. Taking these factors into consideration, MSHA has preliminarily determined that the proposed frequency of periodic sampling is both economically and technologically feasible for mine operators. (See Section VIII. Technological Feasibility and Section IX. Summary of Preliminary Regulatory Impact Analysis.)

As with the baseline sampling in proposed paragraph (a), in meeting the requirements of this paragraph, mine operators would be allowed to sample a representative fraction of at least two miners. The exposure result would be attributed to the remaining miners represented by this sample, as discussed in more detail below. When miners are not performing the same job under the same working conditions, a representative sample would not accurately characterize actual exposures, and individual samples would be necessary.

c. Section 60.12 (c) – Corrective actions sampling.

Under the proposed rule, MSHA would require mine operators to take corrective actions when any sampling shows exposures above the proposed PEL. After such corrective actions, proposed § 60.12(c) would require mine operators to conduct corrective actions sampling to determine whether the control measures taken under proposed § 60.13 have reduced miner exposures to respirable crystalline silica to at or below the proposed PEL. If not, the mine operator would be required to take additional or new corrective actions until subsequent corrective actions sampling indicates miner exposures are at or below the proposed PEL.

Once corrective actions sampling indicates that miner exposures have been lowered to levels at or below the proposed PEL, one of two scenarios could occur. First, if corrective actions sampling taken under proposed § 60.12(c) indicate that miner exposures are at or below the proposed PEL, but at or above the proposed action level, the mine operator would be required to conduct periodic sampling as described in proposed § 60.12(b). The periodic sampling requirements would require mine operators to continue to conduct sampling every three months until two consecutive sampling results indicate miners' exposures are below the action level. Second, if corrective actions sampling taken under proposed § 60.12(c) indicate that miner exposures are below the proposed action level, the mine operator would be required to conduct a subsequent sample within 3 months as described in proposed § 60.12(b); if those results show miners' exposures are below the action level, the mine operator could discontinue periodic sampling.

Sampling after corrective actions would provide operators with specific information regarding the effectiveness of the corrective actions for the mine environment and provide additional data for use in making decisions about updating or improving controls. It would also provide mine operators with an updated profile of miners' exposures against which future samples could be compared.

d. Section 60.12 (d) and (e) – Semi-annual evaluation and post-evaluation sampling.

Historically, MSHA has recognized the importance of qualitatively evaluating changes in mining conditions and processes and assessing the effect of those changes on exposure risk. Operators have general experience with these types of evaluations. The proposed rule would require mine operators to qualitatively evaluate any changes in production, processes, engineering controls, personnel, administrative controls, or other factors including geological characteristics that might result in new or increased respirable crystalline silica exposures, beginning 18 months after the effective date and every 6 months thereafter. Such evaluations could identify changes in miners' exposures to respirable crystalline silica.

The proposed semi-annual evaluation, and post-evaluation sampling, as appropriate, would help confirm that the results of baseline and periodic sampling continue to accurately represent current exposure conditions. These proposed semi-annual evaluation and sampling requirements would also enable mine operators to take appropriate actions to protect exposed miners, such as implementing new or additional engineering controls, and would provide information to miners and their representatives, as necessary. An evaluation could identify a change in operation processes or control measures that might lead to increased exposures to respirable crystalline silica which need to be corrected. Under proposed paragraph (d)(1), the mine operator would be required to make a record of the evaluation, including the date of the evaluation. Under proposed paragraph (d)(2), the mine operator would be required to post the record on the mine bulletin board, and, if applicable, make the evaluation available electronically, for the next 31 days.

Once the evaluation is complete, a mine operator would be required to conduct post-evaluation sampling under proposed § 60.12(e) when the results of the evaluation show that miners may be exposed at or above the action level. Post-evaluation sampling would provide operators with information on whether existing controls are effective, whether additional control measures are needed, and whether respiratory protection is appropriate. When post-evaluation samples indicate that miner exposures are at or above the proposed action level, the mine operator would be required to conduct periodic sampling as described in proposed paragraph (b). Post-evaluation sampling, however, would not be required if the mine operator determines that mining conditions would not reasonably be expected to result in exposures at or above the action level.

e. Section 60.12 (f) – Sampling requirements.

Knowledge of typical respirable dust exposure levels is critical to protect the health of miners. The proposed rule includes certain sampling requirements that would ensure mine operators' respirable crystalline silica monitoring is representative of miners' actual exposures.

(1) Typical Mining Activities and Sampling Device Placement

Proposed paragraph (f)(1) would require mine operators to collect a respirable dust sample for the duration of a miner's regular full shift and during typical mining activities. Many potential sources of respirable crystalline silica are present only when the mine is operating under typical conditions. If a sample is not taken during typical mining activities, the actual risk to the miner may not be known. This proposed requirement would ensure that respirable crystalline silica exposure data accurately reflect actual levels of respirable crystalline silica exposure at miners' normal or regular workplaces throughout their typical workday, even if there are fluctuations in airborne contaminant concentrations during a work shift. As discussed in other sections of this preamble, the sample results from the full shift would be calculated as an 8-hour TWA concentration for comparison with the proposed action level and PEL and for compliance determinations.

This proposed provision is consistent with existing standards and with generally accepted industrial hygiene principles, which recommend taking into consideration the entire duration of time a miner is exposed to an airborne contaminant, even if it exceeds 8 hours. Based on Agency data and experience, MSHA anticipates that operators would not have major challenges in meeting these sampling requirements.

This proposal would continue existing procedures for sampling device placement during sampling. Under proposed § 60.12(f)(2)(i), for MNM miners the regular full-shift, 8-hour TWA exposure would be based on personal breathing-zone air samples. A breathing zone sample is an individual sample that characterizes a miner's exposure to respirable crystalline silica during an entire work shift. More specifically, the sampler remains with the miner for the entire shift, regardless of the task or occupation performed.

For coal miners, under proposed § 60.12(f)(2)(ii), the regular full-shift, 8-hour TWA exposure would be based on an occupational environmental sample collected in compliance with existing standards found in §§ 70.201(c), 71.201(b), and 90.201(b). Under the existing

standards, the sampling device would be worn or carried "portal-to-portal," meaning from the time the miner enters the mine until the miner exits the mine. The sampling device would remain with the miner during the entire shift. For shifts that exceed 12 hours, the operator would be required to switch the sampling pump prior to the 13th-hour of operation. However, except in the case of Part 90 miners, if a miner who is being sampled changes positions or duties, the sampling device would remain with the position or duty chosen for sampling (rather than the miner). For Part 90 miners, the sampling device would be operated portal-to-portal and would remain operational with the miner throughout the Part 90 miner's entire shift, which would include the time spent performing normal work duties and the time spent traveling to and from the assigned work location.

(2) Representative Sampling

Under the proposed rule, mine operators must accurately characterize miners' exposure to respirable crystalline silica. In some cases, this would require sampling all exposed miners. In other cases, as proposed in paragraph (f)(3), sampling a "representative" fraction of miners would be sufficient. Where several miners perform the same tasks on the same shift and in the same work area, the mine operator could sample a representative fraction of miners. Under this proposed rule, a representative fraction of miners would consist of two or more miners performing the same tasks on the same shift and in the same work area and who are expected to have the highest exposures of all the miners in an area. For example, sampling a representative fraction may involve monitoring the exposure of those miners who are closest to the dust source. The sampling results for these miners would then be attributed to the remaining miners in the group. When miners are not performing the same job under the same working conditions, a representative sample would not be sufficient to characterize actual exposures, and therefore individual samples would be necessary.

MSHA has determined that requiring operators to sample at least two miners as representative, where they perform the same tasks on the same shift and in the same work area as

the remaining miners, would be sufficient to ensure that exposures are accurately characterized and health protections are provided. This representative sampling provision of the proposal is similar to the approach that OSHA uses for both general industry (29 CFR 1910.1053(d)(3)) and construction (29 CFR 1926.1153(d)(2)) under the scheduled sampling options.

(3) Sampling Devices

Respirable dust sampling assesses the ambient air quality in mines and evaluates miners' exposure to airborne contaminants. Respirable dust comprises particles small enough that, when inhaled, can reach the gas exchange region of the lung. Measurement of respirable dust exposure is based on the collection efficiency of the human respiratory system and the separation of airborne particles by size to assess their respirable fraction. Proposed paragraph (f)(4) would require mine operators to use sampling devices designed to meet the characteristics for respirable-particle-size-selective samplers that conform to the ISO 7708:1995, *"Air Quality – Particle Size Fraction Definitions for Health-Related Sampling,"* Edition 1, 1995-04 to determine compliance with the proposed respirable crystalline silica action level and PEL. MSHA proposes to incorporate by reference ISO 7708:1995, which is the international consensus standard that defines sampling conventions for particle size fractions used in assessing possible health effects of airborne particles in the workplace and ambient environment. Mine operators could use any type of sampling device they wish for respirable crystalline silica sampling, as long as it is designed to meet the characteristics for respirable-particle-size-selective samplers that conform to the ISO 7708:1995 standard and, where appropriate, meets MSHA permissibility requirements.[31]

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[31] MSHA's permissibility requirements are specified in 30 CFR parts 18 and 74. Part 18, Electric Motor-Driven Mine Equipment and Accessories, specifies the procedures and requirements for obtaining MSHA approval, certification, extension, or acceptance of electrical equipment intended for use in gassy mines. Part 74, Coal Mine Dust Sampling Devices, specifies the requirements for evaluation and testing for permissibility of coal mine dust sampling devices.

Sampling devices, such as cyclones[32] and elutriators,[33] can separate the respirable fraction of airborne dust from the non-respirable fraction in a manner that simulates the size-selective characteristics of the human respiratory tract and that meets the ISO standard. These devices enable collection of dust samples that contain only particles small enough to penetrate deep into the lungs. Size-selective cyclone sampling devices are typically used in the U.S. mining industry. These samplers generally consist of a pump, a cyclone, and a membrane filter. The cyclone uses a rapid vortical flow of air inside a cylindrical or conical chamber to separate airborne particles according to their aerodynamic diameter (i.e., particle size). As air enters the cyclone, the larger particles are centrifugally separated and fall into a grit pot, while smaller particles pass into a sampling cassette where they are captured by a filter membrane that is later analyzed in a laboratory to determine the mass of the respirable dust collected. The pump creates and regulates the flow rate of incoming air. As the flow rate of air increases, a greater percentage of larger and higher-mass particles are removed from the airstream, and smaller particles are collected with greater efficiency. Adjustment of the flow rate changes the particle collection characteristics of the sampler and allows calibration to a specified respirable particle size sampling definition, such as the ISO criterion.

MSHA and many mine operators use cyclone samplers. A cyclone sampler calibrated to operate at the manufacturer's specified air flow rate that conforms to the ISO standard can be

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[32] A cyclone is a centrifugal device used for extracting particulates from carrier gases (e.g., air). It consists of a conically shaped vessel. The particulate-containing gas is drawn tangentially into the base of the cone, takes a helical route toward the apex, where the gas turns sharply back along the axis, and is withdrawn axially through the base. The device is a classifier in which only dust with terminal velocity less than a given value can pass through the formed vortex and out with the gas. The particle cut-off diameter is calculable for given conditions.

[33] An elutriator is a device that separates particles based on their size, shape, and density, using a stream of gas or liquid flowing in a direction usually opposite to the direction of sedimentation. The smaller or lighter particles rise to the top (overflow) because their terminal sedimentation velocities are lower than the velocity of the rising fluid.

used to collect respirable crystalline silica samples under this proposed rule. MSHA reviewed OSHA's feasibility analysis for its 2016 silica final rule and agrees with OSHA that there are commercially available cyclone samplers that conform to the ISO standard and allow for the accurate and precise measurement of respirable crystalline silica at concentrations below both the proposed action level and PEL (OSHA 2016a) Such cyclone samplers include the Dorr-Oliver 10-mm nylon cyclone used by MSHA and many mine operators, as well as the Higgins-Dewell, GK2.69, SIMPEDS, and SKC aluminum cyclone. Each of these cyclones has different operating specifications, including flow rates, and performance criteria, but all are compliant with the ISO criteria for respirable dust with an acceptable level of measurement bias. MSHA's preliminary determination is that cyclone samplers, when used at the appropriate flow rates, can collect a sufficient mass of respirable crystalline silica to quantify atmospheric concentrations lower than the proposed action level and would meet MSHA's crystalline silica sample analysis specifications for samples collected at MNM and coal mines.

MNM mine operators who currently use a Dorr-Oliver 10 mm nylon cyclone could continue to use these samplers at a flow rate of 1.7 L/min, which conforms to the ISO standard, to comply with the proposed requirements. For coal mine operators, the gravimetric samplers previously used to sample RCMD (i.e., coal mine dust personal sampling units (CMDPSUs)) were operated at a 2.0 L/min flow rate. Those CMDPSUs could be adjusted to operate at a flow rate of 1.7 L/min to conform to the ISO standard.

NIOSH's rapid field-based quartz monitoring (RQM) approach is an emerging technology. It provides a field-based method for providing respirable crystalline silica exposure measurements at the end of a miner's shift. With such an end-of-shift analysis, mine operators can identify overexposures and mitigate hazards more quickly. NIOSH Information Circular 9533, "Direct-on-filter Analysis for Respirable Crystalline Silica Using a Portable FTIR Instrument" provides detailed guidance on how to implement a field-based end-of-shift

respirable crystalline silica monitoring program.[34] The current RQM monitor, however, was designed as an engineering tool; it is not currently designed as a compliance tool with tamper-proof components and is susceptible to interferences which can affect its accuracy. This means that the integrity of the sample cannot be guaranteed, and therefore the monitor cannot be used as a compliance tool. MSHA continues to support NIOSH efforts to develop the RQM monitor for use in mines.

f. Section 60.12 (g) – Methods of sample analysis.

Proposed paragraph (g) specifies the methods to be used for analysis of respirable crystalline silica samples, including details regarding the specific analytical methods to be used and the qualifications of the laboratories where the samples are analyzed. Proposed paragraph (g)(1) would require mine operators to use laboratories that are accredited to the International Organization for Standardization (ISO) or International Electrotechnical Commission (IEC) (ISO/IEC) 17025, "*General requirements for the competence of testing and calibration laboratories*" with respect to respirable crystalline silica analyses, where the accreditation has been issued by a body that is compliant with ISO/IEC 17011 "*Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies.*" Accredited

[34] National Institute for Occupational Safety and Health (NIOSH). Direct-on-filter analysis for respirable crystalline silica using a portable FTIR instrument. By Chubb LG, Cauda EG. Pittsburgh PA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2022–108, IC 9533. https://doi.org/10.26616/NIOSHPUB2022108. The document is intended for industrial hygienists and other health and safety mining professionals who are familiar with respirable crystalline silica exposure assessment techniques, but who are not necessarily trained in analytical techniques. It gives general instructions for setting up the field-based monitoring equipment and software. It also provides case studies and examples of different types of samplers that can be used for respirable crystalline silica monitoring. Guidance on the use, storage, and maintenance of portable IR instruments is also provided in the document.

laboratories are held to internationally recognized laboratory standards and must participate in quarterly proficiency testing for all analyses within the scope of the accreditation.

The ISO/IEC 17025 standard is a consensus standard developed by the International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) and approved by ASTM International (formerly the American Society for Testing and Materials). This standard establishes criteria by which laboratories can demonstrate proficiency in conducting laboratory analysis through the implementation of quality control measures. To demonstrate competence, laboratories must implement a quality control program that evaluates analytical uncertainty and provides estimates of sampling and analytical error when reporting samples. The ISO/IEC 17011 standard establishes criteria for organizations that accredit laboratories under the ISO/IEC 17025 standard. For example, the American Industrial Hygiene Association (AIHA) accredits laboratories for proficiency in the analysis of respirable crystalline silica using criteria based on the ISO 17025 and other criteria appropriate for the scope of the accreditation.

Many MNM mine operators currently use third-party laboratories to perform respirable crystalline silica sample analyses, and under the proposed standard, MSHA anticipates that they would continue to use third-party laboratories.

For most coal mine operators, using a third-party accredited laboratory to analyze respirable crystalline silica samples would be a new requirement because respirable coal mine dust samples are currently analyzed only by MSHA. Under the proposed standard, all mine operators would have to use third-party laboratories accredited to ISO/IEC 17025 to have respirable dust samples analyzed for respirable crystalline silica. By requiring all mines to use third-party laboratories, proposed paragraph (g)(1) would ensure that sample analysis requirements and MSHA enforcement efforts are consistent across all mines.

Proposed paragraph (g)(2) would require mine operators to ensure that laboratories evaluate all samples using analytical methods for respirable crystalline silica that are specified by

MSHA, NIOSH, or OSHA. These are validated methods currently being cited by third party accredited labs for measuring respirable crystalline silica in mine dust matrices. MSHA and NIOSH have specific FTIR methods for analyzing quartz in coal mine dust. The NIOSH 7603 method is based on the MSHA P-7 method which was collaboratively tested and specifically addresses the interference from kaolinite clay. All three methods, MSHA P-2, NIOSH 7500, and OSHA ID-142 for analyzing respirable crystalline silica using X-ray diffraction (XRD) have similar procedures for measuring respirable crystalline silica and are capable of distinguishing between the three silica polymorphs. Additional steps such as acid treatment can be taken to remove respirable crystalline silica interferences from other minerals that can be found in mine dust sample matrices. Consistent with MSHA's current practices for the analysis of respirable crystalline silica samples, analytical techniques used for samples from MNM mines and coal mines would generally be different due to potential sources of interference and cost considerations. Under the proposed rule, as discussed below, MSHA expects that samples collected in MNM mines would continue to be analyzed by X-ray diffraction (XRD) and samples collected for coal mines would continue to be analyzed by Fourier transform infrared spectroscopy (FTIR).

Coal mine samples are currently analyzed using the FTIR method because it is cheaper, faster, and better suited for the coal mining sector, where samples contain little or no minerals that could interfere or confound respirable crystalline silica analysis results. Current FTIR methods, however, cannot quantify quartz if either of the other two forms of crystalline silica (cristobalite and tridymite) are present in the sample. Unlike coal dust samples, MNM samples may have a variety of minerals present, which could cause interference with respirable crystalline silica measurements if FTIR were used. Thus, MNM samples are currently analyzed by XRD because the XRD method can distinguish and isolate respirable crystalline silica for measurement, thereby avoiding interference or confounding of respirable crystalline silica analysis results. The XRD method could be used for both MNM and coal samples but using the

XRD method is more time consuming and more costly, with no additional benefit for coal mine sample analysis. For this reason, MSHA does not expect the use of XRD on samples from coal mines.

For MNM samples, the methods used for respirable crystalline silica sample analysis using XRD include MSHA P–2, NIOSH 7500, and OSHA ID–142. For coal samples, the methods used for respirable crystalline silica sample analysis using FTIR include MSHA P–7, NIOSH 7602, and NIOSH 7603. (OSHA does not currently have an established FTIR method for analysis of respirable crystalline silica.)

g. Section 60.12 (h) – Sampling records.

Proposed paragraph (h) would establish requirements for sampling records, including what mine operators would be required to do after receiving the analytical reports from laboratories. For each sample taken, this proposed paragraph would require mine operators to create a record that includes the sample date, the sampled occupations, and the reported concentrations of both respirable dust and respirable crystalline silica. After making such a record, the mine operator would be required to post the record, together with the laboratory report, on the mine bulletin board and, if applicable, make the record and the laboratory report available electronically, for the next 31 days upon receipt.

When electronic means are available, mine operators would be required to use those electronics means such as electronic bulletin boards or newsletters, in addition to physically posting the sampling record and laboratory report on the mine bulletin board. MSHA believes that most mines have the ability to display this information electronically. For any mines where electronic means are not available, mine operators would only be required to physically post the sampling record and laboratory report on the mine bulletin board. Also, as required in proposed § 60.16(b), the sampling records created under this section may be requested at any time by, and must promptly be made available to, miners, authorized representatives of miners, or an authorized representative of the Secretary.

MSHA believes that the posted information including sampling results and methodology and other relevant information would inform miners of the sampled exposures and would encourage them to have heightened awareness of potential health hazards that could impact not only them but other miners. It would also provide them with knowledge to take proactive actions to protect themselves and fellow miners through better and safer work practices and more active participation in health and safety programs. This is consistent with the Mine Act which states that mine operators, with the assistance of miners, have the responsibility to prevent the existence of unsafe and unhealthful conditions and practices in mines. 30 U.S.C. § 801(e). Making miners aware that respirable crystalline silica exposures below the PEL may still pose a health risk could encourage them to take steps to manage their health risks.

6. Section 60.13 – Corrective actions.

This proposed section includes several actions a mine operator would be required to take to protect miners' health and safety when any sampling result indicates that a miner's exposure to respirable crystalline silica exceeds the proposed PEL. Proposed paragraph (a)(1) would require the mine operator to make NIOSH-approved respirators available to affected miners before the start of the next work shift. Proposed paragraph (a)(2) would require mine operators to ensure that affected miners wear respirators for the full shift or during the period of overexposure to protect miners until miner exposures are at or below the PEL.

Proposed paragraph (a)(3) would require operators to take immediate corrective actions to lower the concentration of respirable crystalline silica to levels at or below the PEL. Some examples of corrective actions include increasing air ventilation and/or water flow rates, adding more water sprays, and improving maintenance of the existing engineering controls.

Once corrective actions have been taken, proposed paragraph (a)(4)(i) would require the operator to conduct sampling in accordance with § 60.12(c) to determine if the corrective actions have been successful in lowering exposures to at or below the PEL. If sampling indicates that the corrective actions did not reduce miner exposures to at or below the PEL, proposed

paragraph (a)(4)(ii) would require the operator to implement additional or new corrective actions until sampling indicates miner exposures are at or below the PEL.

Proposed § 60.13(b) would require the mine operator to make a record of corrective actions required under proposed paragraph (a) of this section and the dates of those actions. These records would help the operator and MSHA identify whether existing controls are effective, or whether maintenance or additional control measures are needed.

7. Section 60.14 – Respiratory protection.

This proposed provision addresses the use of respiratory protection equipment. As noted earlier, the use of respiratory protection equipment, including powered air-purifying respirators (PAPRs), would not be permitted as a control to achieve compliance with the proposed PEL because engineering controls are more effective than respirators in protecting miners. However, temporary non-routine use of respirators would be allowed under limited circumstances.

Proposed paragraph (a) would require the mine operator to provide respirators to miners as a temporary measure in accordance with proposed paragraph (c) of this section, when miners are working in concentrations of respirable crystalline silica above the PEL under specific, limited circumstances. Proposed paragraph (a)(1) would require the temporary use of respirators when miners' exposures exceed the proposed PEL during the development and implementation of engineering controls.

Proposed paragraph (a)(2) would require the use of respirators for temporary, nonroutine work to prevent miners' exposures at levels above the proposed PEL. Examples include when a miner is mixing cement to build a stopping to separate a main intake from return airways or is engaged in an unplanned entry into an atmosphere with excessive respirable crystalline silica concentrations to perform a repair or investigation that must occur before feasible engineering or administrative controls can be implemented.

The proposal is consistent with NIOSH's recommendation in the 1995 Criteria Document (NIOSH 1995a) and is similar to the existing standards for MNM and coal mines. NIOSH

(1995a) recommended the use of respirators as an interim measure when engineering controls and work practices are not effective in maintaining worker exposures for respirable crystalline silica at or below the proposed PEL.

MSHA's existing MNM standards in parts 56 and 57 permit mine operators to allow miners to work for reasonable periods of time protected by appropriate respiratory protection in locations where concentrations of contaminants (including respirable crystalline silica) exceed permissible levels and where feasible engineering control measures have not been developed or where necessary by the nature of the work involved (e.g., occasional entry into hazardous atmospheres to perform maintenance or investigation). MSHA's existing standards for respirable coal mine dust require the mine operator to make respiratory protection equipment available while the operator evaluates and implements engineering control measures when a valid sample meets or exceeds the applicable standard during operator exposure monitoring. (30 CFR 70.208(e)(1); 30 CFR 71.206(h)(1); 30 CFR 72.700-72.701; 30 CFR 90.207(c)(1)).

Proposed paragraph (b) addresses situations where miners are not able to wear a respirator while working. Proposed paragraph (b) would require the mine operator, upon written notification by a PLHCP, to transfer an affected miner who is unable to wear a respirator to work in another area of the same mine, or to another occupation at the same mine, where respiratory protection is not required.

The operator must ensure that the occupation and the area of the mine to which the miner is temporarily transferred do not expose the miner to respirable crystalline silica above the proposed PEL. Proposed paragraph (b)(1) would require the mine operator to continue to compensate the affected miner at no less than the regular rate of pay in the occupation held by that miner immediately prior to the transfer. Under proposed paragraph (b)(2), the miner may be transferred back to the initial work area or occupation when the temporary, non-routine use of respirators is no longer required.

MSHA believes that this proposed provision is consistent with the mandate in the Mine Act to provide the maximum health protection for miners. Also, any effect on miners by this provision should be temporary since the concentration of respirable crystalline silica to which the miner would be exposed must be controlled through feasible engineering and administrative controls on a long-term basis.

Proposed paragraph (c) includes the respiratory protection requirements that an operator must address when providing respirators to miners. Proposed paragraph (c)(1), like the existing standards in parts 56, 57, and 72, would require mine operators to provide respiratory protection equipment approved by NIOSH under 42 CFR part 84. Whenever respirators are used by miners, proposed paragraph (c)(1) would require the mine operator to provide miners with NIOSH-approved atmosphere-supplying respirators or air-purifying respirators. Atmosphere-supplying respirators provide clean breathing air from a separate source (e.g., a self-contained air tank), whereas air-purifying respirators use filters, cartridges, or canisters to remove contaminants from the air.

In mines, commonly used types of air-purifying respirators include elastomeric respirators, filtering facepiece respirators (FFRs), and PAPRs. Elastomeric respirators, such as half-facepiece or full-facepiece tight-fitting respirators, are made of synthetic or natural rubber material and can be cleaned, disinfected, stored, and repeatedly re-used. FFRs (i.e., dust masks), designed to cover areas of the wearer's face from the bridge of the nose to the chin, are disposable respirators composed of a weave of electrostatically charged synthetic filter fibers and an elastic head strap. PAPRs utilize a blower to move ambient air through an air-purifying filter that removes particulates and delivers clean air to the wearer. When air-purifying respirators (elastomeric respirators, FFRs, and PAPRs) are used, under proposed paragraph (c)(1), the mine operator would be required to select only high-efficiency NIOSH-certified particulate protection (i.e., 100 series or HE filters) for respirable crystalline silica protection. A 100 series and high efficiency filter means that the filter must demonstrate a minimum efficiency level of 99.97

percent (i.e., the filter is at least 99.97 percent efficient in removing particles of 0.3 μm aerodynamic mass median diameter).

Under proposed paragraphs (c)(1)(i) through (c)(1)(ii), air-purifying respirators would be required to be equipped with one of the following three particulate protection types: (1) particulate protection defined as a 100 series under 42 CFR part 84; or (2) particulate protection defined as High Efficiency "HE" under 42 CFR part 84. MSHA believes that air-purifying respirators with the highest efficiency NIOSH classifications for particulate protection are most suitable in protecting miners from occupational exposure to a carcinogen such as respirable crystalline silica.

Proposed paragraph (c)(2) would require mine operators to follow the provisions, as applicable, of ASTM F3387-19, "*Standard Practice for Respiratory Protection*," when respiratory protection equipment is needed. Under the proposal, MSHA would require that the respiratory program would be in writing and would include the following minimally acceptable program elements: program administration; standard operating procedures; medical evaluations; respirator selection; training; fit testing; and maintenance, inspection, and storage. Beyond the minimally acceptable program elements, mine operators would be allowed to comply with the provisions of the 2019 ASTM standard that they deem applicable. The need for temporary non-routine use of respirators may vary, given the variability of mining processes, activities, and commodities that are mined. MSHA believes that flexibility afforded to mine operators under this paragraph may lead mine operators to focus more appropriately on those provisions that are relevant to their mine-specific situations, allowing them to comply more efficiently and effectively.

ASTM F3387-19 is a voluntary consensus standard published by ASTM International and was approved in 2019. MSHA proposes to incorporate by reference this consensus standard for two reasons.

First, adopting this voluntary consensus standard is consistent with OMB Circular A-119, which encourages Federal agencies to "minimize reliance on government-unique standards where an existing standard would meet the Federal government's objective." ASTM F3387-19 comprehensively addresses all aspects of establishing, implementing, and evaluating respiratory protection programs, and describes respiratory protection program elements which include: program administration; standard operating procedures; medical evaluation; respirator selection; training; fit testing; and respirator maintenance, inspection, and storage.

Second, ASTM F3387-19 reflects current respirator technology and an up-to-date understanding of effective respiratory protection. For example, ASTM F3387-19 provides detailed information on respirator selection that are based on NIOSH's long-standing experience of testing and approving respirators for occupational use and OSHA's research and rulemaking on respiratory protection.

More detailed discussion on ASTM F3387-19 is provided later in *C. Updating MSHA Respiratory Protection Standards: Proposed Incorporation of ASTM F3387-19 by Reference*.

8. Section 60.15 – Medical surveillance for metal and nonmetal miners.

This proposed provision would require MNM mine operators to provide mandatory medical examinations to miners who begin in the mining industry after the effective date of the rule and offer voluntary periodic examinations to all other miners. These medical examinations would be provided by a PLHCP or specialist. The proposed requirements in this section are consistent with the Mine Act's mandate to provide maximum health protection for miners and provide MNM miners with information needed for early detection of respirable crystalline silica-related disease, resulting in prevention of disabling disease.

The proposed requirements for MNM mine operators are also generally consistent with existing medical surveillance requirements for coal mine operators under 30 CFR 72.100 although the requirements differ in some respects. For example, the proposed provision specifies that medical examinations must be provided by a PLHCP or specialist, while the existing

medical surveillance requirements for coal miners in § 72.100 coordinate with the surveillance system managed by NIOSH's Coal Workers' Health Surveillance Program (CWHSP) which works with coal mine operators under NIOSH regulations to provide medical surveillance. Proposed paragraph 60.15(a) would require that each MNM mine operator make medical examinations available to each MNM miner, at no cost to the miner, regardless of whether miners are reasonably expected to be exposed to any level of respirable crystalline silica. This proposed requirement is consistent with section 101(a)(7) of the Mine Act.

Proposed paragraph 60.15(a) would also require medical examinations to be performed by a PLHCP or specialist. A PLHCP is an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows that individual to independently provide or be delegated the responsibility to provide some or all of the required health services (i.e., chest X-rays, spirometry, symptom assessment, and occupational history). A specialist, as defined in proposed § 60.2, refers to an American Board-certified specialist in pulmonary disease or occupational medicine. The Agency believes it is appropriate to allow not only a physician, but also any State-licensed health care professional, to perform the required medical examinations. This would provide operators with the flexibility needed to use professionals with necessary medical skills and minimize cost and compliance burdens.

Proposed paragraph (a)(1) requires periodic examinations to be offered to all MNM miners at the frequencies specified in this section. Proposed paragraph (a)(2) specifies the types of medical examinations and is consistent with the existing requirements for coal mine operators under existing § 72.100.

Proposed paragraphs (a)(2)(i) and (ii) would require MNM operators to provide each miner with a medical examination that includes a review of the miner's medical and work history and a physical examination. The medical and work history would cover a miner's present and past work exposures, illnesses, and any symptoms indicating respirable crystalline silica-related diseases and compromised lung function. The medical and work history should focus not only

on any history of tuberculosis, smoking, or exposure to respirable crystalline silica, but also on any diagnoses and symptoms of respiratory system dysfunction, including shortness of breath, coughing, or wheezing. The physical examination under (a)(2)(ii) would be focused on the respiratory tract. For the reasons stated above, these proposed requirements differ from the existing requirements for coal miners. The existing medical surveillance requirements for coal miners in 42 CFR 37 specify standardized data collection elements for occupational histories and respiratory symptom assessment while proposed paragraphs (a)(2)(i) and (ii) specify a respiratory-focused history and physical examination by a clinician.

Under proposed paragraph (a)(2)(iii), MSHA would require all medical examinations to include a chest X-ray. The required chest X-ray is a posterior/anterior view no less than 14 x 17 inches and no more than 16 x 17 inches at full inspiration, recorded on either film or digital radiography systems. The chest X-ray must be classified by a NIOSH-certified B Reader, in accordance with the Guidelines for the Use of the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses. The ILO recently made additional standard digital radiographic images available and has published guidelines on the classification of digital radiographic images (ILO 2022). This is a standard practice in pneumoconiosis surveillance programs and can potentially detect other respirable crystalline silica-related conditions, including lung cancer (Industrial Minerals Association-North America and Mine Safety and Health Administration, 2008). The test would provide data that can be used to assess for progression of silicosis and for other respirable crystalline silica-related conditions in MNM miners.

MSHA preliminarily concludes that the number of B readers in the U.S. is adequate to classify chest X-rays conducted as part of the respirable crystalline silica rule (OSHA 2016a, 81 FR 16286, 16821). As discussed in OSHA's 2016 final silica rule, the number of B Readers is driven by supply and demand created by a free market, and many physicians choose to become B readers based on demands for such services (OSHA 2016a, 81 FR 16286, 16822). NIOSH is

also able to train enough B readers to handle any potential increase in demand, providing several pathways for physicians to become B readers, such as free self-study materials by mail or download and free B reader examinations (OSHA 2016a, 81 FR 16286, 16822). In addition, courses and examinations for certification are periodically offered for a fee through the American College of Radiology (OSHA 2016a, 81 FR 16286, 16822). Even if B readers are scarce in certain geographical locations, digital X-rays can be easily transmitted electronically to B readers located anywhere in the U.S. (OSHA 2016a, 81 FR 16286, 16822).

Under proposed paragraph (a)(2)(iv), MSHA would require that pulmonary function testing (including spirometry) be part of every medical examination. The pulmonary function test must be administered by a spirometry technician with a current certificate from a NIOSH-approved Spirometry Training Sponsorship. The purpose of spirometry is to measure baseline lung function followed by periodic tests to detect early impairment patterns, such as obstruction of air flow and restriction caused by underlying respiratory disease. This measurement can provide critical information for the primary, secondary, and tertiary prevention of workplace-related lung diseases, including respirable crystalline silica-related diseases. The use of spirometry is consistent with recommendations of the Dust Advisory Committee (U.S. DOL, 1996) and the NIOSH Criteria Document (1974). Indeed, NIOSH (2014a) notes that properly conducted spirometry should be part of a comprehensive workplace respiratory health program. Spirometry and chest X-rays are complementary examinations for detecting adverse health effects from respirable crystalline silica exposures.

In order to maintain a certificate from a NIOSH-approved course, technicians must complete an initial training and then refresher training every five years (OSHA 2016a, 81 FR 16286, 16825). As discussed in OSHA's 2016 silica final rule, course sponsors are located throughout the U.S. and some sponsors will travel to a requested site to teach a course (OSHA 2016a, 81 FR 16286, 16825). One NIOSH-approved sponsor offers instructor-led live virtual initial training. Several live virtual and web-based refresher training options are also available.

Because the required training is not too frequent and course sponsors appear to be widely available throughout the U.S., MSHA preliminarily concludes that the requirement that technicians maintain a certificate from a NIOSH-approved course will not impose substantial burdens on providers of spirometry testing.

MSHA believes that the proposed medical examinations consisting of a medical and work history, a physical examination, a chest X-ray, and a spirometry test would help medical professionals identify early symptoms of respirable crystalline silica-related diseases, assist MNM miners in protecting their health, and lower the risk that MNM miners become materially impaired due to occupational exposure to respirable crystalline silica.

Under proposed paragraph (b), MSHA would require MNM mine operators to provide every miner employed at MNM mines with the opportunity to have periodic medical examinations. Miner participation would be voluntary, as in the case of the examination requirement for coal miners in 30 CFR 72.100(b). Starting on the proposed effective date, mine operators must provide the opportunity for an examination to MNM miners no later than 5 years after the date of their last medical surveillance examination, and in addition, during a 6-month period that begins no less than 3.5 years and not more than 4.5 years from the end of the last 6-month period for medical examinations. Periodic examinations would allow for comparisons with a miner's prior examination results, help detect respirable crystalline silica-related disease including silicosis, and address further progression of existing respiratory disease. If a miner has a positive chest X-ray (ILO category of 1/0+), it is important to intervene as promptly as possible for maximum health protection. In addition, an interval of 5 years or less between each miner's periodic examinations can ensure detection of declines in a miner's lung function due to potential occupational exposure. MSHA believes that the proposed schedule, which is consistent with the periodic examination for coal miners required under § 72.100(b), would provide MNM mine operators with flexibility in offering examinations to miners.

Proposed paragraph (c) would require MNM mine operators to provide a mandatory initial medical examination for each MNM miner who is new to the mining industry. Consequently, if a miner had previous mining experience (such as working in a coal mine) and subsequently came to work in an MNM mine, MSHA would not require that the MNM mine operator provide the miner with an initial examination after the miner begins employment. Mandatory initial examinations would be conducted when miners are first hired in the mining industry and would provide an individual baseline of each miner's health status. This initial examination would assist in the early detection of respirable crystalline silica-related illnesses and conditions that may make the miner more susceptible to the toxic effects of respirable crystalline silica. The individual baseline would also be valuable in assessing any future health changes in each miner. Overall, the initial examination results would enable miners to respond appropriately to information about their health status.

Proposed paragraph (c)(1) would require that the mandatory initial medical examination occur no later than 30 days after a miner new to the industry begins employment. Proposed paragraphs (c)(2) and (3) would require MNM mine operators to provide mandatory follow-up examinations to new miners who were eligible for an initial mandatory medical examination under proposed paragraph (c). MSHA believes follow-up examinations are important for assessments of any changes in a new miner's health status and for future diagnoses.

Under proposed paragraph (c)(2), MSHA would require that the mine operator provide a mandatory follow-up examination to the miner no later than 3 years after the miner's initial medical examination. Under proposed paragraph (c)(3), if a miner's 3-year follow-up examination shows evidence of a respirable crystalline silica-related disease or decreased lung function, the operator would be required to provide the miner with another mandatory follow-up examination with a specialist, as defined in proposed § 60.2, within 2 years. This proposed requirement is intended to ensure that any miner whose follow-up medical examination shows evidence of silicosis or evidence of decreased lung function, as determined by the PLHCP or

specialist, is seen by a professional with expertise in respiratory disease. This would ensure that miners would benefit from not only expert medical judgment but also counseling regarding work practices and personal habits that could affect the miners' health. For the reasons stated above, this proposed requirement differs from the existing requirements for coal miners, which provides for follow up surveillance testing but does not include interaction with a PLHCP or specialist.

Proposed paragraph (d) would require that the results of any medical examination performed under this section be kept confidential and provided only to the miner. The miner is also entitled to request that the medical examination results be provided to the miner's designated physician. Based on MSHA's experience with coal miners' medical surveillance, the Agency believes that confidentiality regarding medical conditions is essential and that it encourages miners to take advantage of the opportunity to detect early adverse health effects due to respirable crystalline silica. *See* 79 FR 24813, at 24928, May 1, 2014.

Under proposed paragraph (e), MNM mine operators would be required to obtain a written medical opinion from a PLHCP or specialist within 30 days of the medical examination that includes only the date of a miner's medical examination, a statement that the examination has met the requirements of this section, and any recommended limitations on the miner's use of respirators. This would allow the mine operator to verify the examination has occurred and would provide the mine operator with information on miners' ability to use respirators. Proposed paragraph (f) would require the mine operator to maintain a record of the written medical opinions obtained from the PLHCP or specialist under proposed paragraph (e).

9. Section 60.16 – Recordkeeping requirements.

Section 60.16 lists all the proposed recordkeeping requirements under this proposed part. To ensure that mine operators track actual or potential exposures, risks, and controls and keep miners, miners' representatives, and other stakeholders informed about them, the proposed part 60 establishes five recordkeeping requirements. Discussion of these requirements follow and are summarized in table 1 to paragraph (a) in § 60.16 of the rule text.

First, this section would require that, once mine operators complete the sampling or semi-annual evaluations required under proposed § 60.12, the operators retain the associated exposure monitoring records for at least 2 years. Examples of exposure monitoring records include the date of sampling or evaluation, names and occupations of miners who were sampled, description of sampling or evaluation method, and laboratory reports of sampling analysis. The 2-year period would give mine operators sufficient exposure monitoring data to evaluate the effectiveness of their engineering and administrative controls over different mining and weather conditions.

Second, mine operators would also be required to retain records of corrective actions made under proposed § 60.13(b) for at least 2 years from the date when each corrective action was taken. This proposed requirement is similar to the recordkeeping requirements related to other corrective-action requirements under parts 56 and 57 (for MNM mines) and parts 70, 71, and 90 (for coal mines).

Third, this proposed section would require mine operators to maintain any written determination records that they receive from a PLHCP or specialist. When a PLHCP or specialist certifies in writing that a miner cannot wear a respirator, including a PAPR, that miner must be temporarily transferred to a different work area or task where respiratory protection is not required (or needed). In such cases, mine operators would be required to retain the written determinations by a PLHCP or specialist for the duration of the miner's employment plus 6 months.

Fourth, under this section, MNM mine operators would be required to maintain written medical opinion records that they obtain from a PLHCP or specialist who conducts medical examinations of their miners under proposed § 60.15. This proposed recordkeeping requirement would apply only to MNM mine operators. Under proposed § 60.15, after the examination has taken place, the MNM mine operator would receive from the PLHCP or specialist a written medical opinion that contains the date of the medical examination, a statement that the

examination has met the requirements under this proposed rule, and any recommended limitations on the miner's use of respirators. Upon receipt, the mine operator would retain the medical opinion for the duration of the miner's employment plus 6 months.

Proposed paragraph (b) would ensure that all the listed records would be made available promptly upon request to miners, authorized representatives of miner(s), and authorized representatives of the Secretary of Labor.

10. Section 60.17 – Severability.

The severability clause under proposed § 60.17 serves two purposes. First, it expresses MSHA's intent that if any section or provision of the *Lowering Miners' Exposure to Respirable Crystalline Silica and Improving Respiratory Protection* rule—including its conforming amendments in sections of 30 CFR parts 56, 57, 70, 71, 72, 75, and 90 that address respirable crystalline silica or respiratory protection—is held invalid or unenforceable or is stayed or enjoined by any court of competent jurisdiction, the remaining sections or provisions should remain effective and operative. Second, the severability clause expresses MSHA's judgment, based on its technical and scientific expertise, that each individual section and provision of the rule can remain effective and operative if some sections or provisions are invalidated, stayed, or enjoined. Accordingly, MSHA's inclusion of this severability clause addresses the twin concerns of Federal courts when determining the propriety of severability: identifying agency intent and clarifying that any severance will not undercut the structure or function of the rule more broadly. *Am. Fuel & Petrochem. Mfrrs.* v. *Env't Prot. Agency*, 3 F.4th 373, 384 (D.C. Cir. 2021) ("Severability 'depends on the issuing agency's intent,' and severance 'is improper if there is substantial doubt that the agency would have adopted the severed portion on its own'") (quoting *North Carolina* v. *FERC*, 730 F.2d 790, 796 (D.C. Cir. 1984) and *New Jersey* v. *Env't Prot. Agency*, 517 F.3d 574, 584 (D.C. Cir. 2008)).

Under the principle of severability, a reviewing court will generally presume that an offending provision of a regulation is severable from the remainder of the regulation, so long as

that outcome appears consistent with the issuing agency's intent, and the remainder of the regulation can function independently without the offending provision. See *K Mart Corp.* v. *Cartier, Inc.,* 486 U.S. 281, 294 (1988) (invalidating and severing subsection of a regulation where it would not impair the function of the statute as a whole and there was no indication the regulation would not have been passed but for inclusion of the invalidated subsection). Consequently, in the event that a court of competent jurisdiction stays, enjoins, or invalidates any provision, section, or application of this rule, the remainder of the rule should be allowed to take effect.

B. Conforming Amendments

The proposed rule would require conforming amendments in 30 CFR parts 56, 57, 70, 71, 72, 75, and 90 based on the proposed new part 60.

1. Part 56 – Safety and Health Standards – Surface Metal and Nonmetal Mines.

a. Section 56.5001 – Exposure limits for airborne contaminants.

For respirable crystalline silica, proposed part 60 would establish exposure limits and other related requirements for all mines. Existing paragraph (a) of § 56.5001 governs exposure limits for airborne contaminants, except asbestos, for surface MNM mines. MSHA is proposing to amend paragraph (a) of § 56.5001 to add respirable crystalline silica as an exception. The amended paragraph (a) of § 56.5001 would govern exposure limits for airborne contaminants other than respirable crystalline silica and asbestos for surface MNM mines.

2. Part 57 – Safety and Health Standards – Underground Metal and Nonmetal Mines.

a. Section 57.5001 – Exposure limits for airborne contaminants.

Existing paragraph (a) of § 57.5001 governs exposure limits for airborne contaminants, except asbestos, for underground MNM mines. Similar to the proposed changes discussed above for § 56.5001, MSHA is proposing to amend paragraph (a) of § 57.5001 to add respirable crystalline silica as an exception. The amended paragraph (a) of § 57.5001 would govern

exposure limits for airborne contaminants other than respirable crystalline silica and asbestos for underground MNM mines.

3. Part 70 – Mandatory Health Standards – Underground Coal Mines.

a. Section 70.2 – Definitions.

MSHA proposes to remove the *Quartz* definition in § 70.2. With the adoption of an independent respirable crystalline silica standard in proposed part 60, the Agency is proposing to remove RCMD when quartz is present in § 70.101 and the term quartz would no longer appear in part 70.

b. Section 70.101 – Respirable dust standard when quartz is present.

MSHA is proposing to remove the entire section and reserve the section number. The RCMD when quartz is present in § 70.101 would no longer be needed because MSHA is proposing an independent respirable crystalline silica standard in proposed part 60.

MSHA's proposed independent standard for respirable crystalline silica would result in miners' exposure to respirable crystalline silica no longer being controlled indirectly by reducing respirable dust. NIOSH, the Secretary of Labor's Advisory Committee on the Elimination of Pneumoconiosis Among Coal Mine Workers (Dust Advisory Committee), and the Department of Labor's Inspector General[35] have each recommended the adoption of an independent standard for respirable quartz exposure in coal mines. NIOSH evaluated the effectiveness of the existing standard and found the approach of controlling miners' exposures to respirable crystalline silica

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[35] Office of Inspector General Audit 05-21-001-06-001, MSHA Needs to Improve Efforts to Protect Coal Miners from Respirable Crystalline Silica (Nov. 12, 2020). The Inspector General recommended that MSHA:

1. Adopt a lower legal exposure limit for silica in coal mines based on recent scientific evidence.

2. Establish a separate standard for silica that allows MSHA to issue a citation and monetary penalty when violations of its silica exposure limit occur.

3. Enhance its sampling program to increase the frequency of inspector samples where needed (e.g., by implementing a risk-based approach).

indirectly through the control of respirable dust did not protect miners from excessive exposure to respirable quartz in all cases (Joy GJ 2012). The study concluded that a separate respirable quartz standard, as described by the 1995 NIOSH Criteria Document, could reduce miners' risk of overexposures to respirable quartz and, by extension, their risk of developing silicosis. The adoption of a separate standard would hold operators accountable, at risk of a citation and monetary penalty, when overexposures of the respirable crystalline silica PEL occur and enhance its sampling program to increase the frequency of operator sampling.

c. Section 70.205 – Approved sampling devices; operation; air flowrate.

MSHA is proposing to amend paragraph (c) of § 70.205 to remove the reference to the reduced RCMD standard. References to the RCMD exposure limit specified in § 70.100 would replace references to the applicable standard. The rest of the section would remain unchanged.

d. Section 70.206 – Bimonthly sampling; mechanized mining units.

MSHA is proposing to amend subpart C, Sampling Procedures, by removing § 70.206 and reserving the section number. Section 70.206 included requirements for bimonthly sampling of mechanized mining units which were in effect until January 31, 2016, and are no longer needed.

e. Section 70.207 – Bimonthly sampling; designated areas.

MSHA is proposing to amend subpart C, Sampling Procedures, by removing § 70.207 and reserving the section number. Section 70.207 included requirements for bimonthly sampling of designated areas that were in effect until January 31, 2016, and are no longer needed.

f. Section 70.208 – Quarterly sampling; mechanized mining units.

MSHA is proposing to amend § 70.208 to remove references to a reduced RCMD standard. Paragraph (c) in § 70.208 would be removed and the paragraph designation reserved. References to the respirable dust standard specified in § 70.100 would replace references to the applicable standard throughout the section.

A new table 1 to § 70.208 would be added. The table contains the Excessive Concentration Values (ECV) for the section based on a single sample, 3 samples, or the average of 5 or 15 full-shift coal mine dust personal sampler unit (CMDPSU) or continuous personal dust monitor (CPDM) concentration measurements. This table contains the remaining ECV after the removal of the reduced standard in § 70.101. It was generated from data contained in existing Tables 70-1 and 70-2 to subpart C of part 70. Conforming changes are made to paragraphs (e) and (f)(1) and (2) to update the name of the table to table 1 to § 70.208.

g. Section 70.209 – Quarterly sampling; designated areas.

Similar to the proposed changes discussed above for § 70.208, MSHA is proposing to amend § 70.209 to remove references to a reduced RCMD standard. Paragraph (b) in § 70.209 would be removed and the paragraph designation reserved. References to the RCMD exposure limit specified in § 70.100 would replace references to the applicable standard.

A new table 1 to § 70.209 would be added. The table contains the ECVs for the section based on a single sample, 2 or more samples, or the average of 5 or 15 full-shift CMDPSU/CPDM concentration measurements. This table contains the remaining ECV after the removal of the reduced RCMD standard in § 70.101. It was generated from data contained in existing Tables 70-1 and 70-2 to subpart C of part 70. Conforming changes are made to paragraphs (c) and (d)(1) and (2) to update the name of the table to table 1 to § 70.209.

h. Subpart C – Table 70-1 and Table 70-2.

MSHA is proposing to amend subpart C, Sampling Procedures, by removing Table 70-1 *Excessive Concentration Values (ECV) Based on Single, Full-Shift CMDPSU/CPDM Concentration Measurements* and Table 70-2 *Excessive Concentration Values (ECV) Based on the Average of 5 or 15 Full-Shift CMDPSU/CPDM Concentration Measurements* because § 70.101 would be removed. These tables would be replaced with new tables added to §§ 70.208 and 70.209.

4. Part 71 – Mandatory Health Standards - Surface Coal Mines and Surface Work Areas of Underground Coal Mines.

a. Section 71.2 – Definitions.

As discussed in the analysis of conforming amendments for § 70.2, MSHA also proposes to remove the *Quartz* definition in § 71.2 because the Agency is proposing to remove the respirable dust standard when quartz is present in § 71.101. The term quartz would no longer appear in part 71.

b. Section 71.101 – Respirable dust standard when quartz is present.

MSHA is proposing to remove the entire section of § 71.101 and reserve the section number. Similar to the proposed conforming amendments for § 70.101, the respirable coal mine dust standard when quartz is present in § 71.101 would no longer be needed because MSHA is proposing an independent respirable crystalline silica standard in part 60.

MSHA's proposal to adopt an independent standard for respirable crystalline silica would replace the existing method of indirectly controlling miners' exposure to silica by reducing respirable coal dust. As stated previously, NIOSH evaluated the effectiveness of the existing standard and found the existing approach of controlling miners' exposures to respirable crystalline silica indirectly through the control of respirable dust did not protect miners from excessive exposure to respirable crystalline silica in all cases. The study concluded that a separate respirable crystalline silica standard, as described by the 1995 NIOSH Criteria Document, could reduce miners' risk of overexposures to respirable crystalline silica and, by extension, their risk of developing silicosis. The adoption of a separate standard would allow MSHA to issue a citation and monetary penalty when overexposures of the respirable crystalline silica PEL occur and enhance its sampling program to increase the frequency of inspector sampling.

c. Section 71.205 – Approved sampling devices; operation; air flowrate.

MSHA is proposing to amend paragraph (c) of § 71.205 to remove the reference to the reduced RCMD standard. References to the respirable dust standard specified in § 71.100 would replace the reference to the applicable standard. The rest of the section would remain unchanged.

d. Section 71.206 – Quarterly sampling; designated work positions.

Similar to the analysis of conforming amendments for §§ 70.208 and 70.209, MSHA is proposing to amend § 71.206 to remove references to the reduced RCMD standard. Paragraph (b) in § 71.206 would be removed and the paragraph designation reserved. Other conforming changes for § 71.206 would remove references to the applicable standard and replace them, where needed, with references to the respirable dust standard specified in § 71.100 throughout the section.

MSHA is also proposing to amend paragraph (l) by removing Table 71-1 *Excessive Concentration Values (ECV) Based on Single, Full-Shift CMDPSU/CPDM Concentration Measurements* and Table 71-2 *Excessive Concentration Values (ECV) Based on the Average of 5 Full-Shift CMDPSU/CPDM Concentration Measurements* since reference to a reduced RCMD standard in § 71.101 would be removed. They would be replaced with a new table added to § 71.206.

Existing paragraph (m) would be modified by removing the language, "in effect at the time the sample is taken, or a concentration of respirable dust exceeding 50 percent of the standard established in accordance with § 71.101," because the reduced standard in § 71.101 would be removed, as discussed above, which removes the reference to the reduced standard and replaces it with a reference to the respirable dust standard specified in § 71.100.

A new table 1 to § 71.206 would be added. This table contains the ECV for the section based on a single sample, two or more samples, or the average of five full-shift CMDPSU/CPDM concentration measurements. This table contains the remaining ECV after the removal of the reduced standard in § 71.101. It was generated from data contained in existing

Tables 71-1 and 71-2 to subpart C of part 71. Conforming changes are made to paragraphs (h) and (i)(1) and (2) to update the name of the table to table 1 to § 71.206.

e. Section 71.300 – Respirable dust control plan; filing requirements.

MSHA is proposing to amend § 71.300 to remove references to the reduced RCMD standard. The respirable dust standard specified in § 71.100 would replace references to the applicable standard. The rest of the section would remain unchanged.

f. Section 71.301 – Respirable dust control plan; approval by District Manager and posting.

MSHA is proposing to amend § 71.301 to remove references to the reduced RCMD standard. The respirable dust standard specified in § 71.100 would replace references to the applicable standard. The rest of the section would remain unchanged.

5. Part 72 – Health Standards for Coal Mines.

a. Section 72.800 – Single, full-shift measurement of respirable coal mine dust.

MSHA is proposing to amend § 72.800 in subpart E, Miscellaneous, and remove references to the reduced RCMD standard. The proposed section would also replace references to Tables 70-1, 71-1, and 90-1 with references to tables in §§ 70.208, 70.209, 71.206, and 90.207.

6. Part 75 – Mandatory Safety Standards – Underground Coal Mines.

a. Section 75.350(b)(3)(i) and (ii) – Belt air course ventilation.

MSHA is proposing to update § 75.350 by revising paragraph (b)(3)(i) and removing paragraphs (b)(3)(i)(A) and (B) and (b)(3)(ii).

Paragraph (b)(3)(i)(A) would be removed because its provision has not been in effect since August 1, 2016. Paragraph (b)(3)(i)(B) would be removed because the proposed revised language in paragraph (b)(3)(i) would be simplified by stating that "[t]he average concentration of respirable dust in the belt air course, when used as a section intake air course, shall be maintained at or below 0.5 mg/m^3." This would ensure that miners would be protected from coal dust overexposures, including respirable crystalline silica overexposures, by maintaining the

RCMD PEL in the belt air course at 50 $\mu g/m^3$. Therefore, paragraph (b)(3)(i)(B) which sets the PEL for belt course air at 0.5 mg/m^3 would be redundant.

Existing paragraph (b)(3)(ii) would be removed since it refers to a reduced RCMD standard under § 70.101 that would also be removed. Existing paragraph (b)(3)(iii) would be redesignated to (b)(3)(ii).

7. Part 90 – Mandatory Health Standards – Coal Miners Who Have Evidence of the Development of Pneumoconiosis.

a. Section 90.2 – Definitions.

Similar to the proposed changes for §§ 70.2 and 71.2, MSHA proposes to remove the *Quartz* definition in § 90.2 because the Agency proposes to remove the respirable dust standard when quartz is present in § 90.101. The term quartz would no longer appear in part 90.

In addition, MSHA is revising the definition of *Part 90 miner* to remove references to the reduced RCMD standard. The respirable dust standard specified in § 90.100 would replace the reference to the applicable standard. The definition of Part 90 miner would also be updated to define Part 90 miners as miners who have exercised the option to work in an area of a mine where the average concentration of respirable dust in the mine atmosphere during each shift to which that miner is exposed is continuously maintained at or below the respirable dust standard specified in § 90.100.

b. Section 90.3 – Part 90 option; notice of eligibility; exercise of option.

MSHA is proposing to revise paragraph (a) in § 90.3 to require that miners diagnosed with pneumoconiosis must be afforded the option to work in an area of a mine where the average concentration of respirable dust is continuously maintained below the respirable dust standard specified in § 90.100 rather than at or below the applicable standard. The rest of the section would remain unchanged.

c. Section 90.101 – Respirable dust standard when quartz is present.

MSHA is proposing to remove the entire section and reserve the section number. The respirable coal mine dust standard when quartz is present in § 90.101 would no longer be needed because MSHA is proposing an independent respirable crystalline silica standard in proposed part 60.

MSHA's proposal to adopt an independent standard for respirable crystalline silica would replace the existing method of indirectly controlling miners' exposure to respirable crystalline silica by reducing respirable coal dust. As stated previously, NIOSH evaluated the effectiveness of the existing standard and found the existing approach of controlling miners' exposures to respirable crystalline silica indirectly through the control of respirable dust did not protect miners from excessive exposure to respirable quartz in all cases. The study concluded that a separate respirable quartz standard, as described by the 1995 NIOSH Criteria Document, could reduce miners' risk of overexposures to respirable quartz and, by extension, their risk of developing silicosis.

d. Section 90.102 – Transfer; notice.

MSHA is proposing to amend § 90.102 to remove references to the reduced RCMD standard. The respirable dust standard specified in § 90.100 would replace references to the applicable standard. The rest of the section would remain unchanged.

e. Section 90.104 – Waiver of rights; re-exercise of option.

MSHA is proposing to amend § 90.104 to remove references to the reduced RCMD standard. The respirable dust standard specified in § 90.100 would replace references to the applicable standard. The rest of the section would remain unchanged.

f. Section 90.205 – Approved sampling devices; operation; air flowrate.

MSHA is proposing to amend § 90.205 to remove the reference to the reduced RCMD standard. The respirable dust standard specified in § 90.100 would replace the reference to the applicable standard. The rest of the section would remain unchanged.

g. Section 90.206 – Exercise of option or transfer sampling.

MSHA is proposing to amend § 90.206 to remove references to the reduced RCMD standard. The respirable dust standard specified in § 90.100 would replace references to the applicable standard. The rest of the section would remain unchanged.

h. Section 90.207 – Quarterly sampling.

Similar to the analysis of conforming amendments for §§ 70.208, 70.209, and 71.206, MSHA is proposing to amend § 90.207 to remove references to the reduced RCMD standard. Paragraph (b) in § 90.207 would be removed and the paragraph designation reserved. The respirable dust standard specified in § 90.100 would replace references to the applicable standard. The rest of the section would remain unchanged.

MSHA is proposing to amend paragraph (g) by removing the Table 90-1 *Excessive Concentration Values (ECV) Based on Single, Full-Shift CMDPSU/CPDM Concentration Measurements* and Table 90-2 *Excessive Concentration Values (ECV) Based on the Average of 5 Full-Shift CMDPSU/CPDM Concentration Measurements* because § 90.101 would be removed.

A new table 1 to § 90.207 would be added to replace the tables removed in paragraph (g). The table contains the ECV for the section based on a single sample, two or more samples, or the average of 5 full-shift CMDPSU/CPDM concentration measurements. This table contains the remaining ECV after the removal of the reduced standard in § 90.101. It was generated from data contained in existing Tables 90-1 and 90-2 to subpart C of part 90. Conforming changes are made to paragraphs (c) and (d)(1) and (2) to update the name of the table to table 1 to § 90.207.

i. Section 90.300 – Respirable dust control plan; filing requirements.

MSHA is proposing to amend § 90.300 to remove references to the reduced RCMD standard. The respirable dust standard specified in § 90.100 would replace references to the applicable standard. The rest of the section would remain unchanged.

j. Section 90.301 – Respirable dust control plan; approval by district manager; copy to Part 90 miner.

MSHA is proposing to amend § 90.301 to remove references to the reduced RCMD standard. The respirable dust standard specified in § 90.100 would replace references to the applicable standard. The rest of the section would remain unchanged.

C. Updating MSHA Respiratory Protection Standards: Proposed Incorporation of ASTM F3387-19 by Reference

MSHA is proposing to update the Agency's existing respiratory protection standard to help safeguard the life and health of all miners exposed to respirable airborne hazards at MNM and coal mines. The proposed rule would incorporate by reference ASTM F3387-19, *"Standard Practice for Respiratory Protection"* (ASTM F3387-19), as applicable, in existing §§ 56.5005, 57.5005, and 72.710, as well as in proposed § 60.14(c)(2). The ASTM F3387-19 standard includes provisions for selection, fitting, use, and care of respirators used to remove airborne contaminants from the air using filters, cartridges, or canisters, as well as respirators that protect in oxygen-deficient or immediately dangerous to life or health (IDLH) atmospheres. ASTM F3387-19 is based on the most recent consensus standards recognized by experts in government and professional associations on the selection, use, and maintenance for respiratory equipment. The ASTM Standard would replace American National Standards Institute's ANSI Z88.2-1969, "*Practices for Respiratory Protection*" (ANSI Z88.2-1969), which is incorporated in the existing standards.

Incorporating this voluntary consensus standard complies with the Federal mandate—as set forth in the National Technology Transfer and Advancement Act of 1995 and OMB Circular A119—that agencies use voluntary consensus standards in their regulatory activities unless doing so would be legally impermissible or impractical. This standard proposed for incorporation would also improve clarity because it is a consensus standard developed by stakeholders.

Under existing standards, whenever respiratory protective equipment is used, mine operators are required to have a respiratory protection program that is consistent with the

provisions of ANSI Z88.2-1969. At the time of its publication, ANSI Z88.2-1969 reflected a consensus of accepted practices for respiratory protection.

Respirator technology and knowledge on respiratory protection have since advanced and as a result, changes in respiratory protection standards have occurred. For example, in 2006, OSHA revised its respiratory protection standard to add definitions and requirements for Assigned Protection Factors (APF) and Maximum Use Concentrations (MUCs) (71 FR 50121, 50122, Aug. 24, 2006). In addition to this rulemaking, OSHA updated Appendix A to § 1910.134: Fit Testing Procedures (69 FR 46986, 46993, Aug. 4, 2004).

After withdrawing the 1992 version of Z-88.2 in 2002, ANSI published the American National Standard, ANSI/AIHA Z88.10-2010, "*Respirator Fit Testing Methods,"* approved in 2010. These rules and standards addressed the topics of APFs and fit testing. APFs provide employers with critical information to use when selecting respirators for employees exposed to atmospheric contaminants found in industry. Finally, in 2015, ANSI published ANSI/ASSE Z88.2-2015, "*Practices for Respiratory Protection,*" which referenced OSHA regulations. These updates included requirements for classification of considerations for selection and use of respirators, establishment of cartridge/canister change schedules, use of fit factor value for respirator fit testing, calculation of effective protection factors, and compliance with compressed air dew requirements, compressed breathing air equipment, and systems and designation of positive pressure respirators. In July 2017, ANSI/ASSE transferred the responsibilities for developing respiratory consensus standards to ASTM International.

ASTM F3387-19 is based on the most recent consensus standards recognized by experts in government and professional associations on the selection, use, and maintenance for respiratory protection equipment. The standard contains detailed guidance and provisions on respirator selection that are based on NIOSH's long-standing experience of testing and approving respirators for occupational use and OSHA's research and rulemaking on respiratory protection. ASTM F3387-19 also addresses all aspects of establishing, implementing, and evaluating

respiratory protection programs and establishes minimum acceptable respiratory protection program elements in the areas of program administration, standard operating procedures, medical evaluation, respirator selection, training, fit testing, respirator maintenance, inspection, and storage. ASTM F3387-19 comprehensively covers numerous aspects of respiratory protection and provides the most up-to-date provisions for current respirator technology and effective respiratory protection. Therefore, MSHA believes that ASTM F3387-19 would provide mine operators with information and guidance on the proper selection, use, and maintenance of respirators, which would protect the health and safety of miners.

Under this proposed rule, MSHA would require that operators establish a respiratory protection program in writing, that includes minimally acceptable program elements: program administration; standard operating procedures; medical evaluations; respirator selection; training; fit testing; and maintenance, inspection, and storage.

Beyond the minimally acceptable program elements, MSHA proposes to provide mine operators with flexibility to select the provisions in ASTM F3387-19 that are applicable to the conditions of their mines and respirator use by their miners. In MSHA's experience, the need for and actual use of respirators varies among mines for different reasons, including the type of commodity mined or processed and the mining method and controls used. At some mines, miners may not use or may only rarely use respirators. At other mines, miners may use respirators more frequently. Recognizing these differences, MSHA would allow mine operators to comply with the provisions in ASTM F3387-19 that they deem are relevant and appropriate for their mining operations and conditions.

MSHA has observed that many operators, in particular larger mine operators, have already implemented in their respiratory programs many OSHA requirements, which are substantially similar to many requirements in ASTM F3387-19. Indeed, ASTM F3387-19 refers to OSHA's regulations on respiratory protection programs, APFs and MUCs, and fit testing. MSHA believes that the mining industry is already familiar with many provisions in ASTM

F3387-19. MSHA anticipates that for many large mine operators, few changes to their respiratory protection program may be warranted, whereas small mines, or mines that use respirators intermittently, may need to revise their respiratory practices in accordance with the requirements, as applicable, in ASTM F3387-19.

1. Respiratory Program Elements

Under the proposed rule, MSHA would require that the respiratory protection program be in writing and that it include the following minimally acceptable program elements: program administration; standard operating procedures; medical evaluations; respirator selection; training; fit testing; and maintenance, inspection, and storage.

a. Program Administration

ASTM F3387-19 specifies several practices related to respiratory protection program administration, including the qualifications and responsibilities of a program administrator. For example, ASTM F3387-19 provides that responsibility and authority for the respirator program be assigned to a single qualified person with sufficient knowledge of respiratory protection. Qualifications could be gained through training or experience; however, the qualifications of a program administrator must be commensurate with the respiratory hazards present at a worksite.

This individual should have access to and direct communication with the site manager about matters impacting worker safety and health. ASTM F3387-19 notes a preference that the administrator be in the company's industrial hygiene, environmental, health physics, or safety engineering department; however, a third-party entity meeting the provisions may also provide this service. ASTM F3387-19 outlines the respiratory program administrator's responsibilities, specifying that they should include: measuring, estimating, or reviewing information on the concentration of airborne contaminants; ensuring that medical evaluations, training, and fit testing are performed; selecting the appropriate type or class of respirator that will provide adequate protection for each contaminant; maintaining records; evaluating the respirator program's effectiveness; and revising the program, as necessary.

b. Standard Operating Procedures (SOP)

SOPs are written policies and procedures available for all wearers of respirators to read and are established by the employer. ASTM F3387-19 states that written SOPs for respirator programs are necessary when respirators are used routinely or sporadically. Written SOPs should cover hazard assessment; respirator selection; medical evaluation; training; fit testing; issuance, maintenance, inspection, and storage of respirators; schedule of air-purifying elements; hazard re-evaluation; employer policies; and program evaluation and audit. ASTM F3387-19 also provides that wearers of respirators be provided with copies of the SOP and that written SOPs include special consideration for respirators used for emergency situations. The procedures are reviewed in conjunction with the annual respirator program audit and are revised by the program administrator, as necessary.

c. Medical Evaluation

Medical evaluations determine whether an employee has any medical conditions that would preclude the use of respirators, limitation on use, or other restrictions. ASTM F3387-19 provides that a program administrator advise the PLHCP of the following conditions to aid in determining the need for a medical evaluation: type and weight of the respirator to be used; duration and frequency of respirator use (including use for rescue and escape); typical work activities; environmental conditions (e.g., temperature); hazards for which the respirator will be worn, including potential exposure to reduced-oxygen environments; and additional protective clothing and equipment to be worn. ASTM F3387-19 also incorporates ANSI Z88.6 *Respiratory Protection – Respirator Use – Physical Qualifications for Personnel*.

d. Respirator Selection

Proper respirator selection is an important component of an effective respiratory protection program. ASTM F3387-19 provides that proper respirator selection consider the following: the nature of the hazard, worker activity and workplace factors, respirator use duration, respirator limitations, and use of approved respirators. ASTM F3387-19 states that

respirator selection for both routine and emergency use include hazard assessment, selection of respirator type or class that can offer adequate protection, and maintenance of written records of hazard assessment and respirator selection.

ASTM F3387-19 provides specific steps to establish the nature of inhalation hazards, including determining the following: the types of contaminants present in the workplace; the physical state and chemical properties of all airborne contaminants; the likely airborne concentration of the contaminants (by measurement or by estimation); potential for an oxygen-deficient environment; an occupational exposure limit for each contaminant; existence of an IDLH atmosphere; and compliance with applicable health standards for the contaminants.

ASTM F3387-19 includes other information to support the respirator selection process, including information on operational characteristics, capabilities, and performance limitations of various types of respirators. These limitations must be considered during the selection process. ASTM F3387-19 also describes types of respirators and consideration for their use, including service life, worker mobility, compatibility with other protective equipment, durability, comfort factors, compatibility with the environment, and compatibility with job and workforce performance. Finally, ASTM F3387-19 provides other essential information regarding respirator selection such as oxygen deficiency, ambient noise, and need for communication.

e. Training

Employee training is essential for correct respirator use. ASTM F3387-19 provides that all users be trained in their area of responsibility by a qualified person to ensure the proper use of respirators. A respirator trainer must be knowledgeable in the application and use of the respirators and must understand the site's work practices, respirator program, and applicable regulations. Employees who receive training include the workplace supervisor, the person issuing and maintaining respirators, respirator wearers, and emergency teams. To ensure the proper and safe use of a respirator, ASTM F3387-19 also provides that the minimum training for each respirator wearer includes: the need for respiratory protection; the nature, extent, and effects

of respiratory hazards in the workplace; reasons for particular respirator selections; reasons for engineering controls not being applied or reasons why they are not adequate; types of efforts made to reduce or eliminate the need for respirators; operation, capabilities, and limitations of the respirators selected; instructions for inspecting, donning, and doffing the respirator; the importance of proper respirator fit and use; and maintenance and storage of respirators. The standard provides for each respirator wearer to receive initial and annual training. Workplace supervisors and persons issuing respirators are retrained as determined by the program administrator. Training records for each respirator wearer are maintained and include the date, type of training received, performance results (as appropriate), and instructor's name.

f. Respirator Fit Testing

A serious hazard may occur if a respirator, even though properly selected, is not properly fitted. For example, if a proper face seal is not achieved, the respirator would provide a lower level of protection than it is designed to provide because the respirator could allow contaminants to leak into the breathing area. Proper fit testing verifies that the selected make, model, and size of a respirator adequately fits and ensures that the expected level of protection is provided. ASTM F3387-19 includes provisions for qualitative and quantitative fit testing to determine the ability of a respirator wearer to obtain a satisfactory fit with a tight-fitting respirator and incorporates ANSI/AIHA Z88.10, *Respirator Fit Testing Methods,* for guidance on how to conduct fit testing of tight-fitting respirators and appropriate methods to be used. ASTM F3387-19 also provides information on conducting quantitative and qualitative fits test to determine how well a tight-fitting respirator fits a wearer. This includes information on the application of fit factors and assigned protection factors, and how these factors are used to ensure that a wearer is receiving the necessary protection. ASTM F3387-19 provides for each respirator wearer to be fit tested before being assigned a respirator (currently at least once every 12 months or repeated when a wearer expresses concern about respirator fit or comfort or has a condition that may interfere with the face piece seal).

g. Maintenance, Inspection, and Storage

Proper maintenance and storage of respirators are important in a respiratory protection program. ASTM F3387-19 includes specific provisions for decontaminating, cleaning, and sanitizing respirators, inspecting respirators, replacing, and repairing parts, and storing and disposing of respirators. For example, the decontamination provisions state that respirators are decontaminated after each use and cleaned and sanitized regularly per manufacturer instructions. Following cleaning and disinfection, reassembled respirators are inspected to verify proper working condition. ASTM F3387-19 states that employers consult manufacturer instructions to determine component expiration dates or end-of-service life, inspect the rubber or other elastomeric components of respirators for signs of deterioration that would affect respirator performance, and repair or replace respirators failing inspection. ASTM F3387-19 also provides that respirators are stored according to manufacturer recommendations and in a manner that will protect against hazards (i.e., physical, biological, chemical, vibration, shock, temperature extremes, moisture, etc.). It also provides that respirators are stored to prevent distortion of rubber or other parts.

2. Section-by-Section Analysis of Incorporation by Reference - ASTM F3387-19

a. Part 56 – Safety and Health Standards – Surface Metal and Nonmetal Mines - Section 56.5005 - Control of exposure to airborne contaminants.

Existing § 56.5005 provides that whenever respiratory protective equipment is used, a program for selection, maintenance, training, fitting, supervision, cleaning, and use shall meet the requirements of paragraph (b). Paragraph (b) requires that mine operators implement a respirator program consistent with the requirements of ANSI Z88.2-1969. MSHA is proposing to revise paragraph (b) to remove the incorporation by reference to ANSI Z88.2-1969 and incorporate by reference ASTM F3387-19.

MSHA is proposing to revise paragraph (b) to state that approved respirators must be selected, fitted, cleaned, used, and maintained in accordance with the requirements of ASTM

F3387-19 “as applicable.” Under the proposal, MSHA would require that the respiratory program be in writing and that it include the following minimally acceptable program elements: program administration; standard operating procedures; medical evaluations; respirator selection; training; fit testing; and maintenance, inspection, and storage.

Also, MSHA is proposing to change paragraph (c) to require the presence of at least one other person with backup equipment and rescue capability when respiratory protection is used in atmospheres that are IDLH. This change is needed to conform to language in the proposed incorporation by reference of ASTM F3387-19, which defines IDLH as “any atmosphere that poses an immediate hazard to life or immediate irreversible debilitating effects on health” (ASTM International 2019).

b. Part 57 – Safety and Health Standards – Underground Metal and Nonmetal Mines - Section 57.5005 - Control of exposure to airborne contaminants.

Existing § 57.5005 provides that whenever respiratory protective equipment is used, a program for selection, maintenance, training, fitting, supervision, cleaning, and use shall meet the requirements of paragraph (b). Paragraph (b) requires that mine operators implement a respirator program consistent with the requirements of ANSI Z88.2-1969. MSHA is proposing to revise paragraph (b) to remove the incorporation by reference to ANSI Z88.2-1969 and incorporate by reference ASTM F3387-19.

MSHA is proposing to revise paragraph (b) to state that approved respirators must be selected, fitted, cleaned, used, and maintained in accordance with the requirements of ASTM F3387-19 “as applicable.” Under the proposal, MSHA would require that the respiratory program be in writing and that it include the following minimally acceptable program elements: program administration; standard operating procedures; medical evaluations; respirator selection; training; fit testing; and maintenance, inspection, and storage.

Also, MSHA is proposing to change paragraph (c) to require the presence of at least one other person with backup equipment and rescue capability when respiratory protection is used in

atmospheres that are IDLH. This change is needed to conform to language in the proposed incorporation by reference of ASTM F3387-19, which defines the term IDLH as "any atmosphere that poses an immediate hazard to life or immediate irreversible debilitating effects on health" (ASTM International 2019).

c. Part 72 – Health Standards for Coal Mines - Section 72.710 - Selection, fit, use, and maintenance of approved respirators.

Existing § 72.710 requires approved respirators be selected, fitted, used, and maintained in accordance with the provisions of ANSI Z88.2-1969, which was incorporated by reference into coal standards in 1995 (60 FR 30398, June 8, 1995). MSHA is proposing to revise § 72.710 by removing the requirement in the first sentence that coal mine operators must ensure that the maximum amount of respiratory protection is made available to miners when respirators are used. MSHA believes that the use of approved respirators and the proposed incorporation by reference of ASTM F3387-19 would ensure that coal miners' health is protected. Under the proposal, MSHA would require that the respiratory program be in writing and that it include the following minimally acceptable program elements: program administration; standard operating procedures; medical evaluations; respirator selection; training; fit testing; and maintenance, inspection, and storage.

VIII. Technological Feasibility

This technological feasibility analysis considers whether currently available technologies, used alone or in combination with each other, can be used by operators to comply with the proposed standard.

MSHA is required to set standards to assure, based on the best available evidence, that no miner will suffer material impairment of health or functional capacity from exposure to toxic materials or harmful physical agents over his working life. 30 U.S.C. 811(a)(6)(A). The Mine Act also instructs MSHA to set health standards to attain "the highest degree of health and safety protection for the miner" while considering "the latest available scientific data in the field, the

feasibility of the standards, and experience gained under this and other health and safety laws." 30 U.S.C. 811(a)(6)(A). But the health and safety of the miner is always the paramount consideration: "[T]he Mine Act evinces a clear bias in favor of miner health and safety," and "[t]he duty to use the best evidence and to consider feasibility are appropriately viewed through this lens and cannot be wielded as counterweight to MSHA's overarching role to protect the life and health of workers in the mining industry." *Nat'l Min. Ass'n* v. *Sec'y, U.S. Dep't of Lab.*, 812 F.3d 843, 866 (11th Cir. 2016); 30 U.S.C. 801(a).

The D.C. Circuit clarified the Agency's obligation to demonstrate the technological feasibility of reducing occupational exposure to a hazardous substance. MSHA "must only demonstrate a 'reasonable possibility' that a 'typical firm' can meet the permissible exposure limits in 'most of its operations." *Kennecott Greens Creek Min. Co.* v. *Mine Safety & Health Admin.*, 476 F.3d 946, 958 (D.C. Cir. 2007) (quoting *American Iron & Steel Inst.* v. *OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991)).

This section presents technological feasibility findings that guided MSHA's selection of the proposed PEL. MSHA's technological feasibility findings are organized into two main sections covering: (1) the technological feasibility of proposed part 60; and (2) the technological feasibility of the proposed revision to existing respiratory protection standards. Based on the analyses presented in the two sections, MSHA preliminarily concludes that the Agency's proposal is technologically feasible. MSHA's feasibility determinations in this rulemaking are supported by its findings that the majority of the industry is already using technology that would be sufficient to comply with the proposed rule.

First, MSHA has preliminarily determined that proposed part 60 is technologically feasible. Many mine operators already maintain respirable crystalline silica exposures at or below the proposed PEL of 50 $\mu g/m^3$, and at mines where there are elevated exposures, operators would be able to reduce exposures to at or below the proposed PEL by properly maintaining existing engineering controls and/or by implementing new engineering and administrative

controls that are currently available. In addition, mines would be able to satisfy the exposure monitoring requirements of proposed part 60 with existing, validated, and widely used sampling technologies and analytical methods.

Second, the analysis shows that the proposed update to MSHA's respiratory protection requirements is also technologically feasible. The mining industry's existing respiratory protection practices for selecting, fitting, using, and maintaining respiratory protection include program elements that are similar to those of *ASTM F3387-19, "Standard Practice for Respiratory Protection"* (ASTM F3387-19), which MSHA is proposing to incorporate by reference.

A. Technological Feasibility of Sampling and Analytical Methods

1. Sampling Methods

MSHA's proposed rule would require mine operators in both MNM and coal mines to conduct sampling for respirable crystalline silica using respirable particle size-selective samplers that conform to the "*International Organization for Standardization (ISO) 7708:1995: Air Quality–Particle Size Fraction Definitions for Health-Related Sampling*" standard. The ISO convention defines respirable particulates as having a 4 micrometer (μm) aerodynamic diameter median cut-point (i.e., 4 μm-sized particles are collected with 50 percent efficiency), which approximates the size distribution of particles that when inhaled can reach the alveolar region of the lungs. For this reason, the ISO convention is widely considered biologically relevant for respirable particulates and provides appropriate criteria for equipment used to sample respirable crystalline silica. MSHA's current sampling method for MNM mines meets the ISO criteria by using a 10 mm Dorr-Oliver cyclone and a sampling pump operated at a flow rate of 1.7 liter per minute (L/min), and MNM mine operators also already use this type of sampler for MNM sampling under existing standards. MSHA's current sampling method for RCMD, including respirable crystalline silica, uses a 10 mm Dorr-Oliver cyclone but operated at 2.0 L/min to approximate the British Mining Research Establishment (MRE) sampling criteria, and thus does

not meet the ISO criteria. Although, the existing sampling pumps can be adjusted to operate at a flow rate of 1.7 L/min flow rate to meet the ISO criteria. To comply with this proposed requirement, coal mine operators that currently use coal mine dust personal sampler units (CMDPSU) would need to adjust their samplers to the flow rate specified by the manufacturer for complying with the ISO.

There are a variety of size-selective samplers on the market that meet the ISO respirable-particle-size selection criteria. Examples include Dorr-Oliver cyclone currently used by MSHA and OSHA, operated at 1.7 L/min; SKC aluminum cyclone (2.5 L/min); HD cyclone (2.2 L/min); SKC GS-3 multi-inlet cyclone (2.75 L/min); and BGI GK 2.69 (4.2 L/min). Each cyclone has different operating specifications and performance criteria, but they all are compliant with the ISO criteria for respirable dust with an acceptable level of measurement bias. Manufacturers of size-selective samplers specify the flow rates that are necessary to conform to the particle size collection criteria of the ISO standard. Samplers used in both MNM and coal mines can be used to perform the proposed sampling, and because other commercially available (already on the market) samplers conform to the ISO standard, MSHA preliminarily finds that sampling in accordance with the ISO standard is technologically feasible.

2. Analytical Methods and Feasibility of Measuring Below the Proposed PEL and Action Level

After a respirable dust sample is collected and submitted to a laboratory, it must be analyzed to quantify the mass of respirable crystalline silica present. The laboratory method must be sensitive enough to detect and quantify respirable crystalline silica at levels below the applicable concentration. The analytical limit of detection (LOD) and/or limit of quantification (LOQ), together with the sample volume, determine the airborne concentration LOD and/or LOQ for a given air sample. MSHA proposes a PEL for respirable crystalline silica of 50 $\mu g/m^3$ as a full shift, 8-hour TWA for both MNM and coal mines. Several analytical methods are available

for measuring respirable crystalline silica at levels well below the proposed PEL of 50 µg/m^3 and action level of 25 µg/m^3.

MSHA uses two main analytical methods (1) *P-2: X-Ray Diffraction Determination Of Quartz And Cristobalite In Respirable Metal/Nonmetal Mine Dust* (analysis by X-ray diffraction, XRD) for MNM mines and (2) *P-7: Determination Of Quartz In Respirable Coal Mine Dust By Fourier Transform Infrared Spectroscopy* (analysis by infrared spectroscopy, FTIR or IR) for coal mines.[36] The MSHA P-2 and P-7 methods, reliably analyze compliance samples collected by MSHA inspectors, including 15 years of MNM compliance samples and 5 years of coal industry compliance samples MSHA used for the exposure profile portion of this technological feasibility analysis. These methods are capable of measuring respirable crystalline silica exposures at levels below the proposed PEL and action level.

For an analytical method to have acceptable sensitivity for determining exposures at the proposed PEL of 50 µg/m^3 and action level of 25 µg/m^3, the LOQ must be at or below the amount of analyte (e.g., quartz) that would be collected in an air sample where the concentration of analyte is equivalent to the proposed PEL or action level. To determine the minimum airborne concentration that can be quantified, the LOQ mass is divided by the sample air volume, which is determined by the sampling flow rate and duration. Table VIII-1 presents minimum quantifiable quartz concentrations, for various cyclones and established analytical methods.

[36] Other similar XRD methods include NIOSH-7500 and OSHA ID-142. XRD methods are able to distinguish between the different polymorphs – quartz, cristobalite and tridymite. Other IR methods include NIOSH 7602 and 7603. IR methods are efficient, but they are more prone to interferences and should only be used for samples with a well-characterized matrix (e.g., coal dust).

Table VIII-1. Minimum Quantifiable Quartz Concentrations, Determined by Reporting Limit or LOQ and Sampling Volume

Sampling Parameters (examples)	Reporting Limit or LOQ = 5 µg	Reporting Limit or LOQ = 9.76 µg	Reporting Limit or LOQ = 12 µg
Airflow rate: 1.7 L/min Sampling minutes: 480 Sample air volume: 816 L	6.1 µg/m^3	12.0 µg/m^3	14.7 µg/m^3
Airflow rate: 2.5 L/min Sampling minutes: 480 Sample air volume: 1,200 L	4.2 µg/m^3	8.1 µg/m^3	10 µg/m^3
Airflow rate: 2.75 L/min Sampling minutes: 480 Sample air volume: 1,320 L	3.8 µg/m^3	7.4 µg/m^3	9.1 µg/m^3
Airflow rate: 4.2 L/min Sampling minutes: 480 Sample air volume: 2,016 L	2.5 µg/m^3	4.8 µg/m^3	6.0 µg/m^3

Notes:

a. An analytical method LOQ may be referred to as a reporting limit (RL) or reliable quantitation limit (RQL).
b. The minimum quantifiable concentration may be adjusted higher by the laboratory based on the laboratory's analytical method, instrumentation, and interferences in the sample.
c. Reporting Limits and LOQ values were taken from limits reported by (1) commercial laboratories (5 µg) (EMSL Analytical, Inc., 2022; RJ Lee Group, 2021; SGS Galson, 2016), (2) OSHA ID-142 (9.76 µg), and (3) MSHA P-2 and P-7 (12 µg).
d. Air volume (in liters) calculated as: (sampling minutes) x (air flow rate as L/min)
e. Concentrations (µg/m^3) calculated as: (µg quartz) / (L air volume) x 1000 L/m^3

Based on this discussion, MSHA preliminarily finds that current analytical methods are sufficiently sensitive to meet the proposed PEL and action level.

3. Laboratory Capacity

MSHA's proposed standard would require that mines conduct baseline sampling, periodic sampling, corrective actions sampling, and post-evaluation sampling with analyses conducted by laboratories that meet *ISO 17025, General Requirements for the Competence of Testing and Calibration Laboratories* (ISO 17025). The majority of U.S. industrial hygiene laboratories that perform respirable crystalline silica analysis are accredited to ISO 17025 by the American Industrial Hygiene Association (AIHA) Laboratory Accreditation Program (LAP). The AIHA LAP lists 23 accredited commercial laboratories nationwide that, as of April 2022, perform respirable crystalline silica analysis using an MSHA, NIOSH or OSHA method.

MSHA interviewed a sample of three laboratories (one small-capacity laboratory,[37] one medium-capacity laboratory,[38] and one large-capacity laboratory[39]) to estimate their sample-processing capacity. Insights from these interviews suggest that laboratories have the ability to provide surge capacity as the proposed rule is phased in. Collectively, these three laboratories could process approximately 33,240 samples by XRD (suitable for MNM mines) and 1,752 samples by FTIR or IR (suitable for coal mines) within a 6-month period. Extrapolating this across all laboratories that can analyze respirable crystalline silica samples, MSHA estimates that 232,680 samples for MNM mines and 12,250 samples for coal mines could be processed in the phase-in 6-month period. Over the first 12 months after the standard goes into effect, analysis would be available for 465,360 samples for MNM mines and 24,500 samples for coal mines.

Based on exposure profiles for the MNM and coal mining industries and MSHA's experience and knowledge of the mining industry, MSHA estimates that within this first 12-month period, mines would seek analysis for a total of 172,907 respirable crystalline silica samples (including 58,126 samples for MNM mines and 12,373 samples for coal mines associated with the 6-month baseline sampling period). In the subsequent 12-month period, mines would require analysis for 102,409 samples (includes process/control measure evaluation samples and periodic samples associated with the proposed action level), a number that will decline over years 1 through 6 as the mine operators reduce some miner exposures below the

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[37] The small capacity laboratory has a maximum respirable crystalline silica sample analysis capacity of 300 samples per month (280 additional samples per month above the current number of samples analyzed), a level which the laboratory could sustain for two months.

[38] The medium capacity laboratory has a maximum respirable crystalline silica sample analysis capacity of 2,025 samples per month. Surge from the mining industry is considered to replace, rather than be in addition to the current number of samples analyzed.

[39] The large capacity laboratory has a maximum respirable crystalline silica sample analysis capacity of 4,500 samples per month (3,700 additional samples per month above the current number of samples analyzed).

proposed action level.[40] Comparing these figures with the surge capacity estimates previously noted above, MSHA believes that there would be sufficient processing capacity to meet the sampling analysis schedule envisioned in the proposed rule.

a. Baseline sampling

MSHA's proposal would require baseline sampling for each miner who is or may reasonably be expected to be exposed to respirable crystalline silica within 180 days (6 months) of the standard's effective date.[41] This would require an initial increase in analytical laboratory capacity of approximately 70,498 sample analyses over 6 months. MSHA expects that with months of lead time during the proposed rule and final rule stages of the rulemaking, laboratories would anticipate the initial baseline period increase in demand and would respond by increasing their analytical capacity. For example, laboratories could acquire additional instrumentation, train additional analysts, or add a second or third operating shift. This is particularly likely given that demand would be based on a regulatory requirement and during the rulemaking process MSHA would conduct outreach to make all relevant stakeholders aware of the rule's provisions. MSHA is specifically soliciting comments on the technological feasibility of laboratory capability to conduct baseline sampling. At this point in the rulemaking, MSHA believes that the proposed rule is technologically feasible for laboratories to conduct baseline sampling analyses.

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[40] MSHA anticipates that in the initial six-month baseline period mine operators will collect 70,498 baseline samples, of which 12,373 will be coal mine samples. In the 12 months beginning after the initial baseline period, mines will collect 88,281 samples for miners who are exposed at or above the proposed action level (25 $\mu g/m^3$), but at or below the proposed PEL, plus 14,128 samples to evaluate corrective action and process change (i.e., processes which must be analyzed to determine whether newly implemented dust control measures are successful and processes newly identified during periodic walk-through evaluations), for a total of 102,409 samples per year (including 25,152 coal mine samples). Estimates are as of December 2022.

[41] Where several miners perform similar activities on the same shift, only a representative fraction of miners (minimum of two miners) would need to be sampled, including those expected to have the highest exposures.

b. Periodic, corrective actions, and post-evaluation sampling

Under proposed § 60.12 (b) - (e), three conditions would require mine operators to conduct additional sampling after the initial 6-month baseline period. First, when the most recent sampling indicates that miner exposures are at or above the proposed action level (25 $\mu g/m^3$) but at or below the proposed PEL (50 $\mu g/m^3$), the mine operator would be required to sample within 3 months of that sampling and continue to sample within 3 months of the previous sampling until two consecutive samplings indicate that miner exposures are below the action level. Second, where the most recent sampling indicates that miner exposures are above the PEL, the mine operator would be required to sample after corrective actions are taken to reduce overexposures, until sampling results indicate miner exposures are at or below the PEL. Third, if the mine operator determines, as a result of the semi-annual evaluation, that miners may be exposed to respirable crystalline silica at or above the action level, the mine operator would be required to perform sampling to assess the full-shift, 8-hour TWA exposure of respirable crystalline silica for each miner who is or may reasonably be expected to be at or above the action level.

MSHA estimates that the total number of analyses (489,860) that laboratories will be able to perform per year is more than 2.5 times the total estimated number of samples for which mines will seek analyses in the first year (172,907). Based on the estimated surplus analyses available beyond baseline sampling (419,362), MSHA preliminarily finds that periodic, corrective actions, and post-evaluation sampling would also be technologically feasible both in the first year and in subsequent years.[42]

[42] 489,860 total annual laboratory analyses divided by 172,907 mine samples to be analyzed, equals 2.83 percent surplus sample analyses. 489,860 total analyses – 70,498 baseline analyses = a surplus of 419,362 analyses available for the 102,409 periodic, corrective actions, and process change sampling.

B. Technological Feasibility of the Proposed PEL

1. Methodology

The technological feasibility analysis for the proposed PEL relies primarily on information from three key sources:

- MSHA's Standardized Information System (MSIS) respirable crystalline silica exposure data, which includes 57,769 MNM and 63,127 coal mine compliance samples collected by MSHA inspectors; these samples were of sufficient mass to be analyzed for respirable crystalline silica by MSHA's analytical laboratory.[43]
- The National Institute for Occupational Safety and Health (NIOSH) series on reducing respirable dust in mines, including: "Dust Control Handbook for Industrial Minerals Mining and Processing, Second Edition" (NIOSH, 2019b) and "Best Practices for Dust Control in Coal Mining, Second Edition" (NIOSH, 2021a).[44] With cooperation from the MNM and coal mining industries, NIOSH has extensively researched and documented engineering and administrative controls for respirable crystalline silica in mines.
- MSHA's knowledge of the mining industry. MSHA has over four decades of experience inspecting surface mines at least twice per year and underground mines at least four times per year and in assisting mine operators and miners with

[43] These respirable crystalline silica exposure data consist of 15 years of MNM mine samples (January 1, 2005, through December 31, 2019) and five years of coal mine samples (August 1, 2016, through July 31, 2021). These MSHA compliance samples represent the conditions identified by MSHA inspectors as having the greatest potential for respirable crystalline silica exposure during the periodic inspection when sampling occurred. While MSHA's laboratory also analyzes mine operators' respirable coal mine dust samples containing respirable crystalline silica, those samples are not included in the data used for this analysis.

[44] Together, these two recent reports provide more than 500 pages of detailed descriptions, discussion, and illustrations of dust control technologies currently used in mines.

technological issues, including control of respirable dust (including respirable crystalline silica) exposure. MSHA offers informational programs, training, publications, onsite evaluations, and investigations that document conditions in mines and help mines operate in a safe and healthy manner.[45]

MSHA also consulted other published reports, scientific journal articles, and information from equipment manufacturers and mining industry suppliers.[46]

2. The Technological Feasibility Analysis Process

a. Mining Commodity Categories and Activity Groups

As described in the Preliminary Regulatory Impact Analysis (PRIA), MSHA categorized mine types into six MNM "commodity categories" (using the method of Watts *et al.*, 2012) based on similarities in exposure characteristics. MNM mine categories include metal, nonmetal, stone, crushed limestone, and sand and gravel. All coal mines are categorized together as one commodity category.

Within each commodity, MSHA further separated mining operations into the four activity groups widely used by the industry: (1) development and production miners (drillers, stone cutters); (2) ore/mineral processing miners (crushing/screening equipment operators and kiln, mill, and concentrator workers in mine facilities); (3) miners engaged in load/haul/dump activities (conveyor, loader, and large haulage vehicle operators, such as dump truck drivers);

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[45] MSHA also analyzes RCMD samples collected by mine operators, including those containing respirable crystalline silica, in addition to the compliance samples collected by MSHA inspectors (mentioned in the first bullet of this series).

[46] Project personnel reviewed 104,365 samples collected and analyzed by MSHA for respirable crystalline silica, plus another 103,745 samples collected but not analyzed due to insufficient respirable dust collected in the sample. They examined over 200 published reports, proceedings, case studies, analytical methods, and journal articles, in addition to inspecting more than 200 webpage, product brochures, user manuals, service/maintenance manuals and descriptive literature for dust control products, mining equipment, and related services.

and (4) miners in all other occupations (mobile and utility workers, such as surveyors, mechanics, cleanup crews, laborers, and operators of compact tractors and utility trucks).

Before determining the feasibility of reducing miners' exposure to respirable crystalline silica, MSHA gathered and analyzed information to understand current miner exposures by creating an "exposure profile," identified the existing (i.e., baseline) conditions and the exposure levels associated with those conditions, and determined whether mines would need additional control methods, and if so, whether those methods were available.

b. Exposure Profiles

MSHA classified all valid respirable crystalline silica samples in the Agency's MSIS data,[47] grouping the data by commodity category, followed by activity group.[48] MSHA created an exposure profile to better examine the sample data for each commodity category. These profiles include basic summary statistics, such as sample count, mean, median, and maximum values, presented as ISO 8-hour TWA values. They also show the sample distribution within the following exposure ranges: ≤ 25 µg/m^3, > 25 µg/m^3 to ≤ 50 µg/m^3, > 50 µg/m^3 to ≤ 100 µg/m^3 (equivalent to 85.7 µg/m^3 in coal mines for a sample calculated as an 8-hour TWA), > 100 µg/m^3 to ≤ 250 µg/m^3, > 250 µg/m^3 to ≤ 500 µg/m^3, and > 500 µg/m^3.[49]

In Table VIII-2, the respirable crystalline silica exposure data for MNM miners are summarized by commodity and for the MNM industry as a whole, while Table VIII-3 presents

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[47] MSHA removed duplicate samples, samples missing critical information, and those identified as invalid by the mine inspector, for example because of a "fault" (failure) of the air sampling pump during the sampling period.

[48] MSHA MSIS respirable crystalline silica data for the MNM industry, January 1, 2005, through December 31, 2019 (version 20220812); MSHA MSIS respirable crystalline silica data for the Coal Industry, August 1, 2016, through July 31, 2021 (version 20220617). All samples were collected by mine inspectors and were of sufficient mass to be analyzed for respirable crystalline silica by MSHA's laboratory.

[49] MSHA selected these ranges based on the proposed PELs under consideration, then multiples of 100 µg/m^3 to show how data are distributed in the higher ranges. Table VIII-5 also presents additional exposure ranges corresponding to the 85.7 µg/m^3 concentration for coal samples.

the exposure profile as the percentage of samples in each exposure range. Overall, approximately 82 percent of the 57,769 MNM compliance samples were at or below the proposed PEL (50 $\mu g/m^3$). The exposure profile shows variability between the commodity categories: approximately 73 percent of metal miner exposures at or below the proposed PEL (50 $\mu g/m^3$) (the lowest among all MNM mines), compared with approximately 90 percent of the crushed limestone miner exposures (the highest among all MNM mines).

Table VIII-4 and Table VIII-5 present the corresponding respirable crystalline silica exposure information for coal miners by location (underground or surface). Overall, approximately 93 percent of the 63,127 samples obtained by MSHA inspectors for coal miners were at or below the proposed PEL (50 $\mu g/m^3$). There was little variation between samples for underground miners and surface miners (with approximately 93 and 92 percent of the samples at or below 50 $\mu g/m^3$, respectively). Exposure values from the coal industry are expressed as ISO 8-hour TWAs, compatible with the proposed PEL.

Table VIII-2. Summary of Respirable Crystalline Silica Exposures in the MNM Industry from 2005 to 2019, by Commodity Category

Commodity	Activity Group	Number of Samples	ISO Concentration, µg/m³		
			Mean	Median	Max
Metal	Overall: metal (all activity groups)	3,499	49.1	25.0	3,588
Nonmetal	Overall: nonmetal (all activity groups)	5,165	26.4	11.0	2,124
Stone	Overall: stone (all activity groups)	15,415	36.6	17.0	1,548
Crushed limestone	Overall: crushed limestone (all activity groups)	15,184	21.7	10.0	4,289
Sand and gravel	Overall: sand and gravel (all activity groups)	18,506	38.7	20.0	3,676
Overall: MNM	Overall: MNM	57,769	33.2	15.0	4,289

Notes:

Summary of personal samples presented as ISO 8-hour TWA concentrations. The proposed permissible exposure limit (PEL) for all mines is 50 µg/m³ as an 8-hour time-weighted average (8-hour TWA) sample collected according to the ISO standard 7708:1995: *Air Quality—Particle Size Fraction Definitions for Health-Related Sampling*.

a. The compliance samples summarized in this table were collected by MSHA inspectors as 8-hour TWAs using ISO-compliant sampling equipment with an air flow rate of 1.7 L/min, with results comparable to the proposed PEL.

b. When the mass of respirable crystalline silica collected was too small to be reliably detected by the laboratory, a mass of 2.5 µg for quartz and 5 µg for cristobalite (1/2 the respective limits of detection for these two forms of crystalline silica) were assumed and used to calculate sample results.

c. The procedure to calculate the ISO 8-hour TWA concentration (µg/m³) is:

$$\text{8-hour TWA} = \frac{quartz\ mass}{(480\ minutes)\ x\ (air\ flow\ rate)}\ x\ 1000\ \frac{L}{m^3}$$

Where: quartz mass is in micrograms (µg); normalized sampling time is 8 hours (480 minutes); flow rate = 1.7 L/min; 1000 Liters (L) per cubic meter (m³)

d. Source: MSHA MSIS respirable crystalline silica data for the MNM industry, January 1, 2005, through December 31, 2019 (version 20220812). All samples were of sufficient mass to be analyzed for respirable crystalline silica.

Table VIII-3. Percentage Distribution of Respirable Crystalline Silica Exposures in the MNM Industry from 2005 to 2019, by Commodity Category

Commodity	Activity Group	Number of Samples	Percentage of Samples in ISO Concentration Ranges, µg/m³						Total %
			≤ 25	> 25 to ≤ 50	> 50 to ≤ 100	> 100 to ≤ 250	> 250 to ≤ 500	> 500	
Metal	Overall: metal (all activity groups)	3,499	51.6%	21.3%	16.3%	8.3%	1.9%	0.6%	100%
Nonmetal	Overall: nonmetal (all activity groups)	5,165	70.5%	15.1%	9.9%	3.8%	0.6%	0.1%	100%
Stone	Overall: stone (all activity groups)	15,415	60.3%	18.7%	13.6%	6.0%	1.1%	0.3%	100%
Crushed limestone	Overall: crushed limestone (all activity groups)	15,184	77.8%	12.5%	6.9%	2.3%	0.4%	0.2%	100%

Table VIII-3. Percentage Distribution of Respirable Crystalline Silica Exposures in the MNM Industry from 2005 to 2019, by Commodity Category									
Commodity	**Activity Group**	**Number of Samples**	**Percentage of Samples in ISO Concentration Ranges, µg/m³**						**Total %**
			≤ 25	**> 25 to ≤ 50**	**> 50 to ≤ 100**	**> 100 to ≤ 250**	**> 250 to ≤ 500**	**> 500**	
Sand and gravel	Overall: sand and gravel (all activity groups)	18,506	58.6%	20.8%	13.2%	5.7%	1.2%	0.4%	100%
Overall: MNM	Overall: MNM	57,769	64.7%	17.6%	11.6%	4.8%	1.0%	0.3%	100%

Notes:

a. Personal samples were collected using ISO-compliant sampling equipment and calculated as an 8-hour time-weighted average (8-hour TWA). Samples were collected using an air flow rate of 1.7 L/min and reported as 8-hour TWAs. See notes in Summary table VIII-1 for additional details.

b. Source: MSHA MSIS respirable crystalline silica data for the MNM industry, January 1, 2005, through December 31, 2019 (version 20220812). All samples were of sufficient mass to be analyzed for respirable crystalline silica.

Table VIII-4. Summary of Respirable Crystalline Silica Exposures in the Coal Mining Industry from 2016 to 2021, by Location

Location	Activity Group	Number of Samples	ISO Concentration (8-hour TWA, µg/m³)		
			Mean	Median	Max
Underground	Overall: underground (all activity groups)	53,095	22.1	16.0	778.6
Surface	Overall: surface (all activity groups)	10,032	20.5	11.1	747.8
Overall: coal	Overall: coal	63,127	21.9	16.0	778.6

Notes: Summary of personal samples presented as ISO 8-hour TWA concentrations. The proposed permissible exposure limit (PEL) for all mines is 50 µg/m³ as an 8-hour time-weighted average (8-hour TWA) sample collected according to the ISO standard 7708:1995: *Air Quality—Particle Size Fraction Definitions for Health-Related Sampling*.

a. The compliance samples summarized in this table were collected by MSHA inspectors for the entire duration of each miner's work shift using sampling equipment with an air flow rate of 2 L/min, with results reported as MRE TWA concentrations. For this rulemaking analysis, MSHA recalculated the samples as ISO-equivalent 8-hour TWA concentrations, comparable to the proposed PEL (since samples were not collected using an ISO-compliant sampling method). The procedure to calculate an ISO-equivalent concentration from an MRE TWA sample concentration involves normalizing the sample concentration to an 8-hour TWA and applying the empirically derived conversion factor of 0.857 recommended by NIOSH (1995a) using the following equation:

b. ISO 8-hour TWA concentration = $(MRE\ TWA\ in\ \mu g/m^3)\ x\ \frac{(original\ sampling\ time)}{(480\ minutes)}\ x\ 0.857$

c. Where: both concentrations (ISO 8-hour TWA and MRE TWA) are concentrations presented as µg/m³; sampling time in minutes.

d. When the mass of respirable crystalline silica collected was too small to be reliably detected by the laboratory, a mass of 1.5 µg (1/2 the limit of detection) was assumed and used to calculate sample results.

e. Source: MSHA MSIS respirable crystalline silica data for the Coal Industry, August 1, 2016, through July 31, 2021 (version 20220617). All samples were of sufficient mass to be analyzed for respirable crystalline silica.

Table VIII-5. Percentage Distribution of Respirable Crystalline Silica Exposures as ISO 8-hour TWA in the Coal Industry from 2016 to 2021, by Location

Location	Activity Group	Number of Samples	Percentage of Samples in ISO Concentration Ranges, 8-hour TWA, µg/m³							Total %
			≤ 25	> 25 to ≤ 50	> 50 to ≤ 85.7	> 85.7 to ≤ 100	> 100 to ≤ 250	> 250 to ≤ 500	> 500	
Underground	*Overall: underground (all activity groups)*	53,095	72.7%	20.6%	5.1%	0.6%	1.0%	0.1%	0.0%	100%
Surface	*Overall: surface (all activity groups)*	10,032	79.5%	12.4%	4.6%	0.8%	2.3%	0.4%	0.1%	100%
Overall: coal	Overall: coal	63,127	73.8%	19.3%	5.0%	0.6%	1.2%	0.1%	0.0%	100%

Notes:

a. Personal samples presented in terms of ISO concentrations, normalized to 8-hour time-weighted averages (TWAs). The samples were originally collected for the entire duration of each miner's work shift, using an air flow rate of 2 L/min. See notes in Summary table VIII-3 for additional details.

Table VIII-5. Percentage Distribution of Respirable Crystalline Silica Exposures as ISO 8-hour TWA in the Coal Industry from 2016 to 2021, by Location

Location	Activity Group	Number of Samples	Percentage of Samples in ISO Concentration Ranges, 8-hour TWA, µg/m³							Total %
			≤ 25	> 25 to ≤ 50	> 50 to ≤ 85.7	> 85.7 to ≤ 100	> 100 to ≤ 250	> 250 to ≤ 500	> 500	

b. Source: MSHA MSIS respirable crystalline silica data for the coal industry, August 1, 2016, through July 31, 2021 (version 20220617). All samples were of sufficient mass to be analyzed for respirable crystalline silica.

c. Existing Dust Controls in Mines (Baseline Conditions)

MNM and coal mines are controlling dust containing respirable crystalline silica in various ways. As shown in Tables VIII-2 through VIII-5, respirable crystalline silica exposures exceeded the proposed PEL of 50 $\mu g/m^3$ in about 18 percent of all MNM samples collected. Of all coal samples, exposure levels exceeded the proposed PEL in about seven percent of the samples. Overall, metal mines and sand and gravel mines had higher exposure levels than other commodity mines.

Despite the extensive dust control methods available, dust control measures have been implemented in some commodity categories to a greater degree than in others. This is partly because some commodity categories tend to have larger mines. MSHA has found that the larger the amount (tonnage) of material a mine moves (including overburden and other waste rock), the faster the mine tends to operate its equipment (i.e., closer to the equipment capacity), creating more air turbulence and therefore generating more respirable crystalline silica. The amount of material moved also influences the number of miners employed at a mine, and therefore, the number of miners can be indirectly correlated to the amount of dust generated. MSHA has observed that in large mines, dusty conditions typically prompt more control efforts, usually in the form of added engineering controls.

MSHA has also found that metal mines, which are typically large operations with higher numbers of miners, tend to have available engineering controls for dust management. On the other hand, sand and gravel mines, which generally employ fewer miners and handle modest amounts of material, have very limited, if any, dust control measures. This is because most of the mined material is a commodity that only requires washing and screening into various sizes of product stockpiles, generating little waste material. Nonmetal, stone, and crushed limestone mines occupy the middle range in terms of employment, existing engineering controls, and maintenance practices.

Over the years, staff from multiple MSHA program areas have worked alongside miners and mine operators to improve safety and health by inspecting, evaluating, and researching mine conditions, equipment, and operations. These key programs, each of which has an onsite presence, include (but are not limited to) Mine Safety and Health Enforcement; Directorate of Educational Policy and Development which includes the National Mine Health and Safety Academy and the Educational Field and Small Mine Services; and the Directorate of Technical Support, which is comprised of the Approval and Certification Center and the Pittsburgh Safety and Health Technology Center (including its Health Field Division, National Air and Dust Laboratory, Ventilation Division, and other specialized divisions). Table VIII-6 reflects the collective observations of these MSHA programs, presented in terms of existing dust control (baseline conditions) and the classes of additional control measures that would provide those mines with the greatest benefit to reduce exposures below the proposed PEL and action level.

Table VIII-6 shows MSHA's assessment of existing dust controls in mines (baseline conditions) and additional controls needed to meet the proposed PEL for each commodity category, including the need for frequent scheduled maintenance. By conducting frequent scheduled maintenance, mine operators can reduce the concentration of respirable crystalline silica. Table VIII-6 shows that metal mines have adopted extensive dust controls, while sand and gravel mines tend to have minimal engineering controls, if any.

Table VIII-6. Baseline Conditions and Class of Additional Controls Needed, by Commodity

	Baseline (existing) Conditions		**Additional Controls Needed to Achieve the Proposed PEL**		
Commodity category	**Extent of engineering controls adopted**	**Dust control equipment maintenance practices**	**Extent of engineering controls needed**	**Extent of maintenance and repair needed**	**Extent of administrative controls needed**
Metal	Extensive	Minimal	Minimal	Extensive	Moderate
Nonmetal	Moderate	Moderate	Moderate	Moderate	Moderate
Stone	Moderate	Moderate	Moderate	Moderate	Moderate
Crushed limestone	Moderate	Moderate	Moderate	Moderate	Moderate

Table VIII-6. Baseline Conditions and Class of Additional Controls Needed, by Commodity					
	Baseline (existing) Conditions		**Additional Controls Needed to Achieve the Proposed PEL**		
Commodity category	**Extent of engineering controls adopted**	**Dust control equipment maintenance practices**	**Extent of engineering controls needed**	**Extent of maintenance and repair needed**	**Extent of administrative controls needed**
Sand and gravel	Minimal	Moderate	Moderate	Moderate	Extensive
Coal	Moderate	Moderate	Moderate	Moderate	Moderate

Notes:
a. Extensive, moderate and minimal are relative terms. "Extensive" indicates that the baseline (existing) condition is widely present among mines within the commodity, or that the additional control class is anticipated to be widely needed. "Moderate" indicates an intermediate level of baseline availability or anticipated need. "Minimal" means little or no baseline availability or need as an additional control (for that commodity).
b. Source: MSHA's experience from multiple program areas.

Based on MSHA's experience, NIOSH research, and effective respirable dust controls currently available and in use in the mining industry, MSHA preliminarily finds that the baseline conditions include various combinations of existing engineering controls selected and installed by individual mines to address respirable crystalline silica generated during mining operations.

d. Respirable Crystalline Silica Exposure Controls Available to Mines

Under the proposal, the mine operator must install, use, and maintain feasible engineering controls, supplemented by administrative controls, when necessary, to keep each miner's exposure at or below the proposed PEL. Engineering controls reduce or prevent miners' exposure to hazards.[50] Administrative controls establish work practices that reduce the duration, frequency, or intensity of miners' exposures (although rotation of miners would be prohibited under the proposed rule).

[50] Control measures that reduce respirable crystalline silica can also reduce exposures to other hazardous particulates, such as RCMD, metals, asbestos, and diesel exhaust. Operator enclosures and process enclosures also reduce hazardous levels of noise by creating a barrier between the operator and the noise source.

MSHA data and experience show that mine operators already have numerous engineering and administrative control options to control miners' exposures to respirable crystalline silica. These control options are widely recognized and used throughout the mining industry. NIOSH has extensively researched and documented engineering and administrative controls for respirable crystalline silica in mines. As noted previously, NIOSH has published a series on reducing respirable dust in mines (NIOSH, 2019b; NIOSH, 2021a).

(1) Engineering controls

Examples of existing engineering controls used at mines and commercially available engineering controls that MSHA considered include:

- Wetting or water sprays that prevent, capture, or redirect dust;
- Ventilation systems that capture dust at its source and transport it to a dust collection device (e.g., filter or bag house), dilute dust already in the air, or "scrub" (cleanse) dust from the air in the work area;
- Process enclosures that restrict dust from migrating outside of the enclosed area, sometimes used with an attached ventilation system to improve effectiveness (e.g., crushing equipment and associated dump hopper enclosure, with curtains and mechanical ventilation to keep dust inside);
- Operator enclosures, such as mobile equipment cabs or control booths, which provide an environment with clean air for an equipment operator to work safely;
- Protective features on mining process equipment to help prevent process failures and associated dust releases (e.g., skirtboards on conveyors, which protect the conveyor system from damage and prevent material on the conveyor from falling off, which generates airborne dust);
- Preventive maintenance conducted on engineering controls and mining equipment that can influence dust levels at a mine, to keep them functioning optimally; and

- Instrumentation and other equipment to assist mine operators and miners in evaluating engineering control effectiveness and recognizing control failures or other conditions that need corrective action.[51]

(2) Administrative controls

Administrative controls include practices that change the way tasks are performed to reduce a miner's exposure. Administrative controls can be very effective and can even prevent exposure entirely. MSHA has preliminarily determined that various administrative controls are readily available to provide supplementary support to engineering controls. Examples of administrative controls would include housekeeping procedures; proper work positions of miners; walking around the outside of a dusty process area rather than walking through it; cleaning of spills; and measures to prevent or minimize contamination of clothing to help decrease miners' exposure to respirable crystalline silica. However, these control methods depend on human behavior and intervention and are less reliable than properly designed, installed, and maintained engineering controls. Therefore, administrative controls would be permitted only as supplementary measures, with engineering controls required as the primary means of protection. Nevertheless, administrative controls play an important role in reducing miners' exposure to respirable crystalline silica.[52]

[51] These instruments include dust monitors; water, air, and differential air pressure gauges; pitot tubes and air velocity meters; and video camera (NIOSH recommends software that pairs video with a dust monitor to track conditions that could lead to elevated exposures if not corrected). These instruments are discussed in NIOSH's best practices guides and dust control handbooks.

[52] Proposed paragraph 60.11(b) prohibits the use of rotation of miners as an administrative control used for compliance with this part.

(3) Combinations of controls

Various control options can also be used in combinations. NIOSH has documented in detail most control methods and has confirmed that they are currently used in mines, both individually and in combination with each other (2019b, 2021a).

e. Maintenance

MSHA preliminarily finds that a strong and feasible preventive maintenance program plays an important role in achieving consistently lower respirable crystalline silica exposure levels. MSHA has observed that when engineering controls are installed and maintained in working condition, respirable dust exposures tend to be below the existing exposure limits. When engineering controls are not maintained, dust control efficiency declines and exposure levels rise. When engineering controls fail due to a lack of proper maintenance, a marked rise in exposures can occur, resulting in noncompliance with MSHA's existing exposure limits. Some examples of the impact that proper maintenance can have on respirable dust levels include:

- Water spray maintenance: An experiment using water spray bars that could be turned on or off showed that dust reduction was less effective each time additional spray nozzles were deactivated. A 10 percent decrease occurred when three of 21 sprays were shut off, but a 50 percent decrease occurred when 12 out of the 21 sprays were shut off. Decreased total water spray volume and gaps in the spray pattern (due to deactivated nozzles) were both partially responsible for the decreased dust control (Seaman *et al.,* 2020).
- Water added to drill bailing air: When introduced into the drill hole (with the bailing air through a hollow drill bit), water mixes with and moistens the drill dust ejected from the hole and can reduce respirable dust by more than 90% (NIOSH 2021a, 2019b). NIOSH reports that this same control measure, and others, are similarly effective for MNM and surface coal mine drills preparing the blasting holes used to expose the material below (whether ore or coal).

- Ventilation system maintenance: The amount of air cleaned by an air scrubber is decreased by up to one-third (33 percent) after one continuous mining machine cut. Cleaning the scrubber screens restores scrubber efficacy, but this maintenance must be performed after every cut. Spare scrubber screens make frequent cleaning practical without slowing production (NIOSH, 2021a).
- Operator enclosure maintenance: Tests with mining equipment showed that maintenance activities including repairing weather stripping and replacing clogged and missing cab ventilation system filters (intake, recirculation, final filters) increased miner protection, by up to 95 percent (NIOSH 2019b, 2021a).
- Filter selection during maintenance: Airflow is as important as filtration and pressurization in operator enclosures; during maintenance, filter selection can influence all three factors. Performing serial end-shift testing of enclosed cabs (on a face drill and a roof/rock bolter) at an underground crushed limestone mine, NIOSH compared installed HEPA filters and an alternative (MERV 16 filters). The latter provided an equal level of filtration and better overall miner protection by allowing greater airflow and cab pressurization. As an added advantage, NIOSH showed that these filters cost less and required less-frequent replacement, reducing maintenance expenses in this mining environment (Cecala *et al*., 2016; NIOSH 2021a, 2019b).[53, 54]
- Proper design and installation – foundation for effective maintenance: A new replacement equipment operator enclosure (control booth) installed adjacent to the primary crusher at a granite stone quarry initially provided 50 to 96 percent respirable

[53] NIOSH believes this study, like many of its other mining studies on operator enclosures and surface drill dust controls, is relevant to both MNM mining and coal mining. NIOSH reports on this study, conducted at an underground limestone mine, in detail in both its Dust control handbook for industrial minerals mining and processing (second edition) (2019b) and its best practices for dust control in coal mining (second edition) (2021a).

[54] Acronyms: High efficiency particulate air (HEPA). Minimum efficiency reporting value (MERV).

dust reduction, even with inadequate pressurization. The protection it offered miners tripled after the booth's second pressurization/filtration unit was activated (Organiscak *et al.*, 2016).

MSHA has observed that when engineering controls are properly maintained, exposure levels decrease or stay low. Metal mines, which typically have substantial controls already installed, primarily need reliable preventive maintenance programs to achieve the proposed PEL. It is also important to repair equipment damage that contributes to dust exposure (for example, damage to conveyor skirtboards that protect the conveyor system from damage and prevent spillage which generates airborne dust). Maintenance and repair programs must ensure that dust control equipment is functioning properly.

3. Feasibility Determination of Control Technologies

MSHA is proposing a PEL of 50 μg/m^3 for MNM and coal mines. As NIOSH has documented, the mining industry has a wide range of options for controlling dust exposure that are already in various configurations in mines (2019b; 2021a). NIOSH has carefully evaluated most of the dust controls used in the mining industry and found that many of the controls may be used in combinations with other control options. NIOSH has documented protective factors and exposure reductions of 30 to 90 percent or higher for many engineering and administrative controls.

MSHA also preliminarily finds that maintaining (including adjusting) or repairing existing controls would help achieve exposures at or below 50 μg/m^3. For example, NIOSH found that performing maintenance on an operator enclosure can restore enclosure pressurization and reduce the respirable dust exposure of a miner by 90 to 98.9 percent (e.g., by maintaining weather stripping, reseating or replacing leaking or clogged filters, and upgrading filtration) (NIOSH, 2019b). When an equipment operator remains inside a well-maintained enclosure for a portion of a shift (for example 75 percent of an 8-hour shift), the cab can reduce the exposure of the operator proportionally, to a level of 50 μg/m^3 (or lower). This point is demonstrated by the

following example involving a bulk loading equipment operator in a poorly maintained booth, exposed to respirable crystalline silica near the existing exposure limit (in the MNM sectors, 100 μg/m^3, as ISO 8-hour TWA value; in the Coal sector, 85.7 μg/m^3 ISO, calculated as an 8-hour TWA). During the 25 percent of their shift (two hours of an eight-hour shift) that the operator was working in the poorly maintained enclosure, their exposure would continue to be 100 μg/m^3, while for the other six hours (operating mobile equipment with a fully refurbished protective cab), the exposure level would be 90 percent lower, or 10 μg/m^3, resulting in an 8-hour TWA exposure of 33 μg/m^3 for that miner's shift.[55] Greater exposure reductions could also be achieved by repairing or replacing the poorly maintained enclosure, or modifying the miner's schedule so that the miner works seven hours, rather than six, inside of the well-maintained enclosure.

Other engineering controls (e.g., process enclosure, water dust suppression, dust suppression hopper, ventilation systems) could reduce dust concentrations in the area surrounding the poorly maintained enclosure, which would reduce the exposure of the operator inside. For example, if the poorly maintained enclosure was an open-air control booth (windows do not close) at a truck loading station, adding a dust suppression hopper (which reduces respirable dust exposure by 39 to 88 percent during bulk loading) (NIOSH, 2019b), would lead to lower exposure during the two hours the miner was inside the open-air booth. The calculated respirable crystalline silica 8-hour TWA exposure of that miner could be reduced from 33 μg/m^3 (with improved operator enclosure alone) to 23 μg/m^3 (improved operator enclosure plus dust

[55] Calculating the exposure for the shift: 8-hour TWA = [(10 μg/m^3 x 6 hours) + (100 μg/m^3 x 2 hours)] / 8 hours = 33 μg/m^3.

suppression hopper). [56] As an added benefit, any helper or utility worker in the truck loading area would also experience reduced exposure.

Similarly, considering an example for a coal miner helper who spends 90 minutes (1.5 hours) per 8-hour shift assisting a drilling rig operator (in a protective operator's cab) drilling blast holes. The combination of controls used to control drilling dust (including water added to the bailing air, which can reduce airborne respirable dust emissions by up to 96 percent) usually maintain the helper's respirable crystalline silica exposure in the range of 35 $\mu g/m^3$ (ISO) as an 8-hour TWA. If, however, the drill's on-board water tank runs dry due to poor maintenance, the respirable crystalline silica concentration near the drill will rise by 95 percent, meaning that the concentration is 20 times greater than the usual level (NIOSH 2021a). If the drill operator idles the drill and calls for water resupply, the helper will not experience an elevated exposure. If instead the drill is operated dry for another 30 minutes until water resupply arrives, the helper will experience a respirable crystalline silica exposure of 77 $\mu g/m^3$ (ISO) as an 8-hour TWA. If dry drilling continued for 1.5 hours, the helper would have an exposure of 160 $\mu g/m^3$ ISO as an 8-hour TWA.[57] After water is delivered, drill respirable dust emissions will return to their normal level once water is again introduced into the drill bailing air.

Based on these examples and the wide range of effective exposure control options available to the mining industry, MSHA preliminarily finds that control technologies capable of reducing miners' respirable crystalline silica exposures are available, proven, effective, and

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[56] Calculating the exposure with both the well-maintained operator enclosure (6 hours) and dust suppression hopper, assuming only the minimum documented respirable dust concentration reduction (39 percent): [(10 $\mu g/m^3$ x 6 hours) + (100 $\mu g/m^3$ x (1- 0.39) x 2 hours)] / 8 hours = 23 $\mu g/m^3$.

[57] The 8-hour TWA exposure level of the helper, including the 30-minute period of elevated exposure, is calculated as: [(35 $\mu g/m^3$ x 7.5 hours) + (35 $\mu g/m^3$ x 20 x 0.5 hours)]/8 hours = 77 $\mu g/m^3$. Drill bits designed for use with water may need to be replaced sooner if used dry.

transferable between mining commodities; however, they must be well-designed and consistently used and maintained.

a. Feasibility Findings for the Proposed PEL

Based on the exposure profiles in Table VIII-2 and Table VIII-3 for MNM mines, and in Table VIII-4 and VIII-5 for coal mines, and the examples in the previous section that demonstrate the beneficial effect of combined controls, MSHA preliminarily finds that the proposed PEL of 50 µg/m^3 is technologically feasible for all mines.

Table VIII-7 summarizes the technological feasibility of control technologies available to the mining industry, by commodity. MSHA preliminarily finds that control technologies are technologically feasible for all six commodities and their respective activity groups. Under baseline conditions, mines in each commodity category have already achieved respirable crystalline silica exposures at or below 50 µg/m^3 for most of the miners represented by MSHA's 57,769 samples for MNM miners and 63,127 samples for coal miners.

Table VIII-7. Summary of Technological Feasibility of Control Technologies in the Mining Industry, by Commodity, Indicating Activity Groups Affected by Respirable Crystalline Silica Exposures

Commodity category	% samples ≤ 50 µg/m^3	Total number of affected activity groups [a]	Number of activity groups for which the proposed PEL is achievable with engineering and administrative controls [b, c]	Number of activity groups for which the proposed PEL is NOT achievable with engineering and administrative controls	Feasibility finding, by commodity category
Metal	73	4	4	0	Feasible
Nonmetal	86	4	4	0	Feasible
Stone	79	4	4	0	Feasible
Crushed limestone	90	4	4	0	Feasible
Sand and Gravel	79	4	4	0	Feasible
Coal (under-ground and surface) [d]	93	7	7	0	Feasible
Overall	--	27	100%	0%	Feasible

Notes:

a) Activity groups include 1) production and development miners; 2) ore/mineral processing miners; 3) miners engaged in load/haul/dump activities; and 4) miners in all other occupations.

b) Engineering controls include wetting and water sprays, ventilation systems, enclosure of dusty processes, and operator enclosures (equipment cabs and control booths). For the purposes of this table, effective maintenance is also an engineering control.

Table VIII-7. Summary of Technological Feasibility of Control Technologies in the Mining Industry, by Commodity, Indicating Activity Groups Affected by Respirable Crystalline Silica Exposures

Commodity category	% samples ≤ 50 µg/m³	Total number of affected activity groups [a]	Number of activity groups for which the proposed PEL is achievable with engineering and administrative controls [b, c]	Number of activity groups for which the proposed PEL is NOT achievable with engineering and administrative controls	Feasibility finding, by commodity category

c) Administrative controls encompass both mine operator policies and miner work practices, such as written operating procedures, miner training, keeping operator enclosure door and windows closed to exclude dust; or walking around, rather than through a dusty area.

d) Coal mines include three activity groups underground and four surface activity groups.

b. Feasibility Findings for the Proposed Action Level

MSHA believes that mine operators can achieve exposure levels at or below the proposed action level of 25 µg/m³, for most miners by implementing additional engineering controls and more flexible and innovative administrative controls, in addition to the existing control methods already discussed in this technological feasibility analysis. MSHA notes that the exposure profiles in Table VIII-2 and Table VIII-3 for MNM mines, and Table VIII-4 and VIII-5 for coal mines indicate that mine operators have already achieved the proposed action level for at least half of the miners who MSHA has sampled in each commodity category. However, to do so reliably for all miners, operators would need to upgrade equipment and facility designs, particularly in mines with higher respirable crystalline silica concentrations, that may be due to an elevated silica content in materials.

One control option would be increased automation, such as expanding the use of existing autonomous or remote-controlled drilling rigs, roof bolters, stone cutting equipment, and packaging/bagging equipment. This type of automation can reduce exposures by increasing the distance between the equipment operator and the dust source. Other options include completely enclosing most processes and ventilating the enclosures with dust extraction equipment or controlling the speed of mining equipment (e.g., longwall shearers, conveyors, dump truck emptying) and process equipment (e.g., crushers, mills) to reduce turbulence that increases dust concentrations in air. Additionally, where compatible with the material, exposure levels can be

reduced by increased wetting to constantly maintain the material, equipment, and mine facility surfaces damp through added water sprays and frequent housekeeping (i.e., hosing down surfaces as often as necessary). In addition, vacuuming will minimize the amount of dust that becomes airborne and prevent dust that does settle on a surface from being resuspended in air.

Mines that only occasionally work with higher-silica-content materials may not be equipped with the controls required to achieve the proposed action level of 25 $\mu g/m^3$, or they may not currently have procedures to ensure miners are protected when they do work with these materials. Examples of these activities include cutting roof or floor rock with a continuous mining machine in underground coal mines; packaging operations that involve materials from an unfamiliar supplier, including another mine; and rebuilding or repairing kilns. To address these activities, under the proposed rule, mine operators would have to add engineering controls to address any foreseeable respirable crystalline silica overexposures. Examples of additional controls include pre-testing batches of new raw materials; improving hazard communication when batches of incoming raw materials contain higher concentrations of crystalline silica, and augmenting enclosure and ventilation (e.g., adding ventilation to all crushing and screening equipment, increasing mine facility ventilation to 30 air changes per hour, and fully enclosing and ventilating all conveyor transfer locations). NIOSH (2019b, 2021a) describes all of the dust control methods described in this section, which are already used in mines, although to a less rigorous extent than would be necessary to reliably achieve exposure levels of 25 $\mu g/m^3$ or lower for all miners.

MSHA preliminarily finds that the proposed action level of 25 $\mu g/m^3$ is technologically feasible for most mines. This finding is based on the exposure profiles, presented in Table VIII-2 and Table VIII-3 for MNM mines, and Table VIII-4 and VIII-5 for coal mines, which shows that within each commodity category, the exposure levels are at or below 25 $\mu g/m^3$ for at least half of the miners sampled. MSHA's finding is also based on the extensive control options documented by NIOSH, which can be used in combinations to achieve additional control of

respirable crystalline silica. Although most mines would need to adopt and rigorously implement a number of the control options mentioned in this section, the technology exists to achieve this level and is already in use in mines.

C. Technological Feasibility of Respiratory Protection (within Proposed Part 60)

Under the proposed rule, respiratory protection would only be allowed for temporary, non-routine use. MSHA has preliminarily determined that it is technologically feasible to limit respirator use to temporary, non-routine activities based on the Agency's knowledge of and experience with the mining industry, evidence presented by NIOSH (2019b, 2020a), and Tables VIII-2 through VIII-5 (exposure profiles for MNM and coal mines). These tables indicate that the proposed PEL (50 $\mu g/m^3$) has already been achieved for approximately 82 percent of the MNM miners and approximately 93 percent of the coal miners sampled by MSHA.

Proposed § 60.14(b) requires that any miner unable to wear a respirator must receive a temporary job transfer to an area or to an occupation at the same mine where respiratory protection is not required. The proposed paragraph would also require that an affected miner continue to receive compensation at no less than the regular rate of pay in the occupation held by that miner immediately prior to the transfer. MNM mine operations have complied with the job transfer provisions under the existing standard in § 57.5060(d)(7) that states miners unable to wear a respirator must be transferred to work in an existing position in an area of the mine where respiratory protection is not required. Proposed § 60.14(b) is similar to these existing requirements. MSHA anticipates that mine operators would have a similar experience implementing the job transfer provisions of proposed § 60.14(b). Therefore, MSHA preliminarily finds that the proposed requirement in § 60.14(b) is technologically feasible.

For miners who would need to wear respiratory protection on a temporary and non-routine basis, proposed § 60.14(c)(1) would require the mine operator to provide NIOSH-approved atmosphere-supplying respirators or NIOSH-approved air-purifying respirators equipped with high-efficiency particulate filters in one of the following NIOSH classifications

under 42 CFR part 84: 100 series or High Efficiency (HE). As previously discussed, MSHA preliminarily finds that particulate respirators meeting these criteria would offer the best filtration efficiency (99.97 percent) and protection for miners exposed to respirable crystalline silica and are widely available and used by most industries. This finding is based on the suitability of the three particulate classifications for respirable size particle filtration and the broad commercial availability of these NIOSH-approved particulate respirators.[58] NIOSH publishes a list of approved respirator models along with manufacturer/supplier information. In November 2022, the NIOSH-approved list contained 221 records on atmosphere-supplying respirator models, 160 records on elastomeric respirators with P-100 classification, and 23 records on filtering facepiece respirators with P-100 classification (NIOSH, 2022 list P-100 elastomeric, P-100 filtering facepiece, and atmosphere-supplying respirator models).[59] Based on this information, MSHA preliminarily finds that proposed § 60.14(c)(1) is technologically feasible.

Proposed § 60.14(c)(2) would incorporate the *ASTM F3387-19 "Standard Practice for Respiratory Protection"* to ensure that the most current and protective respiratory protection practices would be implemented by operators who temporarily use respiratory protection to control miners' exposures to respirable crystalline silica. The Agency is also incorporating this respiratory protection consensus standard under §§ 56.5005, 57.5005, and 72.710. This proposed update is also addressed in the next section (see Technological feasibility of updated respiratory

[58] Class 100 particulate respirators (currently the most widely used respirator filter specification in the U.S.) are available from numerous sources including respirator manufacturers, online safety supply companies, mine equipment suppliers, and local retail hardware stores.

[59] The NIOSH list of approved models does not guarantee that each model is currently manufactured. However, the list does not include obsolete models, and the more popular models are widely available, including in bulk quantities.

protection standards). Based on the information contained in that section, MSHA preliminarily finds that the proposed § 60.14(c)(2) is technologically feasible.

Based on information contained in this section, MSHA preliminarily finds that proposed § 60.14 is technologically feasible.

D. Technological Feasibility of Updated Respiratory Protection Standards (Amendments to 30 CFR parts 56, 57, and 72)

1. Incorporation by Reference

Respirators are commonly used by miners as a means of protection against a multitude of respiratory hazards, including particulates, gases, and vapors. Respirators are needed in immediately life-threatening (i.e., IDLH) situations as well as operations where engineering controls and administrative controls do not provide sufficient protection against respiratory hazards. Where respirators are used, they must seal and isolate the miner's respiratory system from the contaminated environment. The risk that a miner will experience an adverse health effect from a contaminant when relying on respiratory protection is a function of the toxicity or hazardous nature of the air contaminants present, the concentrations of the contaminants in the air, the duration of exposure, and the degree of protection provided by the respirator. When respirators fail to provide the proper protection, there is an increased risk of adverse health effects. Therefore, it is critical that respirators perform as they are designed.

Accordingly, MSHA is proposing to incorporate by reference ASTM F3387-19 under 30 CFR 56.5005, 30 CFR 57.5005, and 30 CFR 72.710. With this action, the Agency intends to assist mine operators in developing effective respiratory protection practices and programs that meet current industry standards. This proposed revision would better protect miners who temporarily wear respiratory protection.

The *American National Standards Practices for Respiratory Protection ANSI Z88.2-1969* is currently incorporated by reference in 30 CFR 56.5005, 30 CFR 57.5005, and 30 CFR

72.710.[60] Since MSHA issued these standards, respirator technology and knowledge on respirator protection have advanced and as a result, changes in respiratory protection standard practices have occurred. ASTM F3387-19 is based on the most recent consensus standard and provides more comprehensive and detailed guidance. MSHA believes that most mines that use respiratory protection are already following current respiratory protection practices and standards such as ANSI/ASSE Z88.2 – 2015 "*Practices for Respiratory Protection*" standard, its similar ASTM replacement (the F3387-19 standard), or OSHA 29 CFR 1910.134 – *Respiratory protection*. ASTM F3387-19 standard practices are substantially similar to the standard practices included in ANSI/ASSE Z88.2-2015 or OSHA's respiratory standards.

2. Availability of Respirators

The updated respiratory protection standard reflects current practice at many mines that currently use respiratory protection and does not require the use of new technology. Thus, MSHA preliminarily finds that the proposed update is technologically feasible for affected mines of all sizes.

3. Respiratory Protection Practices

By incorporating the updated respiratory protection consensus standard (ASTM F3387-19), MSHA intends that mine operators would develop effective respiratory protection practices that meet the updated consensus standard and that would better protect miners from respirable hazards not yet controlled by other methods.

MSHA presumes that most mines with respiratory protection programs, and particularly those MNM mines that have operations under both MSHA and OSHA jurisdiction, are already following either the ANSI/ASSE Z88.2 – 2015 standard, the ASTM F3387-19 standard, or

[60] ASTM 3387-19 is the revised version of ANSI/ASSE Z88.2-2015. In 2017, the Z88 respirator standards were transferred from ANSI/ASSE to ASTM International (source: F3387-19, Appendix XI).

OSHA 1910.134. The respiratory protection program elements under ASTM F3387-19 are largely similar to those in the existing standard.

MSHA expects that some operators may need to adjust their current respiratory protection practices and standard operating procedures to reflect ASTM F3387-19 standard practices. Examples of adjustments include formalizing fit testing and respirator training annually; updating the training qualifications of respirator trainers, managers, supervisors, and others responsible for the respiratory protection program; reviewing the information exchanged with the physician or other licensed health care professional (PLHCP); and formalizing internal and external respiratory protection program reviews or audits.

Overall, MSHA preliminarily finds that the proposed amendments to existing parts 56, 57, and 72 are technologically feasible because the requirements of ASTM F3378-19 are already implemented at some mines.

E. Technological Feasibility of Medical Surveillance (within Proposed Part 60)

Under the proposed rule, mine operators would be required to provide periodic medical examinations for each MNM miner, at no cost to the miner. The proposed medical surveillance standards would extend to MNM miners similar protections available to coal miners under 30 CFR 72.100. The requirements in proposed § 60.15 are consistent with the Mine Act's mandate to provide maximum health protection for miners.

Under the proposed standards, MNM miners new to the mining industry would receive an initial examination, within 30 days. If they are not new to mining, they are categorized as belonging to a group of workers who are eligible for an examination every 5 years. Workers who are new to mining, after they have their initial examination, would be provided another follow-up examination within 3 years. If the 3-year follow-up examination indicates any medical concerns associated with chest X-ray findings or decreased lung function, these miners are eligible to have another follow-up exam in 2 years. After this additional 2-year follow-up exam, or if the 3-year follow-up examination indicates no medical concerns associated with chest

X-ray findings or decreased lung function, these miners will enter the category of miners eligible for periodic 5-year exams.

MSHA is proposing that medical examinations would be performed by a PLHCP or specialist. A medical examination would include a review of the miner's medical and work history and physical examination. The medical and work history would cover a miner's present and past work exposures, illnesses, and any symptoms indicating respirable crystalline silica-related diseases and compromised lung function. The medical examination would include a chest X-ray. The required chest X-ray would be required to be classified by a NIOSH-certified B Reader, in accordance with the Guidelines for the Use of the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses. The ILO recently made additional standard digital radiographic images available and has published guidelines on the classification of digital radiographic images (ILO 2022). These guidelines provide standard practices for detecting changes of pneumoconiosis, including silicosis, in chest X-rays. The proposed rule would also require spirometry test be part of the medical examination.

MSHA has preliminarily determined that it is technologically feasible for MNM mine operators to provide periodic examinations. The procedures required for initial and periodic medical examination are commonly conducted in the general population (i.e., medical history, physical examination, chest X-ray, spirometry test) by a wide range of practitioners with varying medical backgrounds. Because the proposed medical examinations consist of procedures conducted in the general population and because MSHA would be giving MNM mine operators maximum flexibility in selecting a PLHCP who would be able to offer these services, MSHA anticipates that operators would not experience difficulty in finding PLHCPs who are licensed to provide these services.

In addition, in the case of classifying chest X-rays, MSHA has preliminarily determined that the availability of digital X-ray technology allows for electronic submission to remotely located B Readers for interpretation; therefore, MSHA anticipates that the limited number of B

Readers in certain geographic locations would not be an obstacle for MNM operators. Overall, MSHA preliminarily finds that the proposed medical surveillance provisions are technologically feasible.

F. Conclusions

Based on MSHA's technological feasibility analysis, MSHA has determined that all elements of the proposed rule on *Lowering Miners' Exposure to Respirable Crystalline Silica and Improving Respiratory Protection* are technologically feasible.

IX. Summary of Preliminary Regulatory Impact Analysis and Regulatory Alternatives

A. Introduction

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. E.O.s 12866 and 13563 require that regulatory agencies assess both the costs and benefits of regulations.

A regulatory action is considered "significant" if it is likely to "have an annual effect on the economy of $200 million or more…" under E.O. 12866 Section 3(f)(1), as amended by E.O. 14094. The proposed rule "Lowering Miners' Exposure to Respirable Crystalline Silica and Improving Respiratory Protection" is a significant rule. To comply with E.O.s 12866 and 13563, MSHA has prepared a standalone PRIA for this proposed rule. A summary of the PRIA is presented below. The standalone PRIA contains detailed supporting data and explanation for the summary materials presented here, including the mining industry, costs and benefits, and economic feasibility. The standalone PRIA can be accessed electronically at http://www.msha.gov and has been placed in the rulemaking docket at www.regulations.gov, docket number MSHA-2023-0001. MSHA requests comments on all estimates of costs and

benefits presented in this PRIA and on the data, assumptions, and methodologies the Agency used to develop the cost and benefit estimates.

B. Miners and Mining Industry

The proposed rule would affect mine operators and miners. This section provides information on the structure of the Metal/Nonmetal (MNM) and coal mining industries, including the revenue, number, employment by commodity and size; economic characteristics of MNM and coal mines; and the respirable crystalline silica exposure profiles for miners across different occupations in the MNM and coal industry. The data come from the U.S. Department of the Interior (DOI), U.S. Geological Survey (USGS); U.S. Department of Labor (DOL), Mine Safety and Health Administration (MSHA), Educational Policy and Development and Program Evaluation and Information Resources; the Statistics of US Businesses (SUSB); and the Energy Information Administration (EIA).

1. Structure of the Mining Industry

The mining industry can be divided into two major sectors based on commodity: (1) Metal/Nonmetal mines (hereafter referred to as MNM mines) and (2) coal mines with further distinction made regarding type of operation (e.g., underground coal mines or surface coal mines). The MNM mining sector is made up of metal mines (copper, iron ore, gold, silver, etc.) and nonmetal mines. Nonmetal mines can be categorized into four commodity groups: (1) nonmetal (mineral) materials such as clays, potash, soda ash, salt, talc, and pyrophyllite; (2) sand and gravel, including industrial sand; (3) stone including granite, limestone, dolomite, sandstone, slate, and marble; and (4) crushed limestone.

MSHA categorizes mines by size based on employment. For purposes of this industry profile, MSHA has categorized mines into the following four groups for analytical purposes[61] -

[61] Miner employment is based on the information submitted quarterly through the MSHA Form 7000-2, excluding Subunit 99 – Office (professional and clerical employees at the mine or plant working in an office); https://www.msha.gov/sites/default/files/Support_Resources/Forms/7000-2_0.pdf

mines that employ: (1) 1-20 miners (Emp ≤20); (2) 21 to 100 miners (20 < Emp ≤ 100); (3) 101 to 500 miners (100 < Emp ≤500); and (4) 501 or more miners (500 < Emp).

MSHA tracks mine characteristics and maintains a database containing the number of mines by commodity and size, number of employees, and employee hours worked. MSHA also collects data on the number of mining contractors, their employees, and employee hours. While contractors are issued a unique MSHA contractor identification number, they may work at any mine.

Table IX-1 presents an overview of the mining industry, including the number of MNM and coal mines, their employment, excluding contractors, and revenues by commodity and size. All data are current in reference to the year 2019. In 2019, the MNM mining sector of 11,525 mines employed 169,070 individuals, of which 150,928 were miners and 18,142 were office workers. There were 1,106 coal mines that reported production and that employed 52,966 individuals, of which 51,573 were miners and 1,393 were office workers.

Table IX-1. Profile of MNM and Coal Mines, by Mine Size, 2019

Mine Category	Range by Miner Employment	Revenues [a]		Number of Mines		Production Employees		Production Hours (thousands)		Total Employment	
		Millions in $ 2019	%	No.	%	No.	%	No.	%	No.	%
Metal	Emp <= 20	$504.7	*1.9%*	157	*56.1%*	851	*2.3%*	1,433.8	*1.9%*	999	*2.5%*
Metal	20 < Emp <= 100	$1,380.4	*5.1%*	39	*13.9%*	1,947	*5.3%*	3,921.3	*5.1%*	2,251	*5.6%*
Metal	100 < Emp <= 500	$11,298.0	*42.0%*	62	*22.1%*	15,060	*40.7%*	32,094.2	*42.0%*	16,508	*40.7%*
Metal	500 > Emp	$13,716.8	*51.0%*	22	*7.9%*	19,168	*51.8%*	38,965.3	*51.0%*	20,771	*51.2%*
Metal	***Total***	***$26,900.0***	***100.0%***	***280***	***100.0%***	***37,026***	***100.0%***	***76,414.7***	***100.0%***	***40,529***	***100.0%***
Non-Metal	Emp <= 20	$3,218.6	*14.4%*	645	*71.9%*	3,694	*16.3%*	6,397.5	*14.4%*	4,237	*16.6%*
Non-Metal	20 < Emp <= 100	$8,957.7	*40.1%*	207	*23.1%*	8,921	*39.3%*	17,805.0	*40.1%*	10,065	*39.3%*
Non-Metal	100 < Emp <= 500	$8,296.8	*37.1%*	42	*4.7%*	8,220	*36.2%*	16,491.4	*37.1%*	9,163	*35.8%*
Non-Metal	500 > Emp	$1,872.3	*8.4%*	3	*0.3%*	1,845	*8.1%*	3,721.6	*8.4%*	2,134	*8.3%*
Non-Metal	***Total***	***$22,345.4***	***100.0%***	***897***	***100.0%***	***22,680***	***100.0%***	***44,415.4***	***100.0%***	***25,599***	***100.0%***
Stone	Emp <= 20	$3,653.3	*28.5%*	2,002	*83.1%*	11,198	*31.7%*	20,035.5	*28.5%*	12,563	*31.5%*
Stone	20 < Emp <= 100	$5,623.9	*43.8%*	339	*14.1%*	14,779	*41.9%*	30,842.4	*43.8%*	16,824	*42.2%*
Stone	100 < Emp <= 500	$3,357.2	*26.2%*	67	*2.8%*	8,762	*24.8%*	18,411.6	*26.2%*	9,896	*24.8%*
Stone	500 > Emp	$200.4	*1.6%*	1	*0.0%*	539	*1.5%*	1,098.8	*1.6%*	602	*1.5%*
Stone	***Total***	***$12,834.8***	***100.0%***	***2,409***	***100.0%***	***35,278***	***100.0%***	***70,388.3***	***100.0%***	***39,885***	***100.0%***
Crushed Limestone	Emp <= 20	$5,836.3	*45.8%*	1,555	*83.5%*	11,771	*48.8%*	22,834.9	*45.8%*	13,495	*49.7%*
Crushed Limestone	20 < Emp <= 100	$5,790.4	*45.5%*	293	*15.7%*	10,480	*43.5%*	22,655.5	*45.5%*	11,641	*42.9%*
Crushed Limestone	100 < Emp <= 500	$1,102.4	*8.7%*	14	*0.8%*	1,856	*7.7%*	4,313.4	*8.7%*	2,002	*7.4%*
Crushed Limestone	500 > Emp	$0.0	*0.0%*	0	*0.0%*	0	*0.0%*	0.0	*0.0%*	0	*0.0%*
Crushed Limestone	***Total***	***$12,729.1***	***100.0%***	***1,862***	***100.0%***	***24,107***	***100.0%***	***49,803.8***	***100.0%***	***27,138***	***100.0%***
Sand and Gravel	Emp <= 20	$6,267.5	*69.7%*	5,879	*96.7%*	23,887	*75.0%*	39,673.3	*69.7%*	27,262	*75.9%*
Sand and Gravel	20 < Emp <= 100	$2,284.3	*25.4%*	188	*3.1%*	6,703	*21.1%*	14,459.5	*25.4%*	7,320	*20.4%*
Sand and Gravel	100 < Emp <= 500	$438.8	*4.9%*	10	*0.2%*	1,247	*3.9%*	2,777.6	*4.9%*	1,337	*3.7%*
Sand and Gravel	500 > Emp	$0.0	*0.0%*	0	*0.0%*	0	*0.0%*	0.0	*0.0%*	0	*0.0%*
Sand and Gravel	***Total***	***$8,990.7***	***100.0%***	***6,077***	***100.0%***	***31,837***	***100.0%***	***56,910.5***	***100.0%***	***35,919***	***100.0%***
MNM Total	**Emp <= 20**	**$19,480.5**	***23.2%***	**10,238**	***88.8%***	**51,401**	***34.1%***	**90,375.0**	***30.3%***	**58,556**	***34.6%***
MNM Total	**20 < Emp <= 100**	**$24,036.7**	***28.7%***	**1,066**	***9.2%***	**42,830**	***28.4%***	**89,683.7**	***30.1%***	**48,101**	***28.5%***
MNM Total	**100 < Emp <= 500**	**$24,493.3**	***29.2%***	**195**	***1.7%***	**35,145**	***23.3%***	**74,088.3**	***24.9%***	**38,906**	***23.0%***
MNM Total	**500 > Emp**	**$15,789.5**	***18.8%***	**26**	***0.2%***	**21,552**	***14.3%***	**43,785.7**	***14.7%***	**23,507**	***13.9%***
MNM Total	***Total***	***$83,800.0***	***100.0%***	***11,525***	***100.0%***	***150,928***	***100.0%***	***297,932.6***	***100.0%***	***169,070***	***100.0%***
Coal	Emp <= 20	$1,007.5	*3.9%*	707	*63.9%*	4,358	*8.5%*	9,077.4	*7.7%*	4,611	*8.7%*
Coal	20 < Emp <= 100	$3,225.6	*12.6%*	271	*24.5%*	11,814	*22.9%*	27,591.7	*23.5%*	12,145	*22.9%*
Coal	100 < Emp <= 500	$14,414.9	*56.2%*	116	*10.5%*	26,145	*50.7%*	59,897.7	*51.0%*	26,818	*50.6%*
Coal	500 > Emp	$7,001.6	*27.3%*	12	*1.1%*	9,256	*17.9%*	20,962.2	*17.8%*	9,392	*17.7%*
Coal	***Total***	***$25,649.6***	***100.0%***	***1,106***	***100.0%***	***51,573***	***100.0%***	***117,529.0***	***100.0%***	***52,966***	***100.0%***

[a] Coal Revenues were calculated using MSHA Production Figures in Short Tons by Rank: 650.3 million tons Bituminous Coal, 53.2 million tons Lignite Coal, 2.6 million tons Anthracite Coal; and EIA price's per short ton by Coal Rank: EIA Annual Coal Report 2019; Table 31 Average Sales Price of Coal by State And Rank, 2019; US Total: $58.93/ton Bituminous Coal, $19.86/ton Lignite Coal, $102.22/ton Anthracite Coal; https://www.eia.gov/coal/annual/archive/0584_2019.pdf. The revenues for MNM commodities are calculated by applying the proportion of revenues represented by each commodity among all MNM commodities in the 2017 SUSB data and applying that proportion to the 2019 production value for all industrial minerals reported by USGS.

a. Metal Mining

There are 24 groups of metal commodities mined in the U.S. Metal mines, which represent about 2.4 percent (280 out of 11,525) of all MNM mines and employ roughly 24.5 percent of all MNM miners. Of these 280 mines, 157 employ 20 or fewer miners and 22 employ greater than 500 miners. Additionally, the 2019 MSHA data show that there are a total of 13,792 contract miners in the metal mining industry.

b. Non-Metal (mineral) Mining

Thirty-five non-metal commodities are mined in the U.S., not including stone, and sand and gravel. Non-metal mines represent about 7.8 percent of all MNM mines and employ roughly 15 percent of all MNM miners. The majority of non-metal mines (71.9 percent) employ fewer than 20 miners and less than 1 percent employ more than 500 employees. In 2019, there were 11,346 contract miners in the non-metal mining industry.

c. Stone Mining

The stone mining subsector includes eight different stone commodities. Seven of the eight are further classified as either dimension stone or crushed and broken stone. Stone mines make up 20.9 percent of all MNM mines and employ 23.4 percent of all MNM miners. The majority of these mines (83.1 percent) employ less than 20 miners. In 2019, there were 18,559 contract miners in the stone mining industry.

d. Crushed Limestone

Crushed limestone mines make up 16.2 percent of all MNM mines and employ about the same percentage (16.0 percent) of all MNM miners. Of the 1,862 crushed limestone mines, 83.5 percent employ fewer than 20 miners, and there are no crushed limestone mines that employ over 500 miners. In 2019, there were 9,605 contract miners in the crushed limestone mining industry.

e. Sand and Gravel Mining

Sand and gravel mines account for 52.7 percent of all MNM mines and employ 21.1 percent of all MNM miners. Nearly all (96.7 percent) of these mines employ fewer than 20 employees. In 2019, MSHA data show that there were 7,512 contract miners in the sand and gravel mining industry.

f. Coal

In the coal sector, 707 mines (63.9 percent) employed fewer than 20 miners. Overall, coal mine employment in 2019 was 52,966, of which 51,573 were miners and the remaining 1,393 were office workers. Additionally, there were a total of 22,003 contract miners in the coal mining industry in 2019.

2. Economic Characteristics of the Metal/Non-Metal Mining Industry

The value of all MNM mining output in 2019 was estimated at $83.8 billion (U.S. Department of Interior, 2019). Metal mines, which include iron, gold, copper, silver, nickel, lead, zinc, uranium, radium, and vanadium mines, contributed $26.9 billion. In the USGS Mineral Commodity Summaries, nonmetals, stone, sand and gravel, and crushed limestone are combined in to one commodity group called industrial minerals. MSHA estimated the production value of each individual commodity by applying the proportion of revenues represented by each among all commodities in the SUSB and applying that proportion to the 2019 production value for all industrial minerals reported by USGS. This approach yielded the following estimates: metal production was valued at $26.9 billion, non-metal production at $22.3 billion, stone mining at $12.85 billion, sand and gravel at $9.0 billion, and crushed limestone at $12.7 billion.

Production in the U.S. coal sector amounted to 706.1 million tons in 2019.[62] To estimate coal revenues in 2019, MSHA combined production estimates with prices per ton. Mine

[62] Source: MSHA MSIS Data (reported on MSHA Form 7000-2).

production data was taken from MSHA quarterly data and the coal price per ton was taken from the 2019 EIA Annual Coal Report. As shown in Table IX-1, total coal revenues in 2019 equaled $25.6 billion.

The U.S. coal mining sector produces three major types of coal: bituminous, lignite, and anthracite. According to MSHA data, bituminous operations account for approximately 92.1 percent of total coal production in short tons, and 91.9 percent of all coal miners. Lignite operations account for roughly 7.5 percent of total coal production and 6.2 percent of coal miners. Anthracite operations account for 0.4 percent of coal production and 1.9 percent of coal miners.

C. Cost-Benefit Analysis

The PRIA is based on MSHA's Preliminary Risk Analysis and the Technological Feasibility analysis. The PRIA presents estimated benefits and costs of the proposed rule for informational purposes only. Under the Mine Act, MSHA is not required to use estimated net benefits as the basis for its decision. MSHA requests comments on the methodologies, baseline, assumptions, and estimates presented in the PRIA and also asks for any data or quantitative information that may be useful in evaluating the estimated costs and benefits associated with the proposed rule. The PRIA assesses the costs and benefits in the MNM and coal industries of reducing miners' exposures to silica to 50 $\mu g/m^3$ for a full shift, calculated as an 8-hour time weighted average (TWA) and of complying with the standard's ancillary requirements. The PRIA also assesses the costs and benefits from requiring medical surveillance of MNM miners. It also assesses the costs and benefits from revising the existing respiratory protection standards. MSHA is proposing to incorporate by reference ASTM F3387-19, "Standard Practice for Respiratory Protection" (ASTM F3387-19). ASTM F3387-19 would replace the 1969 American National Standards Institute (ANSI) "Practices for Respiratory Protection."

MSHA estimates the proposed rule would have an annualized cost of $57.6 million in 2021 dollars at a real discount rate of 3 percent. Of this cost, over 55 percent is attributable to

exposure monitoring; 30 percent to medical surveillance; 10 percent to engineering, improved maintenance and repair, and administrative controls; 2.4 percent related to the selection, use, and maintenance of approved respirators in accordance with ASTM F3387-19, respiratory protection practices; and 1.8 percent to additional respiratory protection (e.g., when miners need temporary respiratory protection from exposure at the proposed PEL when it would not have been necessary at the existing PEL). MSHA further estimates that the MNM sector will incur $52.7 million (91 percent), and the coal sector will incur $4.9 million (9 percent) in annualized compliance costs (see Table IX-2).

Table IX-2. Summary of Estimated Compliance Costs by Provision and Commodity, 2021 (in Millions of 2021 $)

Provision or Sector	Number of Mines	0 Percent Real Discount Rate		3 Percent Real Discount Rate		7 Percent Real Discount Rate	
		Annualized Cost	Percent	Annualized Cost	Percent	Annualized Cost	Percent
All Mines by Provision							
Exposure Monitoring		$30.60	54.5%	$32.02	55.6%	$34.30	57.3%
Exposure Controls		$5.65	10.1%	$5.75	10.0%	$5.90	9.9%
Respiratory Protection		$1.03	1.8%	$1.03	1.8%	$1.03	1.7%
Medical Surveillance		$17.49	31.2%	$17.37	30.2%	$17.20	28.7%
Subtotal, Part 60 Costs		*$54.76*	*97.6%*	*$56.17*	*97.6%*	*$58.43*	*97.6%*
ASTM 2019		$1.36	2.4%	$1.40	2.4%	$1.46	2.4%
Total, All Mines	***12,631***	***$56.12***	***100.0%***	***$57.57***	***100.0%***	***$59.89***	***100.0%***
All Mines by Sector							
Total, All Mines	***12,631***	***$56.12***	***100.0%***	***$57.57***	***100.0%***	***$59.89***	***100.0%***
Metal/Nonmetal, Total	11,525	$51.31	91.4%	$52.67	91.5%	$54.85	91.6%
Coal, Total	1,106	$4.81	8.6%	$4.90	8.5%	$5.04	8.4%

Note: Medical surveillance cost is the average cost under the assumed participation rates of 75 percent and 25 percent.

In its analysis, MSHA annualizes all costs using 3 percent and 7 percent discount rates as recommended by OMB. MSHA bases the annualization periods for expenditures on equipment life cycles and primarily uses a 10-year annualization period for one-time costs and 20-year for medical surveillance. However, MSHA annualizes the benefits of the proposed rule over a 60-year period to reflect the time needed for benefits to reach the steady-state values projected in

MSHA's PRA. Therefore, MSHA's complete analysis of this rule is 60 years (which corresponds to 45 years of working life and 15 years of retirement for the current miner population). MSHA holds the employment and production constant over this period for purposes of the analysis.[63]

For both MNM and coal mines, the estimated costs to comply with the proposed PEL (50 $\mu g/m^3$), assumes that all mines are compliant with the existing PEL of 100 $\mu g/m^3$ for MNM mines (for a full shift, calculated as an 8-hour TWA) and 85.7 $\mu g/m^3$ for coal mines (for a full shift, calculated as an 8-hour TWA).

MSHA estimates that:

- The proposed respirable crystalline silica rule will result in a total of 799 lifetime avoided deaths (63 in coal and 736 in MNM mines) and 2,809 lifetime avoided morbidity cases (244 in coal and 2,566 in MNM mines) once it is fully effective (i.e., beginning 60 years post rule promulgation through year 120 such that all miners, working and retired, have been exposed only under the proposed PEL) (see Table IX-3).
- Over the first 60 years, annual cases avoided will increase gradually to the steady-state values (i.e., long-run per-year averages). Upon reaching the steady-state values, annual cases avoided will be constant from year 60 onward because all miner cohorts will have identical lifetime risks. From Table IX-4, in the first 60 years, the proposed rule would result in a total of 410 avoided deaths (377 in MNM and 33 in Coal) and 1,420 avoided morbidity cases (1,298 in MNM and 122 in Coal), which are the benefits MSHA monetized in its benefits analysis.

[63] This modeling strategy implicitly assumes that the ten-year cost annualization repeats five more times to cover the same 60-year analytic period as the benefits model. Thus, one-time costs incurred in the first year implicitly repeat in years 11, 21, 31, 41 and 51. This may introduce a tendency toward overestimation of compliance costs.

- The total benefits of the proposed respirable crystalline silica rule from these avoided deaths and morbidity cases are $175.7 million per year in 2021 dollars.
  - The majority (60.7 percent) of these benefits ($108.0 million) are attributable to avoided mortality due to non-malignant respiratory disease (NMRD) ($52.8 million), silicosis ($28.1 million), and end-stage renal disease (ESRD) ($19.9 million), and lung cancer ($7.2 million).
  - Benefits from avoided morbidity due to silicosis are $53.2 million per year: $48.7 million for MNM mines and $4.6 million for coal mines (see Table IX-5).
  - Benefits from avoided morbidity that precedes fatal cases associated with NMRD, silicosis, renal disease, and lung cancer, are $14.5 million: $13.3 million for MNM mines and $1.2 million for coal mines (see Table IX-5).

Table IX-3. Estimated Cases of Avoided Lifetime Mortality and Morbidity Attributable to the Proposed Respirable Crystalline Silica Rule

Health Outcome	Total Lifetime Avoided Cases [a]		
	MNM	Coal	Total
Avoided Morbidity			
Silicosis	2,566	244	2,809
Avoided Morbidity Total (Net of Silicosis Fatalities)	**2,566**	**244**	**2,809**
Avoided Mortality			
NMRD (net of silicosis mortality)	366	35	402
Silicosis	174	12	186
ESRD	139	12	150
Lung Cancer [b]	56	5	61
Avoided Mortality Total	**736**	**63**	**799**

[a] Cases include full-time-equivalent contract miners and assume compliance with the existing limits.
[b] Lung cancer estimates assume a 15-year lag between exposure and health effect.

Table IX-4. Estimated Cases of Avoided Mortality and Morbidity Attributable to the Proposed Respirable Crystalline Silica Rule over 60 Years (Regulatory Analysis Time Horizon)

Health Outcome	Total Avoided Cases over 60 Years [a]		
	MNM	Coal	Total
Avoided Morbidity			
Silicosis	1,298.0	121.7	1,419.7
Avoided Morbidity Total (Net of Silicosis Fatalities)	**1,298.0**	**121.7**	**1,419.7**
Avoided Mortality			
NMRD (net of silicosis mortality)	186.8	16.4	203.2
Silicosis	94.8	8.1	102.9
ESRD	69.7	5.9	75.5
Lung Cancer [b]	26.0	2.3	28.2
Avoided Mortality Total	**377.3**	**32.6**	**409.9**

Numbers may not add up due to rounding
[a] Cases include full-time-equivalent contract miners and assume compliance with the existing limits.
[b] Lung cancer estimates assume a 15-year lag between exposure and health effect.

Table IX-5. Estimated Benefits over 60 Years for the Proposed Respirable Crystalline Silica Rule Annualized at a 3 Percent Real Discount Rate (in Millions 2021 $)

Health Outcome	MNM	Coal	Total
Avoided Morbidity (Not Preceding Mortality)			
Silicosis (Net of Silicosis Mortality)	$48.7	$4.6	$53.2
Avoided Morbidity (Not Preceding Mortality) Total	**$48.7**	**$4.6**	**$53.2**
Avoided Mortality			
NMRD (Net of Silicosis Mortality)	$48.5	$4.2	$52.8
Silicosis	$25.9	$2.2	$28.1
ESRD	$18.3	$1.6	$19.9
Lung Cancer	$6.6	$0.6	$7.2
Avoided Mortality Total	**$99.4**	**$8.6**	**$108.0**
Avoided Morbidity (Preceding Mortality)			
NMRD (Net of Silicosis Mortality)	$6.3	$0.5	$6.9
Silicosis	$3.7	$0.3	$4.0
ESRD	$2.5	$0.2	$2.7
Lung Cancer	$0.8	$0.1	$0.9
Avoided Morbidity (Preceding Mortality) Total	**$13.3**	**$1.2**	**$14.5**
Grand Total	**$161.4**	**$14.3**	**$175.7**

MSHA acknowledges that its benefit estimates are influenced by the underlying assumptions and that the long-time frame of this analysis (first 60 years) is a source of uncertainty. The main assumptions underlying these estimates of avoided mortality and morbidity include the following:

- Employment and production are held constant over the 60 years—the analysis period of the proposed rule.[64]
- Any miners currently exposed above the existing PELs are exposed to levels of respirable crystalline silica at existing standards (100 $\mu g/m^3$ for a full-shift exposure, calculated as an 8-hour TWA at MNM mines and 85.7 $\mu g/m^3$ for a full-shift exposure, calculated as an 8-hour TWA at coal mines).
- The proposed rule will result in miners being exposed at or below the proposed PEL (50 $\mu g/m^3$).

[64] MSHA recognizes that it is impossible to predict economic factors over such a long period. Given known information and forecast limitations, MSHA believes this is a reasonable assumption.

- Miners have identical employment and hence exposure tenures (45 years).

The assumptions inherent in developing the exposure-response functions for the modeled health outcomes are reasonable throughout the exposure ranges relevant to this benefits analysis. In the final rule, the agency plans to augment the Regulatory Impact Analysis, for informational purposes, so as to incorporate different durations of working life based on exposure information, while continuing to also present calculations based on a 45-year working life assumption.

In addition to the above quantified health benefits of the lower PEL, MSHA projects that there would be additional benefits from requiring approved respirators be selected, used, and maintained in accordance with the requirements, as applicable, of ASTM F3387-19. The ASTM standard reflects developments in respiratory protection since MSHA issued its existing standards. These developments include OSHA's research and rulemaking on respiratory protection. Under the proposed rule, MSHA would require operators' respiratory protection plans to include minimally acceptable respiratory program elements: program administration; standard operating procedures (SOPs); medical evaluation; respirator selection; training; fit testing; and maintenance, inspection, and storage. Given the uncertainty about the current state of operator respiratory protection practices, MSHA did not quantify the benefits that would be realized by requiring approved respirators to be selected, used, and maintained in accordance with ASTM F3387-19.

MSHA believes the proposed rule would lower exposures to respirable crystalline silica and respirable coal mine dust. The available exposure-response models do not account for separate health effects from exposure to mixed dust that contains both respirable crystalline silica and coal mine dust. However, MSHA anticipates that there would be additional unquantified benefits provided by the proposed rule -- reduced adverse health outcomes attributable to

respirable coal mine dust exposure, such as CWP.[65] The proposed rule does quantify the benefits of avoided deaths and illnesses from reducing coal miners' exposures to respirable crystalline silica. Among coal miners, MSHA estimates 35 lifetime avoided deaths and illnesses from NMRD (see Table IX-3).

Finally, MSHA also expects that the proposed rule's medical surveillance provisions would reduce mortality and morbidity from respirable crystalline silica exposure among MNM miners. The initial mandatory examination that assesses a new miner's baseline pulmonary status, coupled with periodic examinations, would assist in the early detection of respirable crystalline silica related illnesses. Early detection of illness often leads to early intervention and treatment, which may slow disease progression and/or improve health outcomes. However, as noted, MSHA lacks data to quantify these additional benefits.

The net benefits of the proposed rule are the differences between the estimated benefits and costs. Table IX-6 shows estimated net benefits using alternative discount rates of 0, 3, and 7 percent for benefits and costs. As is observed from the table, the choice of discount rate has a significant effect on annualized costs, benefits, and hence net benefits. While the net benefits of the proposed respirable crystalline silica rule vary considerably depending on the choice of discount rate used to annualize costs and benefits, total benefits exceed total costs under each

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[65] The following references document miner exposures that could be simultaneously below the PEL for RCMD but exceed the PEL for silica: Rahimi, E., Shekarian, Y., Shekarian, N. et al. Investigation of respirable coal mine dust (RCMD) and respirable crystalline silica (RCS) in the U.S. underground and surface coal mines. Sci Rep 13, 1767 (2023). https://doi.org/10.1038/s41598-022-24745-x

Doney BC, Blackley D, Hale JM, Halldin C, Kurth L, Syamlal G, Laney AS. Respirable coal mine dust in underground mines, United States, 1982-2017. Am J Ind Med. 2019 Jun;62(6):478-485. doi: 10.1002/ajim.22974. Epub 2019 Apr 29. PMID: 31033017; PMCID: PMC6800046.

Doney BC, Blackley D, Hale JM, Halldin C, Kurth L, Syamlal G, Laney AS. Respirable coal mine dust at surface mines, United States, 1982-2017. Am J Ind Med. 2020 Mar;63(3):232-239. doi: 10.1002/ajim.23074. Epub 2019 Dec 9. PMID: 31820465; PMCID: PMC7814307.

discount rate considered. MSHA's estimate of the net annualized benefits of the proposed rule, using a uniform discount rate for both costs and benefits of 3 percent, is $118.2 million a year with the largest share ($108.8 million; 92.0 percent) attributable to the MNM sector.

Table IX-6. Annualized Costs, Benefits, and Net Benefits of MSHA's Proposed Respirable Crystalline Silica Rule (in Millions 2021 $)

	MNM			Coal			Total		
Impact Category	**0%**	**3%**	**7%**	**0%**	**3%**	**7%**	**0%**	**3%**	**7%**
Benefits									
Mortality	$160.0	$99.4	$49.4	$13.8	$8.6	$4.3	$73.8	$108.0	$53.8
Morbidity Preceding Mortality	$19.6	$13.3	$7.5	$1.7	$1.2	$0.7	$21.3	$14.5	$8.2
Morbidity Not Preceding Mortality	$67.5	$48.7	$31.3	$6.3	$4.6	$2.9	$73.8	$53.2	$34.2
Total	***$247.1***	***$161.4***	***$88.2***	***$21.8***	***$14.3***	***$7.9***	***$268.9***	***$175.7***	***$96.2***
Costs									
Exposure Monitoring	$27.3	$28.7	$30.9	$3.3	$3.4	$3.5	$30.6	$32.0	$34.3
Exposure Controls	$4.8	$4.9	$5.0	$0.8	$0.9	$0.9	$5.6	$5.7	$5.9
Respiratory Protection	$1.0	$1.0	$1.0	$0.1	$0.1	$0.1	$1.0	$1.0	$1.0
Medical Surveillance	$17.5	$17.4	$17.2	--	--	--	$17.5	$17.4	$17.2
ASTM Update	$0.8	$0.8	$0.8	$0.6	$0.6	$0.6	$1.4	$1.4	$1.4
Total	***$51.3***	***$52.6***	***$54.8***	***$4.8***	***$4.9***	***$5.0***	***$56.1***	***$57.5***	***$59.9***
Net Benefits	***$195.8***	***$108.8***	***$33.4***	***$17.0***	***$9.4***	***$2.9***	***$212.8***	***$118.2***	***$36.3***

Note: Medical surveillance cost is the average cost under the assumed participation rate of 75 percent and 25 percent.

[a] For the purpose of simplifying the estimation of the monetized benefits of avoided illness and death, MSHA simply added the monetized benefits of morbidity preceding mortality to the monetized benefits of mortality at the time of death, and both would be discounted at that point. In theory, however, the monetized benefits of morbidity should be recognized (and discounted) at the onset of morbidity, as this is what a worker's willingness to pay is presumed to measure—that is, the risk of immediate death or an immediate period of illness that a worker is willing to pay to avoid—a practice that would increase the present value of discounted morbidity benefits. A parallel tendency toward underestimation occurs with regard to morbidity not preceding mortality, since it implicitly assumes that the benefits occur at retirement, as per the Buchanan model, but many, if not most, of the 2/0 or higher silicosis cases will have begun years before (with those classifications, in turn, preceded by a 1/0 classification). As a practical matter, however, the Agency lacks sufficient data at this time to refine the analysis in this way.

D. Economic Feasibility

To establish economic feasibility, MSHA uses a revenue screening test—whether the yearly costs of a rule are less than 1 percent of revenues, or are negative (i.e., provide net cost savings)—to presumptively establish that compliance with the regulation is economically feasible for the mining industry. The resulting ratio of annualized compliance costs to revenues from the screener analysis should be interpreted with care. If annualized compliance costs comprise less than 1 percent of revenue, the Department of Labor presumes that the affected entities can incur the compliance costs without significant economic impacts.

For the MNM and coal mining sectors, MSHA estimates the projected impacts of the rule by calculating the average annualized compliance costs for each sector as a percentage of total revenues. To be consistent with costs that are calculated in 2021 dollars, MSHA first inflated

mine revenues expressed in 2019 to their 2021 equivalent using the GDP Implicit Price Deflator. Due to inflation, the nominal value of a dollar in 2021 is estimated to be about 5.4 percent higher than in 2019.

Table IX-7. Total Mines, Revenues and Employment by Sector, 2019

Mine Sector	Mines	2019 Revenues (millions of dollars), Inflated to 2021 Dollars	Miners Including Contractors
Total	***12,631***	***$115,348***	***284,778***
Metal/Nonmetal	11,525	$88,316	211,202
Coal	1,106	$27,032	73,576

Table IX-8 presents the projected impacts of the proposed rule. The table compares aggregate annualized compliance costs for MNM and coal sectors at a 0 percent, 3 percent, and 7 percent real discount rate to total annual revenues. At a 3 percent real discount rate, total aggregate annualized compliance costs are projected to be $57.6 million (including both 30 CFR part 60 and 2019 ASTM Upgrade Costs), while aggregate revenues are estimated to be $115.3 billion in 2021 dollars. Thus, the mining industry is expected to incur compliance costs that comprise 0.05 percent of total revenues.

For the MNM sector, MSHA estimates that the annualized costs of the proposed rule (including ASTM update costs) would be $52.7 million at 3 percent discount rate, which is approximately 0.06 percent of total annual revenue of $88.3 billion ($52.7 million/$88.3 billion) for MNM mine operators. For the coal sector, MSHA estimates that the annualized cost of the proposed rule would also be $4.9 million at 3 percent, which is approximately 0.02 percent of total annual revenue of $27.0 billion ($4.9 million/$27.0 billion) for coal mine operators.

The ratios of screening analysis are well below the 1.0 percent threshold, and therefore, MSHA has concluded that the requirements of the proposed rule are economically feasible, and no sector of the industry will likely incur significant costs.

Table IX-8. Estimated Annualized Compliance Costs as Percent of Mine Revenues by Sector, 2021

Mine Sector	2019 Revenues (millions 2021 dollars)	Annualized Costs (millions of 2021 dollars) 3 Percent Real Discount Rate		Annualized Costs (millions of 2021 dollars) 7 Percent Real Discount Rate	
		Compliance Costs	Cost as % of Revenues	Compliance Costs	Cost as % of Revenues
30 CFR Part 60 Costs					
Total	***$115,348***	***$56.17***	***0.05%***	***$58.43***	***0.05%***
Metal/Nonmetal	$88,316	$51.89	0.06%	$54.03	0.06%
Coal	$27,032	$4.28	0.02%	$4.40	0.02%
30 CFR Part 60 + 2019 ASTM Upgrade Costs					
Total	***$115,348***	***$57.57***	***0.05%***	***$59.89***	***0.05%***
Metal/Nonmetal	$88,316	$52.67	0.06%	$54.85	0.06%
Coal	$27,032	$4.90	0.02%	$5.04	0.02%

E. Regulatory Alternatives

The proposed rule presents a comprehensive approach for lowering miners' exposure to respirable crystalline silica. The proposal includes the following regulatory provisions: lowering miners' respirable crystalline silica exposure to a PEL of 50 μg/m^3 for a full-shift exposure, calculated as an 8-hour TWA; initial baseline sampling for miners who are reasonably expected to be exposed to respirable crystalline silica; periodic sampling for miners who are at or above the proposed action level of 25 μg/m^3 but at or below the proposed PEL of 50 μg/m^3; and semi-annual evaluation of changing mining processes that would reasonably be expected to result in new or increased exposures.

In developing the proposed rule, MSHA considered two regulatory alternatives. Both alternatives include less stringent monitoring provisions than the proposed monitoring provisions. One of the alternatives also combines less stringent monitoring with a more stringent PEL. MSHA discusses the regulatory options in the sections below, from least expensive to most expensive. Both alternatives would retain the respiratory protection updates and medical surveillance from the proposed rule.

1. Regulatory Alternative #1: Changes in Sampling and Evaluation Requirements

Under this alternative, the proposed PEL would remain unchanged at 50 μg/m^3 and the proposed action level would remain unchanged at 25 μg/m^3. Further, mine operators would conduct: (1) baseline sampling for miners who may be exposed to respirable crystalline silica at or above the proposed action level of 25 μg/m^3, (2) periodic sampling twice per year for miners who are at or above the proposed action level of 25 μg/m^3 but at or below the proposed PEL of 50 μg/m^3, and (3) annual evaluation of changing mining processes or conditions that would reasonably be expected to result in new or increased exposures.

Mine operators would be required to undertake sampling under this regulatory alternative and would thus incur compliance costs. However, monitoring requirements under this alternative are less stringent than the requirements under the proposed rule because the number

of miners to be sampled for baseline sampling would be smaller than in the proposed rule and the frequency of periodic sampling and evaluations of changing mining processes or conditions are set at half the frequency of the proposed monitoring requirements. Therefore, the cost of compliance will be lower under this alternative. MSHA estimates that annualized monitoring costs will total $17.3 million for this alternative (at a 3 percent discount rate), compared to $32.0 million for the proposed monitoring requirements, resulting in an estimated $14.7 million in lower costs per year (Table IX-9).

Although this alternative does not eliminate exposure monitoring, the requirements are minimal relative to the monitoring requirements under the proposed rule. However, MSHA believes it is necessary for mine operators to establish a solid baseline for any miner who is reasonably expected to be exposed to respirable crystalline silica. In addition, quarterly monitoring helps mine operators correlate mine conditions to miner exposure levels and see exposure trends more rapidly than would result from semi-annual or annual sampling. This would enable mine operators to take measures necessary to ensure continued compliance with the PEL. Further, more frequent monitoring would enable mine operators to ensure the adequacy of controls at their mines and better protect miners' health. These benefits cannot be quantified, but they are nevertheless material benefits that increase the likelihood of compliance.

Table IX-9. Summary of Part 60 Annualized Compliance Costs (in Millions of 2021 $), Regulatory Alternative 1 and Proposed Requirements: All Mines, 2021

	0 Percent Real Discount Rate		3 Percent Real Discount Rate		7 Percent Real Discount Rate	
Mine Sector	**Annualized Cost (millions of dollars)**	**Percent of Proposed**	**Annualized Cost (millions of dollars)**	**Percent of Proposed**	**Annualized Cost (millions of dollars)**	**Percent of Proposed**
Regulatory Alternative #1: Changes in Sampling and Evaluation Requirements						
Exposure Monitoring	$16.29		$17.33		$19.02	
Exposure Controls	$5.65		$5.75		$5.90	
Respiratory Protection	$1.03		$1.03		$1.03	
Medical Surveillance	$17.49		$17.37		$17.20	
Total, Part 60 Costs	***$40.46***	***73.9%***	***$41.48***	***73.8%***	***$43.15***	***73.8%***
Proposed Requirements						
Exposure Monitoring	$30.60		$32.02		$34.30	
Exposure Controls	$5.65		$5.75		$5.90	

Respiratory Protection	$1.03		$1.03		$1.03	
Medical Surveillance	$17.49		$17.37		$17.20	
Total, Part 60 Costs	***$54.76***	***100.0%***	***$56.17***	***100.0%***	***$58.43***	***100.0%***

MSHA also believes that requiring more frequent periodic sampling would provide mine operators with greater confidence that they are in compliance with the proposed rule. Because of the variable nature of miner exposures to airborne concentrations of respirable crystalline silica, maintaining exposures below the proposed action level provides mine operators with reasonable assurance that miners would not be exposed to respirable crystalline silica at levels above the PEL on days when sampling is not conducted. MSHA believes that the benefits of the proposed sampling requirements justify the additional costs relative to Regulatory Alternative 1.

2. Regulatory Alternative #2: Changes in Sampling and Evaluation Requirements and the Proposed PEL

Under this regulatory alternative, the proposed PEL would be set at 25 μg/m^3; mine operators would install whatever controls are necessary to meet this PEL; and no action level would be proposed. Further, mine operators: (1) would not be required to conduct baseline sampling or periodic sampling; (2) would conduct semi-annual evaluations of changing conditions; and (3) would sample as frequently as necessary to determine the adequacy of controls.

Mine operators would not be required to undertake baseline or periodic sampling. However, mine operators would be required to perform semi-annual evaluations of changing mining processes or conditions. Further, mine operators would be required to perform post-evaluation sampling when the operators determine as a result of the semi-annual evaluation that miners may be exposed to respirable crystalline silica at or above proposed PEL at 25 μg/m^3. When estimating the cost of the proposed monitoring requirements, MSHA assumes that the number of samples for corrective action and semi-annual evaluation are relatively small (2.5 percent of miners) because samples from sampling to determine the adequacy of controls and from MSHA can both be used to meet the requirements. Since this alternative does not require

periodic sampling, MSHA increases samples after each evaluation to 10 percent of miners to ensure the monitoring requirements can be met.

This alternative also sets the proposed PEL at 25 μg/m^3. In addition to the estimated cost of compliance with a PEL of 50 μg/m^3, mine operators would incur additional engineering control costs to meet a PEL of 25 μg/m^3. To estimate these additional engineering control costs, MSHA largely uses the same methodology as for mines affected at the proposed PEL of 50 μg/m^3.

a. Number of Mines Affected Under Regulatory Alternative 2

MSHA first estimated the number of mines expected to incur the cost of implementing engineering controls to reach the more stringent PEL. After excluding mines that are affected at the proposed PEL of 50 μg/m^3 (to avoid double-counting), MSHA finds that 3,477 mines (2,991 MNM mines and 486 coal mines) operating in 2019 had at least one sample at or above 25 μg/m^3 but below 50 μg/m^3.[66]

To this number, MSHA adds the 1,226 affected mines expected to incur costs to reach the proposed PEL of 50 μg/m^3. Based on its experience and knowledge, MSHA does not expect the mines that installed engineering controls to meet the PEL of 50 μg/m^3 will also be able to comply with a PEL of 25 μg/m^3. For example, to comply with the proposed PEL of 50 μg/m^3, a mine might need to add the engineering controls necessary to achieve an additional 10 air changes per hour over that achieved by existing controls, which are costed in the following section. However, such a mine facility would then need to add an additional 10 air changes per hour to meet the more stringent PEL of 25 μg/m^3, which is not costed in the following section. Thus, MSHA expects that the 1,226 affected mines will incur additional costs to meet the PEL of 25 μg/m^3 specified under this alternative.

[66] About 8,053 of mines active in 2019 either did not have a sample > 25 μg/m^3 or did not have a sample in the last 5 years.

MSHA estimates a total of 4,703 mines will incur costs to purchase, install, and operate engineering controls to meet the PEL of 25 μg/m^3 under this alternative. MNM mines account for 4,087 (87 percent) and coal mines 616 (13 percent). Further, of the estimated 4,087 MNM mines and 616 coal mines, 1,096 MNM mines (27 percent) and 130 coal mines (21 percent) are also estimated to incur compliance costs to reach the proposed PEL of 50 μg/m^3.

b. Estimated Engineering Control Costs Under Regulatory Alternative 2

MSHA identified potential engineering controls that would enable mines with respirable crystalline silica dust exposures at or above 25 μg/m^3 but below 50 μg/m^3 categories to meet the PEL of 25 μg/m^3 under consideration for this alternative. While MSHA assumes that mine operators will base such decisions on site-specific conditions such as mine layout and existing infrastructure, MSHA cannot make further assumptions about the specific controls that might be adopted and instead assumes the expected value of purchased technologies should equal the simple average of the technologies listed in each control category.

Where more precise information is unavailable, MSHA assumes operating and maintenance (O&M) costs to be 35 percent of initial capital expenditure and installation cost, when appropriate, will be equal to the initial capital expenditure (Table IX-10). MSHA also assumes the larger capital expenditure controls will have a 30-year service life. MSHA welcomes public comment concerning the engineering controls selected for this analysis and the assumptions used to estimate installation and O&M costs for these controls.

Table IX-10. Selected Engineering Controls to Decrease Respirable Crystalline Silica Dust Exposure by Capital Expenditure Cost Range Under Regulatory Alternative 2

Engineering Control	2021 Capital Cost	2021 Installation Cost [a]	2021 O&M Cost [b]	Expected Service Life [c]
Minimal capital expenditure				
Stone saw enclosure	$0	$0	$1,378	1
Larger capital expenditure				
Increase facility ventilation from 20 to 30 air changes per hour	$157,000	$157,000	$9,153	30
Full length of conveyor enclosed and ventilated	$896,373	$896,373	$51,988	30
Crusher/grinder: appropriate size ventilation for air flow	$184,640	$184,640	$10,709	30
Plumbing for hose installations, floor re-sloping and troughs	$43,076	$43,076	$3,951	30

Average	***$256,218***	***$256,218***	***$15,436***	***24.2***

[a] Unless otherwise specified, installation costs are assumed to be equal to capital cost.
[b] Unless otherwise specified, annual O&M costs are assumed to be equal to 35 percent of capital cost.
[c] Service life assumed to be 10 years if not otherwise specified.

However, the difficulty of meeting a PEL of 25 μg/m^3 is such that MSHA's experience suggests a single control from Table IX-10 will not be sufficient. For example, respirable crystalline silica dust exposure at such a stringent limit as 25 μg/m^3 is likely to occur at more than one area of the mine; in addition to increasing ventilation to a crusher/grinder, enclosing and ventilating the conveyor belt mine would be necessary to reduce concentrations below the limit. Similarly, increasing facility ventilation from 20 to 30 air changes per hour may not be adequate to meet the limit; 40 air changes per hour might be necessary. Therefore, MSHA assumes mine operators will purchase and install at least two of the engineering controls listed in Table IX-10. This may be a conservative assumption.

Table IX-11 presents the average annualized engineering control costs per mine and total annualized engineering control costs by mine sector. Because the service life of nearly all components is expected to be 30 years, the costs of all engineering controls are annualized over 30 years. At a 3 percent real discount rate, the average annualized engineering control costs are about $94,300 per mine, resulting in an additional cost of $443.6 million if the PEL is set at 25 μg/m^3 instead of 50 μg/m^3.

Table IX-11. Estimated Annualized Costs as a Simple Average per Mine and Total Engineering Controls per Mine Under Regulatory Alternative 2, by Category, 2021

	Annualized Cost of Engineering Controls at Specified Real Discount Rate		
	0 Percent	**3 Percent**	**7 Percent**
Annualized Engineering Control Costs per Mine, Over All Controls	$73,574	$94,328	$127,356
Total Annualized Engineering Control Costs by Mine Sector (millions) [a]			
Total	***$346.0***	***$443.6***	***$599.0***
MNM	$300.7	$385.5	$520.5
Coal	$45.3	$58.1	$78.5

[a] Based on an estimated 616 Coal and 4,087 MNM mines, for 4,703 total affected mines.

Table IX-12 summarizes the estimated annualized cost of this alternative under consideration. At a 3 percent real discount rate, exposure monitoring costs less than the proposed rule; however, this lower cost is more than offset by the increased control costs necessitated by the requirement that mines maintain respirable crystalline silica exposure levels below 25 μg/m^3. At an estimated annualized cost of $491.2 million, this alternative would cost nearly eight times more than the proposed requirements.

Table IX-12. Summary of Part 60 Annualized Compliance Costs (in Millions of 2021 $) Under Regulatory Alternative 2 and Proposed Requirements: All Mines, 2021

	0 Percent Real Discount Rate		3 Percent Real Discount Rate		7 Percent Real Discount Rate	
Mine Sector	**Annualized Cost (millions of dollars)**	**Percent of Proposed**	**Annualized Cost (millions of dollars)**	**Percent of Proposed**	**Annualized Cost (millions of dollars)**	**Percent of Proposed**
Regulatory Alternative #2: Changes in PEL and Sampling and Evaluation Requirements						
Exposure Monitoring	$25.1		$24.8		$24.4	
Exposure Controls	$350.3		$447.9		$603.3	
Respiratory Protection	$1.0		$1.0		$1.0	
Medical Surveillance	$17.5		$17.4		$17.2	
Total, Part 60 Costs	***$393.9***	***719.3%***	***$474.39***	***874.4%***	***$646.0***	***1105.3%***
Proposed Requirements						
Exposure Monitoring	$30.6		$32.0		$34.3	
Exposure Controls	$5.7		$5.8		$5.9	
Respiratory Protection	$1.0		$1.0		$1.0	
Medical Surveillance	$17.5		$17.4		$17.2	
Total, Part 60 Costs	***$54.8***	***100.0%***	***$56.2***	***100.0%***	***$58.4***	***100.0%***

This alternative requires exposure monitoring that is more stringent than Regulatory Alternative 1, but less stringent than the proposed requirements. In addition, Regulatory Alternative 2 increases miner protection by proposing to set the PEL at 25 μg/m^3, resulting in measurable avoided mortality and other health benefits. Table IX-13 presents the avoided morbidity and mortality cases over the 60-year regulatory analysis time horizon under this alternative. Under this alternative, the avoided 60-year mortality is expected to be 981, which is 2.4 times higher than the expected avoided mortality of 410 under a proposed PEL of 50 μg/m^3. The avoided 60-year morbidity under the regulatory alternative of 25 μg/m^3 is expected to be

1,948, which is 1.4 times higher than the expected avoided 60-year morbidity of 1,420 under the proposed PEL of 50 μg/m^3.

Table IX-13. Estimated Cases of Avoided Mortality and Morbidity over 60 Years (Regulatory Analysis Time Horizon) Following Rule Promulgation Under Regulatory Alternative 2

Health Outcome	Total Avoided Cases over 60 Years [a]		
	MNM	Coal	Total
Avoided Morbidity			
Silicosis	1,736.9	211.5	1,948.4
Avoided Morbidity Total (Net of Silicosis Fatalities)	1,736.9	211.5	1,948.4
Avoided Mortality			
NMRD (net of silicosis mortality)	408.7	57.8	466.4
Silicosis	206.0	25.6	231.5
ESRD	193.4	27.3	220.8
Lung Cancer [b]	54.7	7.3	62.0
Avoided Mortality Total	**862.8**	**118.0**	**980.7**

[a] Cases include full-time-equivalent contract miners and assume compliance with the current limits.
[b] Lung cancer estimates assume a 15-year lag between exposure and health effect.

Table IX-14 presents the benefits associated with this avoided morbidity and mortality. The expected total benefits, discounted at 3 percent, are $365.5 million, which is twice the expected total benefits of $175.7 million under the proposed PEL of 50 μg/m^3. Under this regulatory alternative, these benefits are made up of $258.0 million due to avoided mortality, $34.5 million due to morbidity preceding mortality, and $73.0 million due to morbidity not preceding mortality. However, when compared to the annualized costs, the net benefits of this alternative are negative at both a 3 percent and 7 percent real discount rate.

Table IX-14. Annualized Monetized Benefits over 60 Years (Regulatory Analysis Time Horizon) Following Rule Promulgation (in Millions of 2021 $) Under Regulatory Alternative 2, by Health Outcome and Discount Rate

Health Outcome	MNM			Coal			Total		
	0%	3%	7%	0%	3%	7%	0%	3%	7%
Avoided Morbidity (Not Preceding Mortality)									
Silicosis (Excluding Silicosis Deaths)	$90.3	$65.1	$41.8	$11.0	$7.9	$5.1	$101.3	$73.0	$46.9
Avoided Morbidity (Not Preceding Mortality) Total	**$90.3**	**$65.1**	**$41.8**	**$11.0**	**$7.9**	**$5.1**	**$101.3**	**$73.0**	**$46.9**
Mortality									
NMRD (Excluding Silicosis Deaths)	$175.7	$106.3	$49.6	$24.9	$15.0	$7.0	$200.6	$121.2	$56.6
Silicosis	$84.3	$56.1	$32.1	$10.3	$7.0	$4.1	$94.4	$63.1	$36.2
ESRD	$82.7	$50.6	$24.8	$11.6	$7.2	$3.6	$94.3	$57.8	$28.3
Lung Cancer	$24.0	$13.9	$5.9	$3.2	$1.9	$0.8	$27.3	$15.8	$6.7
Avoided Mortality Total	**$366.6**	**$226.9**	**$112.4**	**$50.1**	**$31.1**	**$15.4**	**$416.7**	**$258.0**	**$127.8**
Avoided Morbidity (Preceding Mortality)									

Health Outcome	MNM			Coal			Total		
	0%	3%	7%	0%	3%	7%	0%	3%	7%
NMRD (Excluding Silicosis Deaths)	$21.2	$13.9	$7.3	$3.0	$2.0	$1.0	$24.2	$15.8	$8.3
Silicosis	$10.7	$8.0	$5.3	$1.3	$1.0	$0.7	$12.0	$9.0	$6.0
ESRD	$10.1	$6.7	$3.8	$1.4	$1.0	$0.5	$11.5	$7.7	$4.3
Lung Cancer	$2.8	$1.8	$0.8	$0.4	$0.2	$0.1	$3.2	$2.0	$0.9
Avoided Morbidity (Preceding Mortality) Total	**$44.8**	**$30.3**	**$17.1**	**$6.1**	**$4.2**	**$2.3**	**$51.0**	**$34.5**	**$19.5**
Grand Total	**$501.7**	**$322.4**	**$171.3**	**$67.2**	**$43.1**	**$22.8**	**$568.9**	**$365.5**	**$194.1**

MSHA solicits further comment on the extent to which these or other regulatory alternatives (including different ways of calculating respirable crystalline silica concentration) may change the effects of the proposed rule.

X. Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, requires preparation of an Initial Regulatory Flexibility Analysis (IRFA) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 601-612. Because MSHA's proposed rule on respirable crystalline silica, including the incorporation of ASTM F3387-19 by reference, would regulate the mining industry, the proposed rule falls within the purview of the RFA. MSHA has evaluated the impact of the proposed rule on small entities in this IRFA. MSHA's analysis is presented in the following.

Description of the reasons why MSHA is considering regulatory action

Based on its review of the health effects literature, MSHA has preliminarily determined that occupational exposure to respirable crystalline silica causes silicosis and other diseases. Based on its preliminary risk analysis, MSHA has also determined that under its existing standards, miners face a risk of material impairment of health or functional capacity from exposures to respirable crystalline silica.

Based on these preliminary determinations, MSHA proposes to amend its existing standards to better protect miners against occupational exposure to respirable crystalline silica, a carcinogen, and to improve respiratory protection for all airborne contaminants. The proposed rule would establish for mines of all sizes, a PEL of 50 $\mu g/m^3$ for a full shift, calculated as an 8-hour TWA, for all miners, and an action level of 25 $\mu g/m^3$ for a full-shift exposure, calculated as 8-hour TWA. MSHA's proposal would also include other requirements to protect miner health, such as periodic exposure sampling and corrective actions to be taken when miners' exposures exceed the PEL. MSHA also proposes to replace existing requirements for respiratory protection and to incorporate by

reference the ASTM F3387-19 *Standard Practice for Respiratory Protection*. MSHA believes that the proposed changes would significantly improve health protections for all miners over the course of their working lives.

Objectives of, and legal basis for, the proposed rule

The proposed rule would fulfill MSHA's statutory obligation to "promulgate improved mandatory health . . . standards to protect" miners' health under the Mine Act, as amended. 30 U.S.C. 801(g). The Mine Act requires the Secretary of Labor (Secretary) to develop and promulgate improved mandatory health or safety standards to prevent hazardous and unhealthy conditions and protect the health and safety of the nation's miners. 30 U.S.C. 811(a). The Secretary must set standards to assure, based on the best available evidence, that no miners will suffer material impairment of health or functional capacity from exposure to toxic materials or harmful physical agents over their working lives. 30 U.S.C. 811(a)(6)(A). Section 103(h) of the Mine Act gives the Secretary the authority to promulgate standards involving recordkeeping and reporting. 30 U.S.C. 813(h). Additionally, section 508 of the Mine Act gives the Secretary the authority to issue regulations to carry out any provision of the Mine Act. 30 U.S.C. 957.

Description and estimate of the number of small entities to which the proposed rule would apply

The proposed rule would affect MNM and coal mining operations. To determine the number of small entities subject to the proposed rule, MSHA reviewed the North American Industrial Classification System (NAICS), the standard used by Federal statistical agencies in classifying business establishments, as well as information from the Office of Advocacy of the Small Business Administration (SBA). MSHA used its data from the MSHA Standardized Information System (MSIS) to identify the responsible party for each mine. MSHA then combined that information with the size classification information.

First, MSHA determined that mining operations that fall into 25 NAICS-based industry classifications may be subject to the proposed rule. These industry categories and their accompanying six-digit NAICS codes are shown in Table X-1.[67]

Second, MSHA matched the NAICS classifications with SBA small-entity size standards (based on number of employees) to determine the number of small entities within each of the respective NAICS codes. See Table X-1.

Third, MSHA counted the number of small-entity controllers in each NAICS code, after determining that a "controller" who owns and controls a mine as the appropriate unit of this IRFA analysis (based on SBA guidance) (Small Business Administration 2017). A controller is a parent company owning or controlling one or more mines. A controller can also be a firm, whereas a mine can be an establishment. Table X-1 shows the count of all controllers and a count of small-entity controllers in each NAICS code. Some "unique controllers" are included in more than one NAICS code because they own or control multiple mines, each producing a different commodity. For this analysis, however, MSHA single-counted these unique controllers; for example, a controller who owns three mines in three different NAICS codes was only counted once.

Based on this methodology, MSHA estimated that in 2021, there were a total of 5,879 controllers, 5,007 of which were small-entity controllers. Many controllers owned

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[67] The NAICS classifications used in this analysis are drawn from a recent version of the NAICS (though, for reasons described below, not the latest version, which was published in January 2022). SBA established definitions of small entities for each of the categories in the earlier version, which were effective in August 2019. This version of NAICS categories was needed for this analysis, in order for MSHA to cross-tabulate (or crosswalk) its data on mines and controllers with Bureau of Census data on revenues by NAICS codes, where these Census data were organized by the same NAICS codes that were in the earlier version. No comparable revenue data, at this writing, had yet been revised to the most recent NAICS categories, which prevented MSHA from using those categories. MSHA identified 25 NAICS categories (in the previous system) that accounted for all mining activities.

one or two mines, while some controllers owned hundreds of mines nationwide (or worldwide). The 5,007 small-entity controllers owned a total of 8,240 mines out of 11,791 mines in operation in 2021.[68]

Table X-1. Small Entities Potentially Affected by MSHA's Proposed Rule

NAICS Code	Industry Description	SBA Size Standards in Maximum Number of Employees*	Number of All Controllers	Number of Small-Entity Controllers
211120	Crude Petroleum Extraction	1,250	4	0
211130	Natural Gas Extraction	1,250	4	0
212111	Bituminous Coal and Lignite Surface Mining	1,250	9	1
212112	Bituminous Coal Underground Mining	1,500	278	182
212113	Anthracite Mining	250	67	54
212210	Iron Ore Mining	750	19	8
212221	Gold Ore Mining	1,500	108	65
212222	Silver Ore Mining	250	8	2
212230	Copper, Nickel, Lead, and Zinc Mining	750	30	4
212291	Uranium-Radium-Vanadium Ore Mining	250	3	1
212299	All Other Metal Ore Mining	750	12	4
212311	Dimension Stone Mining and Quarrying	500	536	488
212312	Crushed and Broken Limestone Mining and Quarrying	750	763	583

[68] The number of controllers and mines examined in this regulatory flexibility analysis are those specifically known to operate in 2021. The year 2021 is the most current year for which complete information were available. Such information about controllers as parent companies might include, for example, knowledge of whether the parent company is a large, multinational corporation, which has bearing on this regulatory flexibility analysis. Because the benefit-cost analysis performed on the proposed rule did not need this kind of detailed information about controllers, it was able to have a broader scope to include data from other years besides 2021, which it did. As a result, the benefit cost analysis included a larger number of mines (and affected mines) and controllers. The key factor for this regulatory flexibility analysis is the estimated ratio of the regulatory cost per revenue for controllers, as reflected by the most current data. The estimation of this ratio is robustly addressed in MSHA's analysis of the 5,879 controllers in 2021 (which is not impacted by the exclusion of other years in this analysis).

212313	Crushed and Broken Granite Mining and Quarrying	750	103	76
212319	Other Crushed and Broken Stone Mining and Quarrying	500	856	707
212321	Construction Sand and Gravel Mining	500	3,462	3,095
212322	Industrial Sand Mining	500	214	161
212324	Kaolin and Ball Clay Mining	750	9	3
212325	Clay and Ceramic and Refractory Minerals Mining	500	134	81
212391	Potash, Soda, and Borate Mineral Mining	750	11	2
212392	Phosphate Rock Mining	1,000	7	1
212393	Other Chemical and Fertilizer Mineral Mining	500	27	12
311942	Spice and Extract Manufacturing	500	2	1
327310	Cement Manufacturing	1,000	27	1
327410	Lime Manufacturing	750	30	17

*SBA, effective August 19, 2019.

Description of the projected reporting, recordkeeping, and other compliance requirements for small entities

As explained earlier, the proposed rule would establish a PEL of 50 μg/m^3 and an action level of 25 μg/m^3 for a full-shift exposure, calculated as 8-hour TWA. The proposed rule would also include other requirements. Examples include baseline, periodic, and corrective action sampling, semi-annual evaluations, medical surveillance, respiratory protection, and recordkeeping.

With regard to the paperwork burden on small entities, MSHA's proposed rule would create new information collection requests for the mining industry. As described in greater detail in Section XI below, these requirements include the collection of information involving: (1) exposure monitoring – samplings and semi-annual evaluations, (2) corrective actions taken, (3) miners unable to wear respirators, and (4) medical surveillance for MNM miners. Table XI-2 displays an annual estimate of information collection burden for the whole mining industry. Compliance costs on small entities that include recordkeeping costs are discussed below.

Estimation of the Compliance Costs and Relative Burden to Small Entities

MSHA estimated the average annual regulatory cost per small-entity controller (based on a 3 percent discount rate), as well as the average annual revenue per small-entity controller. MSHA estimated, for each controller, the additional annual cost of the proposed regulation as a proportion of that controller's annual revenue. The average of these proportions (weighting controllers equally) was 0.122 percent, below a 3 percent threshold used for significant impact. That is, for every $1 million in revenue earned by a controller, the average regulatory cost was estimated to be $1,220.

Total Compliance Cost. MSHA estimated that the proposed rule would have an average cost of $60.23 million per year in 2021 dollars at a real discount rate of 3 percent. The estimated costs for the proposed rule would represent the additional costs necessary for mine operators to achieve full compliance with the proposed rule.

Compliance Costs by Small-Entity Controllers. Because mines (as well as controllers) vary in the scale of their operations, MSHA first estimated additional regulatory costs on a per-miner basis. MSHA anticipated that the additional regulatory costs per miner would vary across the six major commodity categories: coal, metal, nonmetal, stone, crushed limestone, and sand and gravel. MSHA analyzed employment data linked with controller data. By combining this information with compliance cost information, MSHA derived estimates of the regulatory costs for small-entity controllers. MSHA then estimated the regulatory cost for each of the 5,007 small-entity controllers identified in 2021. See the average annual regulatory cost per controller in Table X-2.

Revenues by Small-Entity Controllers. MSHA estimated revenues for each small-entity controller. The Agency estimated revenues per employee, by mine, and by controller, using data published by the U.S. Bureau of Census in their report, "Statistics of U.S. Businesses" (SUSB).[69] The SUSB data provided revenue estimates for enterprises in each NAICS code and for each "size category" (based on number of employees) within each NAICS code. The enterprise data considered controllers that had operations in more than one NAICS code. MSHA summed the estimated revenue for the establishments within the same NAICS code to create multiple enterprises with different NAICS codes and compare constructed enterprises with the SUSB data to estimate the revenue for each of these size-category-specific enterprises. This methodology

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[69] U.S. Census Bureau, "Statistics of U.S. Businesses," released May 2021. https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html. Data in the report were in reference to the year 2017, which MSHA adjusted to 2021 dollars. Data on revenues are presented in the report under the equivalent term "receipts." MSHA converted the 2017 revenues to 2021 dollars using the GDP Implicit Price Deflator published by the Bureau of Economic Analysis October 26, 2022, Table 1.1.9 Implicit Price Deflators for Gross Domestic Product, Series A191RD. https://apps.bea.gov/histdata/fileStructDisplay.cfm?HMI=7&DY=2022&DQ=Q3&DV=Advance&dNRD=October-28-2022. The index was 107.749 for 2017 and 118.895 for 2021, creating an adjustment factor (from 2017 to 2021 dollars) of 118.895/107.749 or 1.103.

was relevant for the "largest" of small-entity controllers, which controlled more than one mine, sometimes operating in different NAICS categories. Most small-entity controllers operated only one mine, meaning that no summation was required because only the number of employees in a single mine needed to be counted.

MSHA estimated revenues for each small-entity controller. Some small-entity controllers had mines belonging to different NAICS codes. This factor precluded MSHA from being able to precisely categorize small-entity controllers by NAICS code. MSHA estimated each small-entity controller's revenues.[70]

Some of the small-entity controllers may also have operations in non-mining industries. If so, total revenues, including those from non-mining operations, would be higher than estimated here, and the ratios of regulatory costs to revenues shown in the summary table may be overestimated.

MSHA developed estimates of the number of miners for each small-entity controller, and for each NAICS category within each controller's activities. MSHA then combined these data with SUSB data on revenues by NAICS category and size category to generate estimated revenues for each small-entity controller. See the estimated average annual revenue per controller in Table X-2.

Ratio of Compliance Cost to Revenue. From the two sets of estimates described above - costs and revenues - for each small-entity controller, MSHA generated estimates of the ratios of regulatory cost to revenue, for each controller. Table X-2 shows the number of controllers, average annual regulatory costs, average annual revenue, and average cost as a percent of revenue.

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[70] In a small number of cases (in terms of NAICS codes and size categories) the SUSB data were incomplete. In these cases, MSHA imputed revenue/employee ratios based on closely related data for comparable NAICS-size categories. MSHA then used these imputed revenue/employee ratios to estimate the revenues of some small-entity controllers, by the methodology just described.

Table X-2. Annualized Compliance Costs to Revenues for a Typical Small-Entity Controller

Small-Entity Controller	Number of Controllers	Average Annual Regulatory Cost Per Controller (in 2021 $) at a 3 Percent Discount Rate	Average Annual Revenue Per Controller (in 2021 $)	Average of Cost as a Percent of Revenue (Unweighted Average of the Percentages Among All Controllers)*
Coal Small-Entity Controllers	235	$ 3,191	$ 12,816,000	0.025
MNM Small-Entity Controllers	4,772	$ 4,250	$ 3,822,000	0.127
Total	5,007	$ 4,200	$ 4,243,000	0.122

*Note that because column displays the unweighted average of the controller-level percentages across all controllers, it is not equivalent to the ratio of the average cost among all controllers and the average revenue among all controllers in the previous two columns.

Relevant Federal Rules which May Duplicate, Overlap, or Conflict with the Proposed Rule

There are no Federal rules that may duplicate, overlap, or conflict with the proposed rule.

Significant Alternatives and Their Impact on Small Entities

MSHA considered two alternatives in the proposed rule. Under Alternative 1, the proposed PEL would remain unchanged at 50 μg/m^3 and the proposed action level would remain unchanged at 25 μg/m^3. Further, mine operators would conduct: (1) baseline sampling for miners who may be exposed to respirable crystalline silica at or above the proposed action level of 25 μg/m^3, (2) periodic sampling twice per year, and (3) annual evaluation of changing mining processes or conditions that would reasonably be expected to result in new or increased exposures. Under Alternative 2, the proposed PEL would be set at 25 μg/m^3; mine operators would install whatever controls are necessary to meet this PEL; and no action level would be proposed. Further, mine operators would: (1) not be required to conduct baseline sampling or periodic sampling, (2) conduct semi-annual evaluations of changing conditions, and (3) sample as frequently as necessary to determine the adequacy of controls. Additional detail on the two

regulatory alternatives MSHA considered can be found in IX. *Summary of Preliminary Regulatory Impact Analysis and Regulatory Alternatives* and in the standalone PRIA document.

MSHA believes the proposed rule would provide improved health protections for miners and would be achievable for all mines. In developing the proposed rule, MSHA has included flexibilities for operators in the implementation of updated respiratory protection standard, which would reduce the burden on small entities. MSHA has made the following determinations regarding the two alternatives considered:

- Alternative 1, "Changes in Sampling and Evaluation Requirements," would reduce overall costs to the mining industry by 26.2 percent, for costs calculated at both a 3 percent and 7 percent discount rate. These reduced costs would be proportionally experienced by small entities. The average costs as a percent of revenues for small entities would then be reduced (relative to the proposed rule) from 0.12 percent to 0.09 percent.
- Alternative 2, "Changes in Sampling and Evaluation Requirements and the Proposed PEL," would increase overall costs to the mining industry by 701.9 percent, for costs calculated at a 3 percent discount rate, and by 930.2 percent for costs calculated at a 7 percent discount rate. The average costs as a percent of revenues for small entities would then rise (relative to the proposed rule) from 0.12 percent to 0.98 percent, based on a 3 percent discount rate, and from 0.12 percent to 1.259 percent based on a 7 percent discount rate.

MSHA is seeking comments or additional information from stakeholders on whether there are alternatives the Agency should consider that would accomplish the objectives of this rulemaking while reducing the impact on small entities.

Conclusion

MSHA estimated that small-entity controllers would be expected to incur, on average, additional regulatory costs equaling approximately 0.122 percent of their revenues (or $1,220 for every $1 million in revenues).

As required under the RFA, MSHA is complying with its obligation to consult with the SBA's Chief Counsel for Advocacy on this proposed rule and on this initial regulatory flexibility analysis. Consistent with Agency's practice, notes of any meetings with the Chief Counsel for Advocacy's office on this proposed rule, or any written communications, will be placed in the rulemaking record.

XI. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521) provides for the Federal Government's collection, use, and dissemination of information. The goals of the Paperwork Reduction Act include minimizing paperwork and reporting burdens and ensuring the maximum possible utility from the information that is collected under 5 CFR part 1320. The Paperwork Reduction Act requires Federal agencies to obtain approval from the Office of Management and Budget (OMB) before requesting or requiring "a collection of information" from the public.

As part of the Paperwork Reduction Act process, agencies are generally required to provide a notice in the Federal Register concerning each proposed collection of information to solicit, among other things, comment on the necessity of the information collection and its estimated burden, as required in 44 U.S.C. 3506(c)(2)(A). To comply with this requirement, MSHA is publishing a notice of proposed collection of information in the proposed rule titled, Lowering Miners' Exposure to Respirable Crystalline Silica and Improving Respiratory Protection.

This rulemaking would require the creation of a new information collection as well as modification to the burdens for existing collections. As required by the Paperwork Reduction Act, the Department has submitted information collections, including a new information

collection and revisions of two existing collections, to OMB for review to reflect new burdens and changes to existing burdens.

I. New Information Collection Under Proposed Part 60, Respirable Crystalline Silica

Under proposed part 60 entitled "Respirable Crystalline Silica," some new burdens would apply to all mine operators, and other burdens would apply to only some mine operators. Below, the new information collection burden that would be created by proposed part 60 is discussed.

Proposed § 60.16 lists all the recordkeeping requirements related to proposed part 60. Each of the requirements are discussed below:

Proposed § 60.12 would require mine operators to make a record for each sampling and each evaluation conducted pursuant to this section. The sampling record would consist of the sample date, the occupations sampled, and the concentrations of respirable crystalline silica and respirable dust. The mine operator would also retain laboratory reports on sampling results. The semi-annual evaluation record would include the date of the evaluation and a record of the mine operator's evaluation of any changes in mining operations that may reasonably be expected to result in new or increased respirable crystalline silica exposures. In addition, the mine operator would be required to post the sampling and evaluation records and the laboratory report on the mine bulletin board and, if applicable, by electronic means, for the next 31 days, upon receipt. All records would be retained for at least 2 years from the date of each sampling or evaluation.

Proposed § 60.13 would require mine operators to make a record of corrective actions and the dates of the corrective actions. The corrective action records would be retained for at least 2 years from the date of each corrective action.

Proposed § 60.14 would require mine operators to retain a record of the written determination by a PLHCP that a miner who may be required to use a respirator is unable to wear a respirator. The written determination record would be retained for the duration of a miner's employment plus 6 months.

Proposed § 60.15 would require MNM mine operators to obtain a written medical opinion from the PLHCP or specialist within 30 days of a miner's medical examination. The written medical opinion would contain the date of the medical examination, a statement that the examination has met the requirements of this proposed section, and any recommended limitations on the miner's use of respirators. The written medical opinion record would be retained for the duration of a miner's employment plus 6 months.

II. Changes to Existing Information Collections

This proposed rulemaking would result in non-substantive changes to existing information collection packages. One change under OMB Control Number 1219-0011 is to occur after 1219-0NEW, Respirable Crystalline Silica Standard, is approved by OMB. The other change is the discontinuance of the existing information collection package under OMB Control Number 1219-0048 which is also to occur after OMB approval of 1219-0NEW, Respirable Crystalline Silica Standard.

OMB Control Number 1219-0011, Respirable Coal Mine Dust Sampling, involves records for quarterly sampling of respirable dust in coal mines. The supporting statement references quartz and a reduced standard for respirable dust when quartz is present; however, there is no specific recordkeeping requirement that is associated with those references. Due to changes in the proposed rule, MSHA would make a non-substantive change to the supporting statement by removing such references. However, there would be no changes in paperwork burden and costs in this information collection.

OMB Control Number 1219-0048, Respirator Program Records, involves recordkeeping requirements under 30 CFR parts 56 and 57 for MNM mines when respiratory protection is used. MSHA is proposing to update the existing respiratory protection standard and permit mine operators to select the requirements of the standard that are applicable to their mines. This proposed change would eliminate the paperwork burden associated with respiratory protection resulting in the request to discontinue the existing information collection.

A. Solicitation of Comments

Pursuant to the Paperwork Reduction Act, MSHA has prepared and submitted an information collection request (ICR) to OMB for the collection of information requirements identified in this proposed rule for OMB's review in accordance with 44 U.S.C. 3507(d). MSHA is soliciting comments concerning the proposed information collection related to respirable crystalline silica. MSHA is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronic submission of responses).

B. Proposed Information Collection Requirements

I. Type of Review: New Collection.

OMB Control Number: 1219–0NEW.

1. *Title*: Respirable Crystalline Silica Standard

2. *Description of the ICR*: The proposed rule on respirable crystalline silica contains collection of information requirements that would assist miners and mine operators in identifying exposures to respirable crystalline silica in order to track actual and potential occupational exposure and action taken to control such exposure.

There are provisions of this proposed rule that would take effect at different times after the implementation of this proposed rule, and there are provisions that would have different burden hours, burden costs, and responses each year. Therefore, MSHA shows the estimates of burden hours, burden costs, and responses in three separate years.

3. *Summary of the Collection of Information*:

Highlighted below are the key assumptions, by provision, used in the burden estimates in Table XI-1:

Proposed § 60.12 – Exposure monitoring

ICR. Proposed § 60.12 would require mine operators to make a record for each baseline sampling, corrective action sampling, periodic sampling, semi-annual evaluation, and post-evaluation sampling, as previously described.

Number of respondents. For proposed § 60.12, the respondents would consist of all active mines because operators of active mines are assumed to perform baseline sampling and conduct semi-annual evaluations.

MSHA counts the number of active mines in 2019, defining an active mine as one that had at least 520 employment hours (equivalent to 1 person working full time for a quarter) in at least one quarter of 2019. Using this definition, MSHA estimates that a total of 12,631 mines (11,525 MNM mines and 1,106 coal mines) would generate sampling and evaluation records.

Annual number of responses. The estimated average annual number of responses would be 142,408, including 24,439 for baseline sampling, 9,237 for sampling after corrective actions, 64,116 for periodic sampling, 42,103 for semi-annual evaluation recording and posting, and 2,513 for post-evaluation sampling.

MSHA assumes that all the active mines (12,631 mines) would conduct baseline sampling once in the first year. In succeeding years, about 253 new mines would conduct baseline sampling with an average of 5.6 samples per mine. The estimated number of periodic samplings is calculated based on the following factors: the number of miners with sampling

results at or above the proposed action level (25 μg/m^3) but at or below the PEL (50 μg/m^3), the percent of miners needed for representative samples, and the number of quarters mines would be in operation. In year 1, MSHA expects the sampling to begin in the second half of the year, thereby decreasing the number of samples by half. As a result, MSHA estimates that an annual average of 64,116 periodic samples would be conducted in the first three years. Furthermore, MSHA assumes that all 12,631 mines would record semi-annual evaluation results twice a year – except in year 1, when it would be done once - and then post those results on a mine bulletin board, or if applicable, by electronic means. MSHA estimates mines would conduct sampling as a result of their semi-annual evaluations and an average of four miners would be sampled, resulting in an annual average of 2,513 samples.

MSHA estimates that about 22 percent of active mines (2,771 mines in total) would have at least one miner overexposed to respirable crystalline silica. MSHA further estimates that the 2,771 mines that would then conduct corrective action sampling for about four areas per mine. In year 1, they would sample in half as many areas.

Estimated annual burden. The estimated average annual burden would be 31,392 hours, including 6,110 hours for baseline sampling, 2,309 for corrective action sampling, 16,029 hours for periodic sampling, 6,316 hours for semi-annual evaluation recording and posting, and 628 hours for post-evaluation sampling. MSHA estimates that it would take 15 minutes to record the sampling results, 15 minutes to record the results of a semi-annual evaluation, and 3 minutes to post each of the evaluation results on the mine bulletin board, and, if applicable, by electronic means.

Proposed § 60.13 – Corrective actions

ICR. Proposed § 60.13 would require mine operators to make a record of corrective actions, as previously described.

Number of respondents. For proposed § 60.13, only those mines with at least one miner exposure above the proposed PEL are assumed to carry out the proposed requirement. MSHA

estimates that about 22 percent of active mines (2,771 mines in total) would have at least one miner overexposed to respirable crystalline silica.

Annual number of responses. The estimated average annual number of responses would be 14,922, including 9,237 for corrective action records, and 5,685 for miner respirator records. MSHA estimates that the 2,771 mines that will be required to conduct and record corrective actions will do so for about four mine areas, except in year 1, when it would be done in half as many mine areas. MSHA further estimates this will affect 6,822 miners per year – except in year 1, when half as many miners would be affected - with each miner requiring a record of the miner being given access to a respirator until the corrective action is taken.

Estimated annual burden. The estimated average annual burden would be 1,054 hours, including 769.7 for corrective action records and 284.3 for miner respirator records. MSHA estimates that it takes five minutes to record a corrective action and the date. On average, it takes three minutes to note a miner's access to a respirator.

Proposed § 60.14 – Respiratory protection

ICR. Proposed § 60.14 would require mine operators to retain a record of the determination by a PLHCP that a miner who may be required to use a respirator is unable to wear a respirator, as previously described.

Number of respondents. For proposed § 60.14, MSHA assumes that 33 percent of mine operators would have their miners use respiratory protection as a temporary measure and keep records of their miners' ability to wear respirators. The number of respondents would be, on average, 603 mines per year, with each mine assumed to have at least some miners wearing respirators.

Annual number of responses. The estimated annual number of responses would be 1,205, with an average of two miners for each of the 603 mines.

Estimated annual burden. The estimated annual burden would be 603 hours. MSHA assumes it takes 30 minutes to record this information for about two miners for each of the 603 mines.

Proposed § 60.15 - Medical surveillance for mental and nonmetal miners

ICR. Proposed § 60.15 would require MNM mine operators to obtain a written medical opinion from a PLHCP or specialist regarding any recommended limitations on a miner's use of respirators, as previously described.

Number of respondents. MSHA assumes that 75 percent of eligible MNM miners (current MNM miners), including contract workers, would make use of the opportunity to receive a voluntary medical exam that is paid by their mine operator. As a result, an average of 25,175 current miners are estimated to receive voluntary medical exams per year. This estimate represents the upper range of the participation rate of voluntary medical exams by miners. MSHA is using the upper end of the range to avoid underestimating compliance costs.

MSHA further estimates that 8,392 miners in a given year, including contract workers, would be new miners and contractors who would undergo mandatory medical examinations. MSHA estimated that the turnover of MNM miners would be 8,392 miners per year (1/22 of the estimated total of 184,615 MNM workers with an average number of 22 years on the job before leaving the mining industry). The estimated total respondents per year therefore would be 33,567 (= 8,392 + 25,175).

Annual number of responses. The estimated annual number of responses would be 33,567, including 8,392 new miners and 25,175 current miners.

Estimated annual burden. The estimated annual burden would be 8,392 hours, including 2,098 hours for new MNM miners and 6,294 hours for current miners. MSHA estimates it takes 15 minutes to record the medical examination results for each of the 33,567 miners.

Total Recordkeeping and Documentation Burden for Proposed Part 60

Table XI-1. Estimated Average Annual Recordkeeping and Documentation Burden for Part 60

Proposed Provision	Annual Number of Respondents	Annual Number of Responses	Estimated Annual Burden (Hours)
§ 60.12 – Exposure Monitoring	12,631	142,408	31,392
§ 60.13 – Corrective Action	3,411	14,922	1,054
§ 60.14 – Miners unable to wear respirators	603	1,205	603
§ 60.15 – Medical surveillance for MNM miners	33,567	33,567	8,392
Annual Recordkeeping Total	46,198	192,102	41,440

As shown in Table XI-1, the total number of respondents is 46,198: 12,631 mines plus 33,567 miners; the estimated annual number of responses would be 192,102; and the estimated annual burden would be 41,440 hours. These estimates are based on the conservative assumption that 75 percent of eligible current miners would take part in medical surveillance, which could overestimate the recordkeeping cost and burden. The following estimates of information collection burden are summarized in Table XI-2.

1. *Affected Public:* Businesses or For-Profit
2. *Estimated Number of Respondents*: 47,456 respondents in the first year; 46,198 respondents in the second year; and 44,939 respondents in the third year.
3. *Frequency*: On Occasion
4. *Estimated Number of Responses:* 192,990 responses in the first year; 197,021 responses in the second year; and 186,294 responses in the third year.
5. *Estimated Number of Burden Hours:* 44,678 hours in the first year; 41,162 hours in the second year; and 38,480 hours in the third year.
6. *Estimated Hour Burden Costs:* $2,843,901 in the first year; $2,558,724 in the second year; and $2,377,996 in the third year.
7. *Estimated Capital Costs to Respondents:* $25,262 in each of the three years.

Table XI-2. Summary of Information Collection Burden for Proposed Part 60

	Year 1	Year 2	Year 3	Annual Average
Number of Respondents	47,456	46,198	44,939	46,198
Number of Responses	192,990	197,021	186,294	192,102
Number of Burden Hours (Rounded)	44,678	41,162	38,480	41,440
Hour Burden Costs (Rounded)	$2,843,901	$2,558,724	$2,377,996	$2,593,541
Capital Costs to Respondents	$25,262	$25,262	$25,262	$25,262

Most of the reduction in the number of responses and burden hours from the first year to the second year is a result of baseline sampling being carried out in all current mines in the first year while only being carried out in new mines starting from the second year.

For a detailed summary of the burden hours and related costs by provision, see the Preliminary Regulatory Impact Analysis (PRIA) accompanying the proposed rule. The PRIA includes the estimated costs and assumptions for the paperwork requirements related to this proposed rule.

C. Changes to Existing Information Collection Requirements

I. Type of review: Non-substantive change to currently approved information collection.

OMB Control Number: 1219–0011.

1. *Title*: Respirable Coal Mine Dust Sampling.
2. *Description of the ICR*:

Background

In October 2022, MSHA received OMB approval for the reauthorization of the Respirable Coal Mine Dust Sampling under OMB Control Number 1219-0011. This information collection request outlines the legal authority, procedures, burden, and costs associated with recordkeeping and reporting requirements for coal mine operators. MSHA's standards require that coal mine operators sample respirable coal mine dust quarterly and make records of such samples.

Summary of Changes

This non-substantive change request is to revise the supporting statement for this information collection request due to the proposed PEL for respirable crystalline silica for all miners in this proposed rule. These proposed revisions would remove any reference in the information collection request to quartz or the reduction of the respirable dust standard due to the presence of quartz. This change does not modify the authority, affected mine operators, or paperwork burden.

3. *Summary of the Collection of Information:*

Changes in Burden

The calculated burden including respondents and responses remain the same.

Affected Public: Businesses or For-Profit

Estimated Number of Respondents: 676 (0 from this rulemaking)

Frequency: On occasion

Estimated Number of Responses: 995,102 (0 from this rulemaking)

Estimated Number of Burden Hours: 58,259 (0 from this rulemaking)

Estimated Hour Burden Costs: $3,271,611 ($0 from this rulemaking)

Estimated Capital Costs to Respondents: $29,835 ($0 from this rulemaking)

II. Type of Review: Discontinued information collection request.

OMB Control Number: 1219–0048.

1. *Title*: Respirator Program Records.

2. *Description of the ICR*:

Background

Title 30 CFR parts 56 and 57 incorporate by reference requirements of ANSI Z88.2-1969, "*Practices for Respiratory Protection*." Under this standard, certain records are required to be kept in connection with respirators. The proposed rule would incorporate by reference ASTM F3387-19, "*Standard Practice for Respiratory Protection*," in 30 CFR parts 56 and 57 to

replace the Agency's existing respiratory protection standard. The proposal would require mine operators' respiratory protection plans to include certain minimally acceptable program elements, but beyond that, would permit mine operators to select the requirements of ASTM F3387-19 that are applicable to their mines.

Summary of Changes

The proposed rule would remove the paperwork burden associated with respiratory protection in the information collection request.

3. *Summary of the Collection of Information*:

Changes in Burden

MSHA has submitted a request to discontinue OMB Control Number 1219-0048, eliminating all paperwork burden associated with the information collection request. It would discontinue upon the effective date of the final rule.

Affected Public: Businesses or For-Profit

Estimated Number of Respondents: 0 (-350 from this rulemaking)

Frequency: On occasion

Estimated Number of Responses: 0 (-630 from this rulemaking)

Estimated Number of Burden Hours: 0 (-3,588 from this rulemaking)

Estimated Hour Burden Costs: $0 (-$284,084 from this rulemaking)

Estimated Capital Costs to Respondents: $0 (-$140,000 from this rulemaking)

D. Submitting Comments

The information collection package for this proposal has been submitted to OMB for review under 44 U.S.C. 3506(c) of the Paperwork Reduction Act of 1995, as amended. Comments on the information collection requirements should be sent to MSHA by one of the methods previously explained in the DATES section of this preamble.

The information collection request will be available on http://www.regulations.gov. MSHA cautions the commenter against providing any information in the submission that should

not be publicly disclosed. Full comments, including personal information provided, will be made available on www.regulations.gov and www.reginfo.gov.

The public may also examine publicly available documents at the Mine Safety and Health Administration, 201 12th South, Suite 4E401, Arlington, VA 22202-5450. Sign in at the receptionist's desk on the 4th floor via the East elevator. Before visiting MSHA in person, call 202-693-9440 to make an appointment and determine if any special health precautions are required in keeping with the Department of Labor's COVID-19 policy.

Questions about the information collection requirements may be directed to the contact person listed in the FOR FURTHER INFORMATION section of this preamble.

E. Docket and Inquiries

Those wishing to download comments and other materials relating to paperwork determinations should use the procedures described in this preamble. One may also obtain a copy of this ICR by going to http://www.reginfo.gov/public/do/PRAMain, clicking on "Currently under Review - Open for Public Comments" and scrolling down to "Department of Labor."

A Federal agency cannot conduct or sponsor a collection of information unless it is approved by OMB under the Paperwork Reduction Act and displays a currently valid OMB control number. The public is not required to respond to a collection of information unless the collection of information displays a currently valid OMB control number.

XII. Other Regulatory Considerations

A. National Environmental Policy Act

The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq.), requires each Federal agency to consider the environmental effects of final actions and to prepare an Environmental Impact Statement on major actions significantly affecting the quality of the environment. MSHA has reviewed the proposed standard in accordance with NEPA requirements, the regulations of the Council on Environmental Quality (40 CFR part 1500), and

the Department of Labor's NEPA procedures (29 CFR part 11). As a result of this review, MSHA has determined that this proposed rule will not have a significant environmental impact. Accordingly, MSHA has not conducted an environmental assessment nor provided an environmental impact statement.

B. The Unfunded Mandates Reform Act of 1995

MSHA has reviewed the proposed rule under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). The Unfunded Mandates Reform Act requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any 1 year (5 U.S.C. 1532(a)). MSHA has determined that this proposed rule does not result in such an expenditure. Accordingly, the Unfunded Mandates Reform Act requires no further Agency action or analysis.

C. The Treasury and General Government Appropriations Act of 1999: Assessment of Federal Regulations and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 (5 U.S.C. 601 note) requires agencies to assess the impact of Agency action on family well-being. MSHA has determined that the proposed rule will have no effect on family stability or safety, marital commitment, parental rights and authority, or income or poverty of families and children, as defined in the Act. The proposed rule impacts the mine industry and does not impose requirements on states or families. Accordingly, MSHA certifies that this proposed rule will not impact family well-being, as defined in the Act.

D. Executive Order 12630: Government Actions and Interference with Constitutionally Protected Property Rights

Section 5 of E.O. 12630 requires Federal agencies to "identify the takings implications of proposed regulatory actions . . ." MSHA has determined that the proposed rule does not

implement a taking of private property or otherwise have takings implications. Accordingly, E.O. 12630 requires no further Agency action or analysis.

E. Executive Order 12988: Civil Justice Reform

The proposed rule was written to provide a clear legal standard for affected conduct and was carefully reviewed to eliminate drafting errors and ambiguities so as to minimize litigation and avoid undue burden on the Federal court system. Accordingly, the proposed rule meets the applicable standards provided in section 3 of E.O. 12988, Civil Justice Reform.

F. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

E.O. 13045 requires Federal agencies submitting covered regulatory actions to OMB's Office of Information and Regulatory Affairs (OIRA) for review, pursuant to E.O. 12866, to provide OIRA with (1) an evaluation of the environmental health or safety effects that the planned regulation may have on children, and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency. In E.O. 13045, "covered regulatory action" is defined as rules that may (1) be significant under Executive Order 12866 Section 3(f)(1) (i.e., a rulemaking that has an annual effect on the economy of $200 million or more or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities), and (2) concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children. Environmental health risks and safety risks refer to risks to health or to safety that are attributable to products or substances that the child is likely to come in to contact with or ingest through air, food, water, soil, or product use or exposure.

MSHA has determined that, in accordance with E.O. 13045, while the proposed rule is considered significant under E.O. 12866 Section 3(f)(1), it does not concern an environmental health or safety risk that may have a disproportionate impact on children. MSHA's proposed

rule would lower the occupational exposure limit to respirable crystalline silica for all miners, take other actions to protect miners from adverse health risks associated with exposure to respirable crystalline silica, and require updated respiratory standards to better protect miners from all airborne hazards.

MSHA is aware of studies which have characterized and assessed the risks posed by "take-home" exposure pathways for hazardous dust particles. However, the proposed rule's primary reliance on engineering and administrative controls to protect miners from respirable crystalline silica exposures helps minimize risks associated with "take-home" exposures by reducing or eliminating silica that is in the mine atmosphere or the miner's personal breathing zone. The risks of take-home exposures are further minimized by MSHA's existing standards, operators' policies and procedures, and operators' use of clothing cleaning systems.

MSHA's existing standards limit miners' exposures to respirable crystalline silica. MSHA also requires coal mine operators to provide miners bathing facilities and change rooms. Miners have access to these facilities to shower and change their work clothes at the end of each shift. In addition, some mine operators provide miners with clean company clothing for each shift, have policies and procedures for cleaning or disposing of contaminated clothing, and provide a boot wash for miners to clean work boots during and after each shift. Moreover, some operators use clothing cleaning systems that can remove dust from a miner's clothing. Many of these systems include NIOSH-designed dust removal booths that use compressed air to remove dust, which is then vacuumed through a filter to remove airborne contaminants. Overall, the Agency's standards, mine operators' policies and procedures, and other safety practices including the use of clothing cleaning systems help to reduce or eliminate the amount of take-home exposure, therefore protecting other persons in a miner's household or persons who come in to contact with the miner outside of the mine site.

MSHA identified one epidemiological study (Onyije et al., 2022) that suggests a possible association between paternal exposure to respirable crystalline silica and childhood leukemia.

However, this study does not provide dose-response data which would be needed to establish the dose of respirable crystalline silica which results in a no-adverse-effect-level (NOAEL) for childhood leukemia. This potential association has not been independently confirmed by another study. MSHA invites comment on the identification of any other scientific or academic study or information that evaluates the potential association between paternal exposure to respirable crystalline silica and childhood leukemia during the NPRM's public comment period.

MSHA also invites comment on the identification of any scientific or academic study or information that evaluates the potential risks to female workers who are exposed to respirable crystalline silica during pregnancy.

MSHA has no evidence that the environmental health or safety risks posed by respirable crystalline silica, including "take-home" exposure to respirable crystalline silica, disproportionately affect children. Therefore, MSHA preliminarily concludes no further analysis or action is needed, in accordance with E.O. 13045.

G. Executive Order 13132: Federalism

MSHA has determined that the proposed rule does not have "federalism implications" because 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." Accordingly, under E.O. 13132, no further Agency action or analysis is required.

H. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

MSHA has determined the proposed rule does not have "tribal implications" because it will not "have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." Accordingly, under E.O. 13175, no further Agency action or analysis is required.

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

E.O. 13211 requires agencies to publish a Statement of Energy Effects for "significant energy actions," which are agency actions that are "likely to have a significant adverse effect on the supply, distribution, or use of energy" including a "shortfall in supply, price increases, and increased use of foreign supplies." MSHA has reviewed the proposal for its impact on the supply, distribution, and use of energy because it applies to the mining industry. The proposed rule would result in annualized compliance costs of $4.85 million using a 3 percent real discount rate and $4.97 million using a 7 percent real discount rate for the coal mine industry relative to annual revenue of $27.03 billion. The proposal would also result in annualized compliance costs of $54.23 million using a 3 percent real discount rate and $55.72 million using a 7 percent real discount rate for the metal/nonmetal mine industry relative to annual revenue of $88.32 billion. Because it is not "likely to have a significant adverse effect on the supply, distribution, or use of energy" including a "shortfall in supply, price increases, and increased use of foreign supplies," it is not a "significant energy action." Accordingly, E.O. 13211 requires no further agency action or analysis.

J. Executive Order 13272: Proper Consideration of Small Entities in Agency Rulemaking

MSHA has thoroughly reviewed the proposed rule to assess and take appropriate account of its potential impact on small businesses, small governmental jurisdictions, and small organizations. MSHA's analysis is presented in Section X. Initial Regulatory Flexibility Analysis.

K. Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities Through the Federal Government

E.O. 13985 provides "that the Federal Government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and

inequality." E.O. 13985 defines "equity" as "consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality." To assess the impact of the proposed rule on equity, MSHA considered two factors: (1) the racial/ethnic distribution in mining in NAICS 212 (which does not include oil and gas extraction) compared to the racial/ethnic distribution of the U.S. workforce (Table XII-1), and (2) the extent to which mining may be concentrated within general mining communities (Table XII-2).

In 2008, NIOSH conducted a survey of mines, which entailed sending a survey packet to 2,321 mining operations to collect a wide range of information, including demographic information on miners. NIOSH's 2012 report, entitled "National Survey of the Mining Population: Part I: Employees" reported the findings of this survey (NIOSH 2012a). Race and ethnicity information about U.S. mine workers is presented in Table XII-1. Of all mine workers, including miners as well as administrative employees at mines, 93.4 percent of mine workers were white, compared to 80.6 percent of all U.S workers.[71] There were larger percentages of American Indian or Alaska Native and Native Hawaiian or Other Pacific Islander people in the mining industry compared to all U.S. workers, while there were smaller percentages of Asian, Black or African American, and Hispanic/Latino people in the mining industry compared to all U.S. workers.

[71] National data on workers by race were not available for the year 2008; comparable data for 2012 are provided for comparison under the assumption that there would not be major differences in distributions between these two years.

Table XII-2 shows that there are 22 mining communities, defined as counties where at least 2 percent of the population is working in the mining industry.[72] Although the total population in this table represents only 0.15 percent of the U.S. population, it represents 12.0 percent of all mine workers. The average per capita income in these communities in 2020, $47,977,[73] was lower than the U.S. average, $59,510, representing 80.6 percent of the U.S. average. However, each county's average per capita income varies substantially, ranging from 56.4 percent of the U.S. average to 146.8 percent.

The proposed rule would lower exposure to respirable crystalline silica and improve respiratory protection for all mine workers. MSHA determined that the proposed rule is consistent with the goals of E.O. 13985 and would support the advancement of equity for all workers at mines, including those who are historically underserved and marginalized.

Table XII-1: Racial and Ethnic Distribution of Mine Workers* (2012)

	Number of Workers in Mining (except oil and gas) (NAICS 212)	**As a Percent of Total Mine Workers Who Self-Identified in These Categories (Latest Data for 2008)**	**Percent of All Workers in the United States for Comparison (Latest Data 2012)******
Ethnicity			
Hispanic/Latino	26,622	12.1	15.0
Non-Hispanic or Latino	192,839	87.9	85.0
Total	**219,461**	**100.0**	**100.0**
Race**			
American Indian or Alaska Native***	4,050	1.9	0.8
Asian	183	0.1	5.4

[72] Although 2 percent may appear to be a small number for identifying a mining community, one might consider that if the average household with one parent working as a miner has five members in total, then approximately 10 percent of households in the area would be directly associated with mining. While 10 percent may also appear small, this refers to the county. There are likely particular areas that have a heavier concentration of mining households.

[73] This is a simple average rather than a weighted average by population.

Black or African American	8,893	4.3	13.0
Native Hawaiian or Other Pacific Islander	634	0.3	0.2
White	194,016	93.4	80.6
Total	**207,776**	**100.0**	**100.0**

*Mine workers includes miners and other workers at mines such as administrative employees.

**Does not include mine workers who did not self-report in one of these categories. Some of the surveyed mine workers may not have self-reported in one of these categories if they are affiliated with more than one race, or if they chose not to respond to this survey question.

***Includes mine workers who self-identified as an American Indian or Alaskan Native as a single race, not in combination with any other races. No other data on mine workers in this racial group were available from this source. In other employment statistics often reported on American Indians and Alaska Natives, their population is based on self-reporting as being American Indian or Alaska Native in combination with any other race, which has resulted in the reporting of much higher employment levels. See BLS, *Monthly Labor Review*, "Alternative Measurements of Indian Country: Understanding Their Implications for Economic, Statistical, and Policy Analysis," https://www.bls.gov/opub/mlr/2021/article/alternative-measurements-of-indian-country.htm.

**** More recent data from the 2020 Decennial Census were not available in September 2022.

Sources: National Institute for Occupational Safety and Health (NIOSH). 2012a. National Survey of the Mining Population Mining Publication: Part 1: Employees, DHHS (NIOSH) Pub. No. 2012-152, June 2012; U.S. Census Bureau, 2012 American Community Survey (ACS).

Table XII-2. Mining Counties: Counties in the United States with Relatively High Concentrations of Mine Workers (At Least 2 Percent of the County Population)

#	County	Number of Mine Workers (First Quarter 2022)	Population of County (Latest Data in 2021)	Estimated Percent of Population Who Are Mine Workers
1	White Pine County, Nevada	1,288	9,182	14.0
2	Pershing County, Nevada	771	6,741	11.4
3	Humboldt County, Nevada	1,549	17,648	8.8
4	Campbell County, Wyoming	3,547	46,401	7.6
5	Winkler County, Texas	513	7,415	6.9
6	Mercer County, North Dakota	555	8,323	6.7
7	Chase County, Kansas	166	2,598	6.4
8	Shoshone County, Idaho	723	13,612	5.3
9	Logan County, West Virginia	1,643	31,909	5.1
10	Sweetwater County, Wyoming	2,050	41,614	4.9
11	Glasscock County, Texas	56	1,149	4.9
12	Livingston County, Kentucky	431	8,959	4.8
13	Buchanan County, Virginia	946	19,816	4.8
14	McDowell County, West Virginia	660	18,363	3.6
15	Big Horn County, Wyoming	413	11,632	3.6
16	Sevier County, Utah	601	21,906	2.7
17	Boone County, West Virginia	582	21,312	2.7

18	Moffat County, Colorado	349	13,185	2.6
19	Nye County, Nevada	1,062	43,946	2.4
20	Raleigh County, West Virginia	1,647	73,771	2.2
21	Wyoming County, West Virginia	456	21,051	2.2
22	Elko County, Nevada	1,090	53,915	2.0
	Total	**20,963**	**494,448**	**4.2**
	All U.S. Counties	174,387	331,893,745	
	Mine Workers in Mining Counties as a Percent of All U.S. Mine Workers	12.0%		
	Population of Mine Counties as a Percent of U.S. Population		0.15%	

Source: Bureau of Labor Statistics (BLS), Quarterly Employment and Wages First Quarter 2022 (2022); Bureau of Economic Analysis, Personal Income by County, Metro, and Other Areas 2020 (2020); U.S. Census Bureau, "Annual Estimates of the Resident Population for Counties: April 1, 2020 to July 1, 2021 (CO-EST2021-POP)." *Census.gov.* Accessed DATE. Available at: *https://www.census.gov/data/tables/time-series/demo/popest/2020s-counties-total.html*; U.S. Census Bureau, Quick Facts, available at: https://www.census.gov/quickfacts/fact/table/US/PST045221 (accessed DATE).

L. Availability of Materials to be Incorporated by Reference

The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 5 U.S.C. 552(a); 1 CFR part 51. These regulations require that information that is incorporated by reference in a rule be "reasonably available" to the public. They also require discussion in the preamble to the rule of the ways in which materials it proposes to incorporate by reference are reasonably available to interested parties or how it worked to make those materials reasonably available to interested parties. Additionally, the preamble to the rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR's requirements, MSHA provides in the following: (a) summaries of the materials to be incorporated by reference and (b) information on the public availability of the materials and on how interested parties can access the materials during the comment period and upon finalization of the rule.

*ASTM F3387-19, "Standard Practice for Respiratory Protection" (ASTM F3387-19)*ASTM F3387-19 is a voluntary consensus standard that represents up-to-date advancements in respiratory protection technologies, practices, and techniques. The standard includes provisions for selection, fitting, use, and care of respirators designed to remove airborne

contaminants from the air using filters, cartridges, or canisters, as well as respirators that protect miners in oxygen-deficient or immediately dangerous to life or health atmospheres. These provisions are based on NIOSH's long-standing experience of testing and approving respirators for occupational use and OSHA's research and rulemaking on respiratory protection. The proposed rule would incorporate by reference ASTM F3387-19 in existing §§ 56.5005, 57.5005, and 72.710 and in proposed § 60.14(c)(2) to better protect all miners from airborne hazards. MSHA believes that incorporating by reference ASTM F3387-19 would provide mine operators with up-to-date requirements for respirator technology, reflecting an improved understanding of effective respiratory protection and therefore better protecting the health and safety of miners. For further details on MSHA's proposed update to the Agency's existing respiratory protection standard, please see section VII.C of this preamble, Updating MSHA Respiratory Protection Standards by Incorporating by Reference ASTM F3387-19.

A paper copy or printable version of ASTM F3387-19 may be purchased by mine operators or any member of the public at any time from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959; https://www.astm.org/. ASTM International makes read-only versions of its standards that have been referenced or incorporated into Federal regulation or laws available free of charge at its online Reading Room, https://www.astm.org/products-services/reading-room.html. During the comment period, a read-only version of ASTM F3387-19 will be made available free of charge.[74]

In addition, during the comment period and upon finalization of this rule, ASTM F3387-19 will be available for review free of charge at MSHA headquarters at 201 12th Street South, Arlington, VA 22202-5450 (202-693-9440).

ISO 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related

[74] The read-only version of ASTM F3387-19 available for public review during the comment period can be accessed using the following link – https://tinyurl.com/mwk97hjn.

Sampling.

ISO 7708:1995 is an international consensus standard that defines sampling conventions for particle size fractions used in assessing possible health effects of airborne particles in the workplace and ambient environment. It defines conventions for the inhalable, thoracic, and respirable fractions. The proposed rule would incorporate by reference ISO 7708:1995 in proposed § 60.12(f)(4) to ensure consistent sampling collection by mine operators through the utilization of samplers conforming to ISO 7708:1995.

A paper copy or printable version of ISO 7708:1995 may be purchased by mine operators or any member of the public at any time from ISO, CP 56, CH-1211 Geneva 20, Switzerland; phone: + 41 22 749 01 11; fax: + 41 22 733 34 30; website: www.iso.org/. ISO makes read-only versions of its standards that have been incorporated by reference in the CFR available free of charge at its online Incorporation by Reference Portal, http://ibr.ansi.org/Default.aspx.

In addition, during the comment period and upon finalization of this rule, ISO 7708:1995 will be available for review free of charge at MSHA headquarters at 201 12th Street South, Arlington, VA 22202-5450 (202-693-9440).

TLV's Threshold Limit Values for Chemical Substances in Workroom Air Adopted by ACGIH for 1973.

This material is referenced in the amendatory text of this document but has already been approved for appendix A. No changes are proposed.

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XIV. Appendix

Appendix A

Description of MSHA Respirable Crystalline Silica Samples

This document describes the respirable crystalline silica samples used in this rulemaking. The Mine Safety and Health Administration (MSHA) collected these samples from metal/nonmetal **(**MNM) and coal mines and analyzed the data to support this rulemaking. Technical details are discussed in the following attachments.

MNM Respirable Dust Sample Dataset, 2005-2019

From January 1, 2005, to December 31, 2019, 104,354 valid MNM respirable dust samples were entered into the MSHA Technical Support Laboratory Information Management

System (LIMS) database.[75] The dataset includes MNM mine respirable dust personal exposure samples collected by MSHA inspectors. A total of 57,824 samples contained a respirable dust mass of 0.100 mg or greater (referred as "sufficient-mass dust samples"), while a total of 46,530 samples contained a respirable dust mass of less than 0.100 mg (referred as "insufficient-mass dust samples").

Respirable dust samples collected by MSHA inspectors are assigned a three-digit "contaminant code" based on the contaminant in the sample. MSHA's contaminant codes group contaminants based on their health effects[76] and are assigned by the MSHA Laboratory based on sample type and analysis results. The codes link information, such as contaminant description, permissible exposure limit (PEL), and the units of measure for each contaminant sampled.

The MNM respirable crystalline silica dataset includes five contaminant codes.

MNM Respirable Dust Sample Contaminant Codes

- Contaminant code 521 – MNM respirable dust samples that were not analyzed for respirable crystalline silica.
- Contaminant code 523 – MNM respirable dust samples containing 1 percent or more quartz.
- Contaminant code 525 – MNM respirable dust samples containing cristobalite.
- Contaminant code 121 – MNM respirable dust samples containing less than 1 percent quartz where the commodity is listed as a "nuisance particulate" in Appendix E of the

[75] Only valid (non-void) MNM respirable dust samples were included in the LIMS dataset. Voided samples include any samples with a documented reason which occurred during the sampling and/or the MSHA's laboratory analysis for invalidating the results.

[76] For example, contaminant code 523 indicates that dust from that sample contained 1 percent or more respirable crystalline silica (quartz). Exposure to respirable crystalline silica has been linked to the following health outcomes: silicosis, non-malignant respiratory disease, lung cancer, and renal disease.

TLVs® Threshold Limit Values for Chemical Substances in Workroom Air Adopted by ACGIH for 1973 (reproduced in Table A-1).

- Contaminant code 131 – MNM respirable dust samples containing less than 1 percent quartz where the commodity is not listed as a "nuisance particulate" in Appendix E of the 1973 ACGIH TLV® Handbook.

Table A-1: Reproduction of TLVs® Threshold Limit Values for Chemical Substances in Workroom Air Adopted by ACGIH for 1973 Appendix E, Threshold Limit Values Material List: "Some Nuisance Particulates*; Threshold Limit Value – 10 mg/m^3"

Alundum (Al_2O_3)	Gypsum	Rouge
Calcium Carbonate	Kaolin	Silicon Carbide
Cellulose (paper fiber)	Limestone	Starch
Corundum (Al_2O_3)	Magnesite	Sucrose
Emery	Marble	Tin Oxide
Glass, fibrous** or dust	Pentaerythritol	Titanium Dioxide
Glycerin Mist	Plaster of Paris	Vegetable oil mists (except castor, cashew nut, or similar irritant oils)
Graphite (synthetic)	Portland Cement	

*When toxic impurities are not present, e.g., quartz < 1 percent
** <5-7 μm in diameter
Note: This list contains examples of certain materials that are considered "nuisance" particulates when the material is in dust form. This list is not intended to be exclusive. If the miner sampled is exposed to one or more of the listed materials, then the TLV® for "nuisance" dust should be applied.
Source: American Conference of Governmental Industrial Hygienists (ACGIH). 1973. TLVs® Threshold Limit Values for Chemical Substances in Workroom Air Adopted by ACGIH for 1973. Cincinnati, Ohio.

MNM Respirable Dust Samples with a Mass of at Least 0.100 milligram (mg) (Sufficient-Mass Dust Samples)

The 57,824 samples that contained at least 0.100 mg of respirable dust were analyzed to quantify their respirable crystalline silica content – mostly respirable quartz but also respirable cristobalite. The respirable crystalline silica concentrations were entered into the MSHA Standardized Information System (MSIS) database (internal facing) and Mine Data Retrieval System (MDRS) database (public facing). Those MNM respirable dust samples with a mass of at least 0.100 mg are analyzed and contained in MSIS. MSIS and MDRS differ from LIMS in that some of the fields associated with a sample can be modified or corrected by the inspector.

These correctable fields include Mine ID, Location Code, and Job Code. Inspectors cannot access or modify the fields in the LIMS database.

From the database, 55 samples[77] were removed because they were erroneous, had an incorrect flow rate, had insufficient sampling time, or were duplicated. This resulted in a final dataset of 57,769 MNM samples that contained a mass of at least 0.100 mg of respirable dust. Datasets containing the analyzed samples that MSHA removed and retained can be found in the rulemaking docket MSHA-2023-0001.

MNM Respirable Dust Samples with a Mass of Less Than 0.100 mg (Insufficient-Mass Samples)

The LIMS database also included 46,530 MNM respirable dust samples that contained less than 0.100 mg of respirable dust. These samples did not meet the minimum dust mass criterion of 0.100 mg and were not analyzed for respirable crystalline silica by MSHA's Laboratory.

From these 46,530 samples, 167 samples[78] were removed because they were erroneous, had an incorrect flow rate, or had insufficient sampling time. This resulted in 46,363 remaining MNM samples containing less than 0.100 mg of respirable dust. These samples were assigned to

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[77] There were 55 samples removed: 7 samples had no detected mass gain (denoted as "0 mg"); 1 sample was a partial shift that was not originally marked correctly; 1 sample was removed at the request of the district; 44 samples had flow rates outside the acceptable range of 1.616 – 1.785 L/min; and 2 samples were duplicates of samples that were already in the dataset. This resulted in the final sample size of 57,769 = 57,824 – (7 + 1 + 1 + 44 + 2).

[78] There were 167 samples removed: 75 samples had a cassette mass less than -0.03 mg (based on instrument tolerances, samples that report a cassette mass between -0.03 mg and 0 mg were treated as having a mass of 0 mg, samples with masses below that threshold of -0.03 mg were excluded); 52 samples had Mine IDs that did not report employment for any year from 2005-2019; 31 samples had flow rates outside the acceptable range of 1.615 – 1.785 L/min ; six samples had sampling times of less than 30 minutes; and three samples had invalid Job Codes. This resulted in the final sample size of 46,363 = 46,530 – (75 + 52 + 31 + 6 + 3).

contaminant code 521, indicating that the samples were not analyzed for quartz. Datasets containing the unanalyzed samples that MSHA removed and retained can be found in the rulemaking docket MSHA-2023-0001.

All MNM Respirable Dust Samples

After removing the 222 samples mentioned above (55 sufficient-mass and 167 insufficient-mass), the dataset consisted of 104,132 MNM respirable dust samples: 57,769 sufficient-mass samples and 46,363 insufficient-mass samples. A breakdown of the MNM respirable dust samples is included in Table A-2.

Table A-2: Distribution of MNM Respirable Dust Samples

Contaminant Code	Description	Number of Samples
	Total LIMS samples with dust mass ≥ 0.100 mg (sufficient-mass samples)	*57,824*
	Samples removed with dust mass ≥ 0.100 mg	55
	Samples retained with dust mass ≥ 0.100 mg	**57,769**
523	Dust respirable fraction, ≥ 1% quartz	39,772
525	Containing cristobalite	7
121	Nuisance dust, listed, respirable fraction, <1% silica	9,256
131	Unlisted dust, respirable fraction, <1% silica	8,734
	Total LIMS samples with dust mass < 0.100 mg (insufficient-mass samples)	*46,530*
	Samples removed with dust mass < 0.100 mg	167
	Samples retained with dust mass < 0.100 mg	**46,363**
521	Respirable dust samples not analyzed for quartz	46,363
	Total Samples	*104,354*
	Total Samples Removed	222
	Total Samples Retained	**104,132**

Sources: MSHA MDRS/MSIS respirable crystalline silica data for the MNM industry, January 1, 2005, through December 31, 2019 (version 20220615); MSHA Personal Health Samples Public Dataset.

Coal Respirable Dust Sample Dataset, 2016 –2021

From August 1, 2016, to July 31, 2021, 113,607 valid respirable dust samples from coal mines were collected by MSHA inspectors and entered in the LIMS database.[79] For coal mines, the analysis is based on samples collected by inspectors beginning on August 1, 2016, when Phase III of MSHA's 2014 respirable coal mine dust (RCMD) standard went into effect. Samples taken prior to implementation of the RCMD standard would not be representative of current respirable crystalline silica exposure levels in coal mines.

Of these samples collected by MSHA inspectors, 67,963 samples were analyzed for respirable crystalline silica; 45,644 samples were not. Respirable dust samples from coal mines contain the records of the sample type, and the occupation of the miner sampled. A coal sample's type is based on the location within the mine as well as the occupation of the miner sampled. Below is a list of coal sample types and descriptions, as well as the mass of respirable dust required for that type of sample to be analyzed for respirable crystalline silica.

- Type 1 – Designated occupation (DO). The occupation on a mechanized mining unit (MMU) that has been determined by results of respirable dust samples to have the greatest respirable dust concentration. Designated occupation samples must contain at least 0.100 mg of respirable dust to be analyzed for respirable crystalline silica.
- Type 2 – Other designated occupation (ODO). Occupations other than the DO on an MMU that are also designated for sampling, required by 30 CFR part 70. These samples must contain at least 0.100 mg of respirable dust to be analyzed for respirable crystalline silica.

[79] Only valid (non-void) coal respirable dust samples were included in the LIMS dataset. Voided samples include any samples with a documented reason which occurred during the sampling and/or the MSHA's Laboratory analysis for invalidating the results.

- Type 3 – Designated area (DA). Designated area samples are from specific locations in the mine identified by the operator in the mine ventilation plan under 30 CFR 75.371(t), where samples will be collected to measure respirable dust generation sources in the active workings. These samples must contain at least 0.100 mg of respirable dust to be analyzed for respirable crystalline silica.
- Type 4 – Designated work position (DWP). A designated work position in a surface coal mine or surface work area of an underground coal mine designated for sampling to measure respirable dust generation sources in the active workings. Designated work position samples must contain at least 0.200 mg of respirable dust to be analyzed for respirable crystalline silica. There are exceptions for certain occupations: bulldozer operator (MSIS general occupation code 368), high wall drill operator (code 384), high wall drill helper (code 383), blaster/shotfirer (code 307), refuse/backfill truck driver (code 386), or high lift operator/front end loader (code 382). Samples from these occupations must have at least 0.100 mg of respirable dust to be analyzed for respirable crystalline silica.
- Type 5 – Part 90 miner. A Part 90 miner is employed at a coal mine and has exercised the option under the old section 203(b) program (36 FR 20601, Oct. 27, 1971) or under 30 CFR 90.3 to work in an area of a mine where the average concentration of respirable dust in the mine atmosphere during each shift to which a miner is exposed is continuously maintained at or below the applicable standard and has not waived these rights. A sample from a Part 90 miner must contain at least 0.100 mg of respirable dust to be analyzed for respirable crystalline silica.
- Type 6 – Non-designated area (NDA). Non-designated area samples are taken from locations in the mine that are not identified by the operator in the mine ventilation plan under 30 CFR 75.371(t) as areas where samples will be collected to measure respirable

dust generation sources in the active workings. These samples are not analyzed for respirable crystalline silica.

- Type 7 – Intake air samples are taken from air that has not yet ventilated the last working place on any split of any working section or any worked-out area, whether pillared or non-pillared, as per 30 CFR 75.301. These samples are not analyzed for respirable crystalline silica.
- Type 8 – Non-designated work position (NDWP). A work position in a surface coal mine or a surface work area of an underground coal mine that is sampled during a regular health inspection to measure respirable dust generation sources in the active workings but has not been designated for mandatory sampling. For the analysis of respirable crystalline silica, these samples must have at least 0.200 mg of respirable dust. There are exceptions for certain occupations: bulldozer operator (MSIS general occupation code 368), high wall drill operator (code 384), high wall drill helper (code 383), blaster/shotfirer (code 307), refuse/backfill truck driver (code 386), or high lift operator/front end loader (code 382). Samples taken from these occupations must contain at least 0.100 mg respirable dust to be analyzed for respirable crystalline silica.

Coal Respirable Dust Samples Analyzed for Respirable Crystalline Silica

There were 67,963 samples from coal mines collected by MSHA inspectors from underground and surface coal mining operations that were analyzed for respirable crystalline silica. These results were entered first into LIMS, and then into MSIS and MDRS. Results from MSIS were used as they may be updated by the inspectors at later dates.[80] From those 67,963

[80] As mentioned in the section concerning samples for MNM mines, MSIS and MDRS differ from LIMS in that some data fields can be modified or corrected by the inspector. These correctable fields include Mine ID, Location Code, and Job Code.

samples, 4,836 samples were removed as they were environmental samples, voided in MSIS, or had other errors.[81] This resulted in a dataset of 63,127 samples from coal mines that were analyzed for respirable crystalline silica. Datasets containing the analyzed samples that MSHA removed and retained can be found in the rulemaking docket MSHA-2023-0001.

Coal Respirable Dust Samples Not Analyzed for Respirable Crystalline Silica

Similar to MNM respirable dust samples, the LIMS database includes 45,644 coal samples that did not meet the criteria for analysis and were thus not analyzed for respirable crystalline silica content.[82] After removing 13,243[83] samples that were environmental samples, erroneous, or had voided controls, there were 32,401 samples that were not analyzed for respirable crystalline silica. Datasets containing the unanalyzed samples that MSHA removed and retained can be found in the rulemaking docket MSHA-2023-0001.

All Coal Respirable Dust Samples

In total, 18,079 respirable dust samples from coal mines were removed from the original datasets: 4,836 samples that were analyzed for respirable crystalline silica and 13,243 samples that were not. This created a final dataset of 95,528 samples: 63,127 analyzed samples and

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[81] There were 4,836 samples removed: 4,199 samples were environmental and not personal samples (see Sample Type explanation for more detail); 631 samples had been voided after they had been entered into MSIS; and 6 had invalid Job Codes. This resulted in the final sample size of 63,127 = 67,963 – (4,199 + 631 + 6).

[82] In addition to the criteria listed above, samples from Shop Welders (code 319) are not analyzed for respirable crystalline silica as they are instead analyzed for welding fumes.

[83] There were 13,243 samples removed: 6 samples had typographical errors; 14 samples had a cassette mass less than -0.03 mg (based on instrument tolerances, samples that report a cassette mass between -0.03 mg and 0 mg were treated as having a mass of 0 mg); 92 samples had invalid Job Codes; 12,724 were environmental samples; 44 samples had an occupation code of 000 despite having a personal sample 'Sample Type'; 271 samples had controls that were voided; and 92 came from Job Code 319 – Welder (see Footnote 82). This resulted in the final sample size of 32,401 = 50,545 – (6 + 14 + 92 + 12,724 + 44 + 271 + 92).

32,401 samples that were not analyzed.[84] A breakdown of respirable dust samples from coal mines is included in Table A-3.

Table A-3: Distribution of Coal Respirable Dust Samples

Sample Type	Number of Samples
Total LIMS Samples Analyzed for Respirable Crystalline Silica Content	*67,963*
Analyzed Samples Removed	4,836
Analyzed Samples Retained	**63,127**
Type 1	10,149
Type 2	42,828
Type 4	4,788
Type 5	365
Type 8	4,997
Total LIMS Samples Not Analyzed for Respirable Crystalline Silica Content	*45,644*
Unanalyzed samples removed	13,243
Unanalyzed samples retained	**32,401**
Total Samples	*113,607*
Total Samples Removed	18,079
Total Samples Retained	**95,528**

Source: MSHA MDRS/MSIS respirable crystalline silica data for the coal industry, August 1, 2016, through July 31, 2021 (version 20220617).

Attachment 1. MNM Samples Analyzed for Cristobalite

Cristobalite is one of the three polymorphs of respirable crystalline silica analyzed by MSHA's Laboratory upon request that is included in this proposed rule. At the request of the inspector, MNM[85] respirable dust samples that contain at least 0.050 mg of respirable dust are

[84] This dataset did not include any other coal mine respirable dust sample types collected by MSHA inspectors - i.e., sample types 3 (designated area samples), types 6 (Non-face occupations) and 7 (Intake air), samples taken on the surface mine shop welder (n=319), and all voided samples. Voided samples are any samples that have a documented reason which occurred during the sampling and/or laboratory analysis for invalidating the results.

[85] See Attachment 2. Technical Background about Measuring Respirable Crystalline Silica, for more information.

analyzed for cristobalite. Of the 57,769 retained MNM samples that contained at least 0.050 mg of respirable dust, 0.6 percent (or 359 samples) were analyzed for cristobalite. Coal respirable dust samples are not analyzed for cristobalite.[86]

Table A1-1: MNM Respirable Dust Samples Analyzed for Cristobalite

Description	Number of Samples	Percent of Samples
Samples with mass ≥ 0.100 mg	57,769	
Samples analyzed for Cristobalite	359	0.6%
Samples not analyzed for Cristobalite	57,410	99.4%

Sources: MSHA MDRS/MSIS respirable crystalline silica data for the MNM industry, January 1, 2005, through December 31, 2019 (version 20220615); MSHA Personal Health Samples Public Dataset.

While the samples that were analyzed for cristobalite were assigned to all four contaminant codes seen in this dataset, the majority were assigned contaminant code 523.

Table A1-2: Distribution of MNM Respirable Dust Samples Analyzed for Cristobalite, by Contaminant Code

Code	Contaminant	Number of Samples	Percent of Samples
	Total Samples Analyzed for Cristobalite	**359**	
523	Dust respirable fraction, ≥ 1% quartz	215	59.9%
525	Containing cristobalite	6	1.7%
121	Nuisance dust, listed, respirable fraction, <1% silica	32	8.9%
131	Unlisted dust, respirable fraction, <1% silica	106	29.5%

Sources: MSHA MDRS/MSIS respirable crystalline silica data for the MNM industry, January 1, 2005, through December 31, 2019 (version 20220615); MSHA Personal Health Samples Public Dataset.

The distribution of the 359 samples by cristobalite mass can be seen in Table A1-3.[87]

Table A1-3: Distribution of Analyzed Samples by Cristobalite Mass

Cristobalite Mass (µg)	Number of Samples	Percent of Samples
5	334	93.1%
11-20	14	3.9%
21-30	7	1.9%

[86] See Attachment 2. Technical Background about Measuring Respirable Crystalline Silica, for more information.

[87] Of the 369 samples that were analyzed for cristobalite, 334 had a value for cristobalite mass that was less than the limit of detection (LOD) for cristobalite, 10 µg. As such these samples were assigned a value of 5 µg of cristobalite, one half the LOD. See Attachment 2. Technical Background about Measuring Respirable Crystalline Silica, for more information.

31-40	3	0.8%
> 40	1	0.3%
Total	**359**	**100%**

Sources: MSHA MDRS/MSIS respirable crystalline silica data for the MNM industry, January 1, 2005, through December 31, 2019 (version 20220615); MSHA Personal Health Samples Public Dataset.

The mass of each sample was then used to calculate a cristobalite concentration by dividing the mass of cristobalite by the volume of air sampled (0.816 m^3). The calculated concentrations ranged from 6 µg/m^3 to 53 µg/m^3.[88]

Table A1-4: Samples Analyzed for Cristobalite by Concentration (µg/m^3)

Cristobalite Concentration (µg/m^3)	Number of Samples	Percent of Samples
6	334	93.1%
12-20	12	3.3%
21-30	5	1.4%
31-40	5	1.4%
41-50	2	0.6%
> 50	1	0.3%
Total	**359**	**100%**

Sources: MSHA MDRS/MSIS respirable crystalline silica data for the MNM industry, January 1, 2005, through December 31, 2019 (version 20220615); MSHA Personal Health Samples Public Dataset.

[88] One sample had a cristobalite concentration of 53 µg/m^3. It was sampled in July of 2011 at Mine ID 4405407 and cassette number 610892. The commodity being mined was Stone: Crushed, Broken Quartzite. The occupation of the miner being sampled was Miners in Other Occupations: Job Code 513 – Building and Maintenance.

Attachment 2. Technical Background about Measuring Respirable Crystalline Silica

In the proposed rule, respirable crystalline silica refers to three polymorphs: quartz, cristobalite, and tridymite. MSHA's Laboratory uses two methods to analyze respirable crystalline silica content in mine respirable dust samples. The first method, X-ray diffraction (XRD), separately analyzes quartz, cristobalite, and tridymite contents in respirable dust samples that mine inspectors obtain at MNM mine sites (MSHA Method P-2, 2018a). The second method, Fourier transform infrared spectroscopy (FTIR), is used to analyze quartz in respirable dust samples obtained at coal mines (MSHA Method P-7, 2018b and 2020). Although the XRD method can be expanded from MNM to coal dust samples, MSHA chooses to use the FTIR method for coal dust samples because it is a faster and less expensive method. However, the current MSHA P-7 FTIR method cannot quantify quartz if cristobalite and/or tridymite are present in the sample. The method also corrects the quartz result for the presence of kaolinite, an interfering mineral for quartz analysis in coal dust.

Limits of Detection and Limits of Quantification for Silica Sample Data

The Limits of Detection (LOD) and Limits of Quantification (LOQ) are the two terms used to describe the method capability. The LOD refers to the smallest amount of the target analyte (respirable crystalline silica) that can be detected in the sample and distinguished from zero with an acceptable confidence level that the analyte is actually present. It can also be described as the instrument signal that is needed to report with a specified confidence that the analyte is present. The LOQ refers to the smallest amount of the target analyte that can be repeatedly and accurately quantified in the sample with a specified precision. The LOQ is higher than the LOD. The values of the LOD and LOQ are specific to MSHA's Laboratory as well as the instrumentation and analytical method used to perform the analysis. These values do not change from one batch to another when samples are analyzed on the same equipment using the same method. However, their levels may change over time due to updated analytical methods

and technological advances. The values of the LOD and LOQ for the methods (XRD and FTIR) used in analyzing respirable crystalline silica samples are explained in MSHA documents for MNM samples and coal samples (MSHA Method P-2, 2018a; MSHA Method P-7, 2018b and 2020). MSHA periodically updates these values to reflect progress in its analytical methods. The values of LOD and LOQ were last updated in 2022 for MNM samples and in 2020 for coal samples.

The values of LODs and LOQs for respirable crystalline silica in samples from MSHA inspectors depend on several factors, including the analytical method used (XRD or FTIR) and the silica polymorph analyzed (quartz, cristobalite, or tridymite), as presented in Table A2-1.

For a sample with respirable crystalline silica content less than the method LOD, the maximum concentration is calculated as the respirable crystalline silica mass equivalent to LOD divided by the volume of air sampled. For example, if no quartz is detected by XRD analysis for an MNM sample, the method LOD is 5 µg. If that sample is collected at 1.7 L/min air flow rate for 480 minutes (i.e., 8 hours), the air sample volume would be 816 L (= 1.7 L/min * 480 minutes), or 0.816 m^3. The calculated maximum concentration associated with a sample having respirable crystalline silica mass below the method LOD would be 6 µg/m^3 (= 5 µg/0.816 m^3). The "half maximum concentration" is the midpoint between 0 and the calculated maximum respirable crystalline silica concentration, which is 3 µg/m^3 (= ½ * 6 µg/m^3) in this example.

Table A2-1: Calculated Maximum Concentration for Samples Below LOD, by Analytical Method and Respirable Crystalline Silica Polymorph

Sample Dates	MSHA Analytical Method (Method Name[A])	Respirable Crystalline Silica Analysis Type (polymorph)	Air Volume for Sample (flow rate)	Limit of Quantification (µg per filter)	Limit of Detection (µg per filter)	Calculated Maximum Concentration ("Half maximum concentration)
MNM Mines						
01/01/2005 - 12/31/2019	XRD (P-2-2018)	Quartz	816 L=0.816 m^3 in 8 hours (1.7 L/min)	20 µg	5 µg	6 µg/m^3 (half = 3 µg/m^3)
01/01/2005 - 12/31/2019	XRD (P-2-2018)	Cristobalite	816 L=0.816 m^3 in 8 hours (1.7 L/min)	40 µg	10 µg	12 µg/m^3 (half = 6 µg/m^3)

Coal Mines						
08/01/2016 - 08/31/2020	FTIR (P-7-2018)	Quartz	*X* L= Sampling time (min) x 2.0 L/min / 1000 m^3	20 µg	4 µg	Value is variable based on sampling time (min)
09/01/2020 - 07/31/2021	FTIR (P-7-2020)	Quartz	*X* L= Sampling time (min) x 2.0 L/min / 1000 m^3	12 µg	3 µg	

Notes:
(A)Samples in the designated sampling years are collected and analyzed using the corresponding analytical methods. The values of LOQ and LOD are determined by the analytical method, polymorph, and air volume for each sample. The analytical methods used are P-2-2018 for MNM, and P-7-2018 or P-7-2020 for coal, respectively. For example, method P-2-2018 is used in measuring both quartz and cristobalite for MNM samples taken from January 1, 2015, to December 31, 2019. The values of LOQ are different for quartz and cristobalite in MNM samples. MSHA updated its methods for coal in 2020 (Method P-7-2020) and MNM in 2022 (method P-2-2022).
(B)As of the 2018 SOP the LOQ for cristobalite was 40 µg based on the instrumentation and software in use at the time. The current LOQ as updated in the 2022 SOP is 20 µg, as based on the instrumentation and software currently in use.

The air volume is treated differently for MNM and coal samples under the existing standards. In the case of MNM samples, 8-hour equivalent time weighted averages (TWAs) are calculated using 480 minutes (8 hours) and a flow rate of 1.7 L/min, even if samples are collected for a longer duration. In contrast, coal TWAs are calculated using the full duration of the shift and a flow rate of 2.0 L/min and converted to an MRE equivalent concentration under existing standards.

Assumptions for Analyzed Samples

Samples from MNM mines that contain at least 0.100 mg of dust mass are analyzed for the presence of quartz and/or cristobalite. For samples from coal mines, the minimum amount of respirable dust in a sample to be analyzed for respirable crystalline silica is determined by sample type and the occupation of the miner sampled. For Sample Types 1, 2, and 5, the sample must contain at least 0.100 mg of respirable dust. For Sample Types 4 and 8, the sample must contain at least 0.200 mg of respirable dust unless it comes from one of the following occupations: bulldozer operator (MSIS general occupation code 368), high wall drill operator (code 384), high wall drill helper (code 383), blaster/shotfirer (code 307), refuse/backfill truck driver (code 386), and high lift operator/front end loader (code 382). Samples taken from these occupations must contain at least 0.100 mg respirable dust to be analyzed for respirable

crystalline silica. Samples from Shop Welders (code 319) are never analyzed for quartz, as they instead are sent for welding fume analysis.

MSHA makes separate assumptions based on the mass of respirable crystalline silica for a sample, whether it is above or below the method LOD. For all samples reporting a mass of respirable crystalline silica greater or equal to the method LOD, MSHA used the reported values to calculate the respirable crystalline silica concentration for the sample. For samples with values below the method LOD, including samples reported as containing 0 µg of silica, MSHA used ½ of the LOD to calculate the respirable crystalline silica concentration of the sample. MSHA understands that its assumptions regarding samples with respirable crystalline silica mass below the method LOD will have a minimal impact on the assessment.[89]

Table A2-2: MSHA's Assumptions of Values Used to Calculate Concentration of Quartz and Cristobalite

Measured Mass	Value Used to Calculate RCS Concentration
Quartz	
≥LOQ	Measured Value
≥LOD and <LOQ	Measured Value
>0 µg/m^3 and <LOD	½ LOD
0 µg/m^3	½ LOD
Cristobalite	
≥LOQ	Measured Value
≥LOD and <LOQ	Measured Value
>0 µg/m^3 and <LOD	½ LOD
0 µg/m^3	½ LOD

Source: MSHA.

The reported value of respirable crystalline silica mass from an MNM or coal sample can fall under one of the four groups: 1) at or above the method LOQ, 2) at or above the method

[89] In its Final Regulatory Economic Analysis (FREA) for its 2016 silica rule, OSHA observed: "…that XRD analysis of quartz from samples prepared from reference materials can achieve LODs and LOQs between 5 and 10 µg was not disputed in the [rulemaking] record." (OSHA, 2016).

LOD but below the LOQ, 3) greater than 0 µg but less than the method LOD, or 4) equal to 0 µg. MSHA treats these samples differently based on their respirable crystalline silica mass.

Quartz Mass at or above the Method LOQ

For MNM and coal samples reporting quartz mass at or above the method LOQs, MSHA uses the values reported by the MSHA's Laboratory.

Quartz Mass Between Method LOD and LOQ

For MNM and coal samples reporting quartz mass at or above the method LOD but below the LOQ, MSHA uses the values reported by the MSHA's Laboratory.

Quartz Mass Between the Method LOD and 0 µg

A review of respirable crystalline silica samples in LIMS reveals that some samples had a respirable crystalline silica mass below the LOD of the analytical methods but greater than 0 µg. Values in this range (i.e., below the method LOD but greater than 0 µg) cannot reliably indicate the presence of respirable crystalline silica. The mass of silica in these is too small to reliably detect, but the concentration of silica could be up to the calculated maximum concentration based on the method LOD. For example, consider a sample from an MNM mine that was analyzed for quartz and had a reported quartz mass of 4 µg. This falls below the LOD of 5 µg but above 0 µg, and as such the sample could actually contain anywhere from 0 µg of quartz up to the LOD value of 5 µg of quartz.

In these cases, MSHA used ½ the LOD value to calculate respirable crystalline silica concentration. MSHA explored other options to treat these samples such as treating the reported silica mass as 0 $\mu g/m^3$ (lower bound) as well as assuming the sample silica mass is just below the LOD and assigning each sample a value of the method LOD (upper bound). The use of the ½ LOD value is considered a reasonable assumption since using either the lower bound of 0 $\mu g/m^3$ or the upper bound of the associated method's LOD could under or overestimate exposures,

respectively. The assumption is not expected to impact the assessment of silica concentration because any sample results with respirable crystalline silica mass below the method LODs (between 3-10 µg/m^3) would also have been well below the lowest exposure profile range (<25 µg/m^3).

Quartz Mass of 0 µg

A portion of the MNM and coal samples below the LOD are listed as having respirable crystalline silica (specifically quartz) mass levels of 0 µg. For these samples, instead of treating the mass of silica in the sample as a true zero, MSHA replaced the value with ½ the LOD of the associated method. Although the respirable crystalline silica mass of these samples is less than the LOD, it is likely that the sample still contains a small amount of respirable crystalline silica. Hence, MSHA assumes a value of ½ LOD in its calculation of respirable crystalline silica concentration for these samples. This assumption is considered to be reasonable because using the lower bound of 0 µg/m^3 for these samples could underestimate the respirable crystalline silica concentration while using the upper bound of method LODs could overestimate the respirable crystalline silica concentration.

Table A2-3 presents an example for quartz, one of the respirable crystalline silica polymorphs. This table shows the LOD of quartz mass and the possible range of quartz concentrations for samples reporting a quartz mass of 0 µg. These adjusted concentrations are expected to have a limited impact of the assessment of respirable crystalline silica concentration, as supported by MSHA's sensitivity analyses.

Table A2-3: Recast Concentration of Samples with 0 µg/m^3 Quartz

Sample Dates	Quartz Mass LOD (Value Less than LOD listed)	Range of Concentrations (µg/m^3)	Recast Concentration
MNM			
01/01/2005 - 12/31/2019	5 µg (0 µg)	0 µg/m^3	Recast using ½ LOD
01/01/2005 - 12/31/2019	5 µg (1 to <5 µg)	1 to <6 µg/m^3	Recast using ½ LOD

Coal			
08/01/2016 - 08/31/2020	3 µg (0 µg)	0 µg/m^3	Recast using ½ LOD
08/01/2016 - 08/31/2020	3 µg (1 to <3 µg)	1 to 2 µg/m^3	Recast using ½ LOD
09/01/2020 - 07/31/2021	3 µg (0 µg)	0 µg/m^3	Recast using ½ LOD
09/01/2020 - 07/31/2021	3 µg (1 to <3 µg)	1 to 2 µg/m^3	Recast using ½ LOD

Sources: MSHA MDRS/MSIS respirable crystalline silica database January 1, 2005, through December 31, 2019, for MNM, August 1, 2016 - July 31, 2021, for Coal.

Cristobalite Measurement

Respirable dust samples from MNM mines are rarely analyzed for cristobalite by MSHA, and respirable coal dust samples are not analyzed for the presence of cristobalite. MNM samples are analyzed for the presence of cristobalite only when requested by MSHA inspectors because the geological or work conditions indicate this specific polymorph may be present. The LIMS database includes samples for which cristobalite was analyzed, either with or without quartz analysis. MSHA uses similar assumptions for cristobalite and quartz.

The cristobalite LOD for these samples is 10 µg. The MSHA Laboratory-reported values are used for analyzed dust samples with cristobalite mass values equal to or above the method LODs. Samples that were analyzed for cristobalite and had a cristobalite mass value below the method LOD were assigned values of ½ LOD, or 5 µg. For example, 267 samples, or 74.4 percent of the 359 samples that were analyzed for cristobalite, reported a value of 0 µg of cristobalite; these were assigned a value of 5 µg.

When a sample is analyzed for two polymorphs (i.e., both quartz and cristobalite), detectable quartz and cristobalite are summed to generate the total respirable crystalline silica. If only one of these polymorphs is detected, the sample concentration is based on the detected polymorph. If the concentrations of both polymorphs (quartz and cristobalite) are reported as 0 µg/m^3, ½ mass LOD is assumed in calculating the concentrations and the resulting concentrations are summed.

Unanalyzed Samples

There are also samples whose dust mass fell below their associated mass threshold, and as such, they were not analyzed for the presence of quartz and/or cristobalite. The respirable dust mass for a sample was considered to be 0 µg when the net mass gain of dust was 0 µg or less.

References

MSHA. 2018. P-2: X-Ray Diffraction Determination of Quartz and Cristobalite in Respirable Metal/Nonmetal Mine Dust.

MSHA. 2018a. P-7: Infrared Determination of Quartz in Respirable Coal Mine Dust

MSHA. 2020. P-7: Determination of Quartz in Respirable Coal Mine Dust by Fourier Transform Infrared Spectroscopy.

OSHA, 2016. Final Regulatory Economic Analysis (FEA) for OSHA's Final Rule on Respirable Crystalline Silica, Chapter IV.3.2.3 - Sensitivity of Sampling and Analytical Methods.

Appendix B
Mining Commodity Groups

For this rulemaking analysis, the mining industries are grouped into six commodities – Coal, Metal, Nonmetal, Stone, Crushed Limestone, and Sand and Gravel. The table below shows the six commodity groupings based on the Standard Industrial Classification (SIC) codes and the North American Industry Classification System (NAICS) codes. The SIC system is a predecessor of NAICS using industry titles to standardize industry classification. The NAICS is widely used by Federal statistical agencies, including the Small Business Administration (SBA), for classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy.

SIC Industry Titles and NAICS Codes in Mining Industries

Mining Commodity Group	SIC Code Industry Title	2022 NAICS Code	2022 NAICS Industry
Nonmetal	Oil Shale, Oil Sand, Oil Mining	211120	Crude Petroleum and Natural Gas Extraction
Nonmetal	Natural Gas	211130	Natural Gas Extraction
Coal	Bituminous Coal, Lignite, and Anthracite Coal	212114	Surface Coal Mining
Coal	Bituminous and Anthracite Coal	212115	Underground Coal Mining
Metal	Iron Ore, Magnetite	212210	Iron Ore Mining
Metal	Gold Ore, Silver Ore	212220	Gold Ore and Silver Ore Mining
Metal	Copper Ore NEC, Nickel, Lead-Zinc Ore, Zinc	212230	Copper, Nickel, Lead, and Zinc Mining (partial: Copper and Nickel only)
Metal	Chromite Chromium Ore, Cobalt Ore, Columbium Tantalum Ore, Manganese Ore, Molybdenum Ore, Tungsten Ore, Miscellaneous Metal Ore NEC, Aluminum Ore-Bauxite, Antimony Ore, Beryl-Beryllium Ore, Mercury Ore, Platinum Group Ore, Rare Earths Ore, Tin Ore, Titanium Ore, Zirconium Ore, Uranium-Vanadium Ore, Uranium Ore, Vanadium Ore	212290	Other Metal Ore Mining
Stone	Dimension Stone NEC, Dimension Granite, Dimension Limestone, Dimension Marble, Dimension Sandstone, Dimension Slate, Dimension Traprock, Dimension Basalt, Dimension Mica, Dimension Quartzite	212311	Dimension Stone Mining and Quarrying

Mining Commodity Group	SIC Code Industry Title	2022 NAICS Code	2022 NAICS Industry
Crushed Limestone	Crushed, Broken Limestone NEC	212312	Crushed and Broken Limestone Mining and Quarrying
Stone	Crushed, Broken Granite	212313	Crushed and Broken Granite Mining and Quarrying
Stone	Crushed, Broken Stone NEC; Crushed, Broken Marble; Crushed, Broken Sandstone; Crushed, Broken Slate; Crushed, Broken Traprock; Crushed, Broken Basalt; Crushed, Broken Mica; Crushed, Broken Quartzite	212319	Other Crushed and Broken Stone Mining and Quarrying
Sand and Gravel	Construction Sand and Gravel, Common Sand	212321	Construction Sand and Gravel Mining
Sand and Gravel	Industrial Sand NEC, Ground Silica, Ground Cristobalite, Ground Quartz	212322	Industrial Sand Mining
Nonmetal	Kaolin and Ball Clay, Clay, Ceramic, and Refractory Minerals, Aplite, Bentonite, Brucite, Common Clays NEC, Feldspar, Fire Clay, Fullers Earth, Kyanite, Magnesite, Common Shale	212323	Kaolin, Clay, and Ceramic and Refractory Minerals Mining
Nonmetal	Miscellaneous Nonmetallic Mineral NEC, Asbestos, Cryolite, Diatomaceous Earth (Diatomite), Gilsonite, Graphite, Gypsum, Leonardite, Mica, Perlite, Pumice, Pyrophyllite, Shell, Crushed Dimension Soapstone, Talc, Tripoli, Vermiculite, Zeolites, Wollastonite, Gemstones, Agate, Amethyst, Emerald, Garnet, Olivine, Crystal Quartz, Sapphire, Turquoise, Potash, Soda, and Borate Minerals NEC, Boron Minerals, Potash, Sodium Compounds, Trona, Potassium Compounds, Phosphate Rock, Colloidal Phosphates, Chemical and Fertilizer Mineral NEC, Barite Barium Ore, Fluorspar, Lithium Minerals, Pigment Minerals, Pyrites, Salt, Sulfur, Brine Evaporated Salt	212390	All Other Nonmetallic Mineral Mining
Stone	Cement	327310	Cement Manufacturing
Stone	Lime	327410	Agricultural Lime Manufacturing
Metal	Alumina	331313	Alumina Refining and Primary Aluminum Production

Appendix C

Occupational Categories for Respirable Crystalline Silica Sample Collection

This Appendix explains how MSHA categorized MNM and coal samples in constructing respirable crystalline silica exposure profile tables for the current rulemaking. MSHA has developed respirable crystalline silica exposure profile tables using its inspectors' sampling data and results. One set of exposure profile tables displays the analysis of 15 years of respirable crystalline silica sampling data from MNM mines (Attachment 1), and the other set displays the analysis of 5 years of respirable crystalline silica samples collected at coal mines (Attachment 2).[90] In the MNM tables, the respirable crystalline silica concentration information is broken out by 5 commodities (e.g., "Metal," "Crushed Limestone," etc.) and then by 11 occupational categories (e.g., "Drillers," "Stone Cutting Operators," etc.). The data for coal mining is disaggregated by 2 locations ("Underground" and "Surface") and then by 9 occupational categories (e.g., "Crusher Operators," "Continuous Mining Machine Operators," etc.).

Job Codes and Respirable Dust Sampling

MSHA inspectors use job codes to label samples of respirable dust when they conduct health inspections.[91] Following the sampling strategy outlined in the most recent MSHA Health Inspection Procedures Handbook (December 2020; PH20-V-4), the inspectors determine potential airborne hazards to which miners may be exposed, including respirable dust, and then

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[90] For coal mines, the analysis is based on samples collected by inspectors beginning on August 1, 2016, when Phase III of MSHA's 2014 RCMD standard went into effect. Samples taken prior to implementation of the RCMD standard would not be representative of current respirable crystalline silica exposure levels in coal mines.

[91] The job codes have been referred to as both job codes and occupation codes by MSHA. For example, in the Mine Data Retrieval System, they are called job codes; in other materials, including MSHA's Inspection Application System (IAS), they are called occupational codes. For the purposes of this document, the term job code has been used to clearly differentiate the job codes from the occupational categories.

take samples from the appropriate miners or working areas at a mine. Using gravimetric samplers, the inspectors collect respirable dust samples at MNM and coal mines. When submitting the collected samples to MSHA's Laboratory for analysis, the inspectors label their samples with the three-digit job code that best describes the duties that each miner was performing during the sampling period.

The three-digit job codes are taken from MSHA's Inspection Application System (IAS), which includes 220 job codes for coal mines and 121 job codes for MNM mines. Attachments 3 and 4 include the IAS job codes for coal and MNM operations, respectively.

Coal Job Codes: The coal job codes have generally been consistent over time, with new codes added when needed. For example, IAS has the same job code for the duties of a coal "supervisor/foreman" as two predecessor documents – the "Job Code Pocket Cards" for coal mining, used by MSHA's predecessor, the Mining Enforcement and Safety Administration (MESA) (see Attachment 5), and a Fall 1983 Mine Safety and Health publication. An example is presented below in Table C-1. In the three-digit coal job code, the first digit generally identifies where the work is taking place in the mine: 0 (Underground Section Workers - Face); 1 (General Underground - Non-Face); 2 (Underground Transportation - Non-Face); 3 (Surface); 4 (Supervisory and Staff); 5 (MSHA – State); and 6 (Shaft and Slope Sinking). The coal codes starting with 6 were added in 2020 to better delineate the samples for miners conducting shaft and slope sinking activities.

Table C-1: Example of Consistent Coal Job Classifications - Occupations Classified as "Supervisor/Foreman."

Occupation / Activity	MESA Pocket Card	1983 Publication[1]	2022 IAS
	Job Code	Job Code	Job Code
Section Foreman	049	049	049
Bullgang Foreman/Labor Foreman	149	149	149
Maintenance Foreman	418	418	418
Assist Mine Foreman/Assist Mine Manager	430	430	430

Occupation / Activity	MESA Pocket Card	1983 Publication[1]	2022 IAS
	Job Code	Job Code	Job Code
Mine Foreman/Mine Manager	449	449	449
Fire Boss Pre-Shift Examiner	462	462	462
Superintendent	481	481	481
Outside Foreman	489	489	489
Preparation Plant Foreman	494	494	494

1 Fall 1983 Mine Safety and Health publication (page 6).

MNM Job Codes: Many of the 121 MNM job codes are similar to the coal job codes, as noted in Attachment 4. One major difference is that unlike the coal job codes, MNM job codes are not based on the location of the work/job. The first digit of the three-digit MNM job code does not indicate whether a job is located at an underground or surface area of the mine. For example, a "MNM Diamond Drill Operator" (Job Code 034) could be working on the surface or underground, whereas a "Coal Drill Operator" would have a different job code based on the miner's location within a mine (Job Code 034 – underground at the face; Job Code 334 – at the surface).

Occupational Categories for the Respirable Crystalline Silica Rulemaking

Some of the original work to group the MNM job codes into occupational categories was completed in 2010 in support of earlier rulemaking efforts. The MNM occupational categories were developed first and were later updated with additional sampling data as it became available. The coal occupational categories were developed several years later and were generally modeled after the MNM tables; however, coal occupational categories are first divided based on surface and underground locations because occupational activities at different locations of a mine can have differing impacts on coal miners' exposures to respirable crystalline silica. In 2020, MSHA's Laboratory used 9 coal and 14 MNM occupational categories for its respirable crystalline silica data analyses.

For the respirable crystalline silica exposure profile tables in the proposed respirable crystalline silica rule, MSHA made no change to the 9 coal occupational categories, but

condensed the 14 MNM occupational categories to 11. These occupational categories are meant to reasonably group multiple job codes with similar occupational activities/tasks and engineering controls. The grouping of job codes into occupational categories purposely focused on the occupational activities/tasks and exposure risk of the miner performing a particular job rather than the type of mining equipment utilized by the miner. The creation of occupational categories based on the types of equipment utilized by miners would have failed to accurately characterize the risk of individual miners.

Coal Occupational Categories

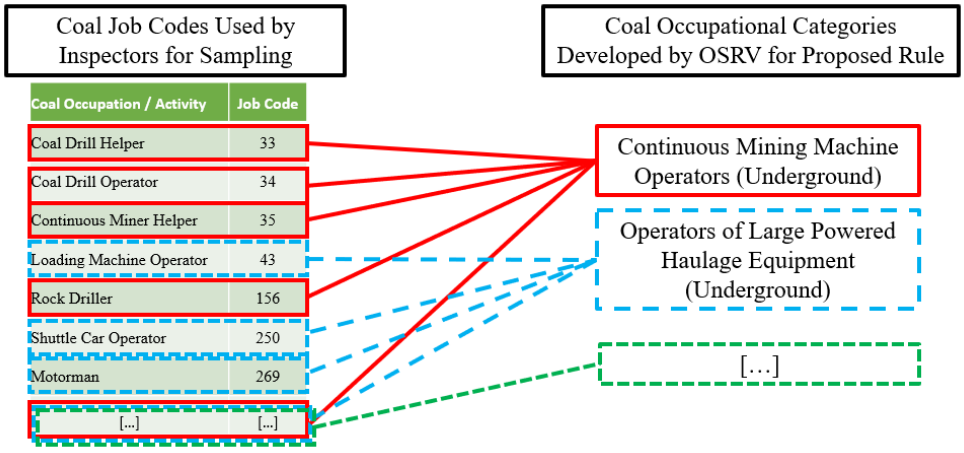
There are 220 job codes for coal miners in IAS.[92] Overall, 209 job codes are included in the 9 occupational categories. Some job codes were excluded, primarily because sampling data were not available for those job codes. The codes that have been excluded are:

- Job code 0 "Area," because area samples are not specific to any one occupation.
- Job code 398 "Groundman," because there were no sample data for this code in the respirable crystalline silica sampling dataset.
- Job codes 590 "Education Specialist," 591 "Mineral Industrial Safety Officer," 592 "Mine Safety Instructor," and 594 "Training Specialist," because there were no coal respirable crystalline silica (quartz) data for these codes for the timeframe selected.
- Job codes 602 "Electrician," 604 "Mechanic," 609 "Supply Person," 632 "Ventilation Worker," and 635 "Continuous Miner Operator Helper," because there were no sample data for these codes in the respirable crystalline silica sampling dataset.

[92] IAS also contains 272 coal job codes that are used to fill out a Mine Accident, Injury and Illness Report (MSHA Form 7000-1). These codes were not included in the respirable crystalline silica exposure profile tables and are not discussed further in this document.

The remaining 209 coal job codes are first divided by the job location - underground or surface - because potential respirable crystalline silica exposures at coal mines can vary depending on where a miner works at a given mine. (Three job codes are used in both underground and surface locations: job codes 402 "Master Electrician," 404 "Master Mechanic," and 497 "Clerk/Timekeeper.") The underground and surface job codes are further grouped on the basis of the types of tasks and typical engineering controls. For example, as shown in Figure 1, the underground "Continuous Mining Machine Operators" occupational category includes 14 different occupations that involve drilling activities—occupations such as "Coal Drill Helper," "Coal Drill Operator," and "Rock Driller." The underground "Operators of Large Powered Haulage Equipment" occupational category has 12 similar occupations including "Loading Machine Operator," "Shuttle Car Operator," and "Motorman."

Figure C-1: Examples of the Grouping of Coal Job Codes into Coal Occupational Categories



There are five categories of underground occupations and four categories of surface occupations.

The five underground occupational categories include:

(1) Continuous Mining Machine Operators (e.g., Coal Drill Helper and Coal Drill Operator);

(2) Operators of Large Powered Haulage Equipment (e.g., Shuttle Car, Tractor, Scoop Car);

(3) Longwall Workers (e.g., Headgate Operator and Jack Setter (Longwall));

(4) Roof Bolters (e.g., Roof Bolter and Roof Bolter Helper); and

(5) Underground Miners (e.g., Electrician, Mechanic, Belt Man/Conveyor Man, and Laborer, etc.).

The four surface occupational categories include:

(1) Drillers (e.g., Coal Drill Operator, Coal Drill Helper, and Auger Operator);

(2) Operators of Large Powered Haulage Equipment (e.g., Backhoe, Forklift, and Shuttle Car);

(3) Crusher Operators (e.g., Crusher Attendant, Washer Operator, and Scalper-Screen Operator); and

(4) Mobile Workers (e.g., Electrician, Mechanic, Blaster, Cleanup Man, Mine Foreman, etc.).

Attachments 1 and 3 provide the full lists of occupational categories and coal job codes.

MNM Occupational Categories

From the 121 MNM job codes in IAS, 120 job codes are included in the occupational categories and 1 job code is excluded. The code that has been excluded is:

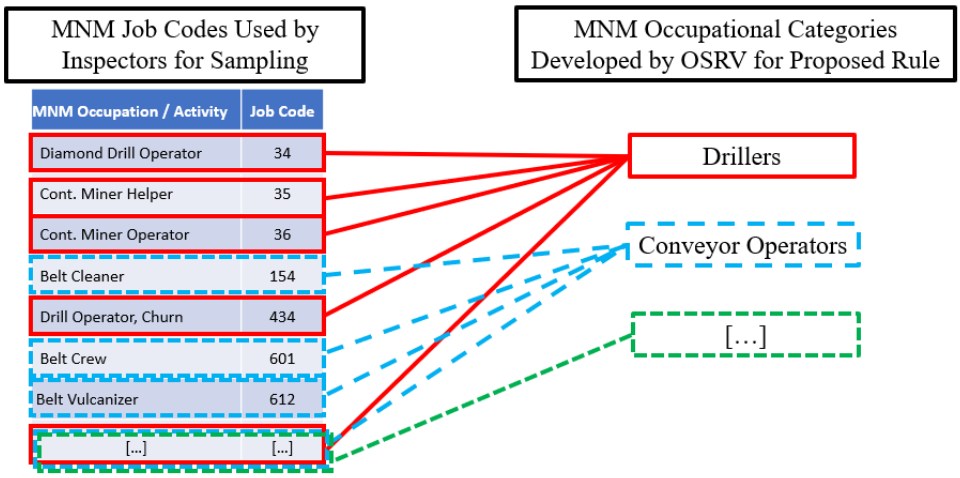
- Job code 413 "Janitor," because there were no sample data for this code in the respirable crystalline silica sampling dataset.

Of the 120 job codes included, 1 job code was listed in both the "Crushing Equipment and Plant Operators" occupational category and the "Kiln, Mill and Concentrator Workers" category. The code that was used twice is:

- Job Code 388 "Screen/Scalper Operators," because MNM job codes do not indicate the location where the work is taking place and this work can be conducted either in a plant or on the surface of the mine.

The final 121 MNM job codes (with job code 388 included twice) were first grouped into 14 occupational categories based on the types of tasks and typical engineering controls used. For example, as seen in Figure 2, the "Drillers" occupational category includes the 20 different occupations that involve drilling activities, such as "Diamond Drill Operator," "Drill Operator Churn," and "Continuous Miner Operator." "Belt Cleaner," "Belt Crew," and "Belt Vulcanizer" are included in the occupational category, "Conveyor Operators." Similar tasks were grouped together because the work activities and respirable crystalline silica exposures were anticipated to be comparable.

Figure C-2: Examples of the Grouping of MNM Job Codes into MNM Occupational Categories



The 14 occupational categories were:

(1) Bagging Machines;

(2) Stone Saws;

(3) Stone Trimmers, Splitters;

(4) Truck Loading Stations;

(5) Mobile Workers (e.g., Laborers, Electricians, Mechanics, and Supervisors);

(6) Conveyors;

(7) Crushers;

(8) Dry Screening Plants;

(9) Kilns/Dryers, Rotary Mills, Ball Mills, and Flotation/Concentrators;

(10) Large Powered Haulage Equipment (e.g., Trucks, FELs, Bulldozers, and Scalers);

(11) Small Powered Haulage Equipment (e.g., Bobcats and Forklifts);

(12) Jackhammers;

(13) Drills; and

(14) Other Occupations.

After additional consideration, it was determined that the original 14 categories could be further condensed into the final 11 categories since some of the occupational categories contained job codes where the types of tasks and engineering and administrative controls were similar enough to be combined.

The final 11 occupational categories include:

(1) Drillers (e.g., Diamond Drill Operator, Wagon Drill Operator, and Drill Helper);

(2) Stone Cutting Operators (e.g., Jackhammer Operator, Cutting Machine Operator, and Cutting Machine Helper);

(3) Operators of Large Powered Haulage Equipment (e.g., Trucks, Bulldozers, and Scalers);

(4) Conveyor Operators (e.g., Belt Cleaner, Belt Crew, and Belt Vulcanizer);

(5) Crushing Equipment and Plant Operators (Crusher Operator/Worker, Scalper Screen Operator, and Dry Screen Plant Operator);

(6) Kiln, Mill, and Concentrator Workers (e.g., Ball Mill Operator, Leaching Operator, and Pelletizer Operator);

(7) Operators of Small Powered Haulage Equipment (e.g., Bobcats, Shuttle Car, and Forklifts);

(8) Packaging Equipment Operators (e.g., Bagging Operator and Packaging Operations Worker);

(9) Truck Loading Station Tenders (e.g., Dump Operator and Truck Loader);

(10) Mobile Workers (Laborers, Electricians, Mechanics, and Supervisors, etc.); and

(11) Miners in Other Occupations (Welder, Dragline Operator, Shotcrete/Gunite Man, and Dredge/Barge Operator, etc.).

The sampling data for each of the 11 occupational categories were then summarized by commodity group ("Metal," "Nonmetal," "Stone," "Crushed Limestone," and "Sand and Gravel") based on the material being extracted.[93] The available sampling data were then collated for each occupation and commodity and summarized by concentration ranges in the exposure profile tables for MNM mines.

[93] Crushed Limestone and Sand and Gravel were considered separately because these commodities make up a large percentage of inspection samples. Watts *et al*. (2012). Respirable crystalline silica [Quartz] Concentration Trends in Metal and Nonmetal Mining, J Occ Environ Hyg 9:12, 720-732.

Attachment 1: Tables for MNM

Table C1-1: Summary of Respirable Crystalline Silica in the Metal/Nonmetal (MNM) Industry from 2005 to 2019, by Commodity and Occupational Category

Commodity	Occupation	Number of Samples	ISO Concentration, µg/m³		
			Mean (µg/m³)	Median (µg/m³)	Max (µg/m³)
Metal	Drillers	352	31.0	16.0	549
	Stone Cutting Operators	10	92.0	81.5	195
	Operators of Large Powered Haulage Equipment	673	28.5	17.0	426
	Conveyor Operators	29	57.4	29.0	382
	Crushing Equipment and Plant Operators	628	79.3	50.0	1,263
	Kiln, Mill, and Concentrator Workers	467	35.4	20.0	588
	Operators of Small Powered Haulage Equipment	38	104.4	7.0	3,361
	Packaging Equipment Operators	88	36.4	9.0	371
	Truck Loading Station Tenders	21	31.2	15.0	179
	Mobile Workers	1,004	52.0	26.0	3,588
	Miners in Other Occupations	189	67.5	25.0	1,690
	Metal OVERALL (All Occupations)	**3,499**	**49.1**	**25.0**	**3,588**
Nonmetal	Drillers	194	22.0	6.0	353
	Stone Cutting Operators	81	39.1	7.0	566
	Operators of Large Powered Haulage Equipment	922	16.9	7.0	449
	Conveyor Operators	31	10.2	6.0	37
	Crushing Equipment and Plant Operators	586	27.8	13.0	613
	Kiln, Mill, and Concentrator Workers	423	24.0	13.0	384
	Operators of Small Powered Haulage Equipment	237	25.4	10.0	190
	Packaging Equipment Operators	1,390	36.2	18.0	2,124
	Truck Loading Station Tenders	42	15.1	3.0	134
	Mobile Workers	1,053	25.3	10.0	574
	Miners in Other Occupations	206	14.4	3.0	191
	Nonmetal OVERALL (All Occupations)	**5,165**	**26.4**	**11.0**	**2,124**

Table C1-1: Summary of Respirable Crystalline Silica in the Metal/Nonmetal (MNM) Industry from 2005 to 2019, by Commodity and Occupational Category

Commodity	Occupation	Number of Samples	ISO Concentration, µg/m³		
			Mean (µg/m³)	Median (µg/m³)	Max (µg/m³)
Stone	Drillers	707	35.3	16.0	1,148
	Stone Cutting Operators	1,969	73.7	48.0	999
	Operators of Large Powered Haulage Equipment	3,223	20.2	9.0	559
	Conveyor Operators	44	41.1	23.0	309
	Crushing Equipment and Plant Operators	2,764	35.8	20.0	613
	Kiln, Mill, and Concentrator Workers	308	29.0	10.0	675
	Operators of Small Powered Haulage Equipment	404	34.3	20.0	315
	Packaging Equipment Operators	508	30.0	7.0	1,130
	Truck Loading Station Tenders	113	19.9	3.0	190
	Mobile Workers	4,778	36.2	17.0	1,548
	Miners in Other Occupations	597	24.7	12.0	347
	Stone OVERALL (All Occupations)	**15,415**	**36.6**	**17.0**	**1,548**
Crushed Limestone	Drillers	670	25.5	7.0	1,306
	Stone Cutting Operators	143	75.8	38.0	574
	Operators of Large Powered Haulage Equipment	5,522	15.8	7.0	567
	Conveyor Operators	24	27.7	12.0	164
	Crushing Equipment and Plant Operators	3,593	23.2	11.0	613
	Kiln, Mill, and Concentrator Workers	162	11.0	3.0	81
	Operators of Small Powered Haulage Equipment	162	25.7	10.0	342
	Packaging Equipment Operators	270	11.9	3.0	113
	Truck Loading Station Tenders	122	11.7	3.0	112
	Mobile Workers	3,931	27.8	11.0	4,289
	Miners in Other Occupations	585	17.3	6.0	613
	Crushed Limestone OVERALL (All Occupations)	**15,184**	**21.7**	**10.0**	**4,289**
Sand and Gravel	Drillers	169	46.6	20.0	959
	Stone Cutting Operators	243	94.3	55.0	1,095

Table C1-1: Summary of Respirable Crystalline Silica in the Metal/Nonmetal (MNM) Industry from 2005 to 2019, by Commodity and Occupational Category

Commodity	Occupation	Number of Samples	ISO Concentration, µg/m³		
			Mean (µg/m³)	Median (µg/m³)	Max (µg/m³)
	Operators of Large Powered Haulage Equipment	6,676	22.3	12.0	613
	Conveyor Operators	87	69.9	28.0	1,605
	Crushing Equipment and Plant Operators	3,994	42.9	25.0	613
	Kiln, Mill, and Concentrator Workers	442	81.5	44.0	1,800
	Operators of Small Powered Haulage Equipment	269	61.4	29.0	580
	Packaging Equipment Operators	724	75.1	51.0	652
	Truck Loading Station Tenders	155	59.3	37.0	613
	Mobile Workers	4,450	46.4	23.0	3,676
	Miners in Other Occupations	1,297	28.0	11.0	613
	Sand and Gravel OVERALL (All Occupations)	**18,506**	**38.7**	**20.0**	**3,676**
	MNM OVERALL	**57,769**	**33.2**	**15.0**	**4,289**

Notes:
Summary of personal samples presented as ISO 8-hour TWA concentrations. The proposed permissible exposure limit (PEL) for all mines is 50 µg/m³ as an 8-hour time-weighted average (8-hour TWA) sample collected according to the ISO standard 7708:1995: *Air Quality—Particle Size Fraction Definitions for Health-Related Sampling*.

a. The compliance samples summarized in this table were collected by MSHA inspectors as 8-hour TWAs using ISO-compliant sampling equipment with an air flow rate of 1.7 L/min, with results comparable to the proposed PEL.

b. When the mass of respirable crystalline silica collected was too small to be reliably detected by the laboratory, a mass of 2.5 µg for quartz and 5 µg for cristobalite (1/2 the respective limits of detection for these two forms of crystalline silica) were assumed and used to calculate sample results.

c. The procedure to calculate the ISO 8-hour TWA concentration (µg/m³) is:

$$\text{8-hour TWA} = \frac{quartz\ mass}{(480\ minutes)\ x\ (air\ flow\ rate)}\ x\ 1000\ \frac{L}{m^3}$$

Where: quartz mass is in micrograms (µg); normalized sampling time is 8 hours (480 minutes); flow rate = 1.7 L/min; 1000 Liters (L) per cubic meter (m³)

Source: MSHA MSIS respirable crystalline silica data for the MNM industry, January 1, 2005, through December 31, 2019 (version 20220812). All samples were of sufficient mass to be analyzed for respirable crystalline silica.

Table C1-2: Sample Count Distribution of Respirable Crystalline Silica Exposure in the Metal/Nonmetal (MNM) Industry from 2005 to 2019, by Commodity and Occupational Category

Commodity	Occupation	Number of Samples	Sample Counts in ISO Concentration Ranges, µg/m³					
			≤ 25	> 25 to ≤ 50	> 50 to ≤ 100	> 100 to ≤ 250	> 250 to ≤ 500	> 500
Metal	Drillers	352	220	74	42	13	2	1
	Stone Cutting Operators	10	1	2	3	4	0	0
	Operators of Large Powered Haulage Equipment	673	423	142	80	26	2	0
	Conveyor Operators	29	12	8	4	4	1	0
	Crushing Equipment and Plant Operators	628	173	143	165	115	26	6
	Kiln, Mill, and Concentrator Workers	467	276	99	68	18	5	1
	Operators of Small Powered Haulage Equipment	38	30	5	1	1	0	1
	Packaging Equipment Operators	88	60	8	11	8	1	0
	Truck Loading Station Tenders	21	13	5	1	2	0	0
	Mobile Workers	1,004	500	227	164	82	24	7
	Miners in Other Occupations	189	98	33	32	18	4	4
	Metal SUBTOTAL (All Occupations)	**3,499**	**1,806**	**746**	**571**	**291**	**65**	**20**
Nonmetal	Drillers	194	144	29	13	7	1	0
	Stone Cutting Operators	81	58	8	6	6	2	1
	Operators of Large Powered Haulage Equipment	922	768	94	38	19	3	0
	Conveyor Operators	31	27	4	0	0	0	0
	Crushing Equipment and Plant Operators	586	384	108	68	22	3	1

Table C1-2: Sample Count Distribution of Respirable Crystalline Silica Exposure in the Metal/Nonmetal (MNM) Industry from 2005 to 2019, by Commodity and Occupational Category

Commodity	Occupation	Number of Samples	Sample Counts in ISO Concentration Ranges, µg/m³					
			≤ 25	> 25 to ≤ 50	> 50 to ≤ 100	> 100 to ≤ 250	> 250 to ≤ 500	> 500
	Kiln, Mill, and Concentrator Workers	423	292	81	40	9	1	0
	Operators of Small Powered Haulage Equipment	237	166	30	31	10	0	0
	Packaging Equipment Operators	1,390	808	276	210	83	9	4
	Truck Loading Station Tenders	42	35	4	2	1	0	0
	Mobile Workers	1,053	782	129	93	38	10	1
	Miners in Other Occupations	206	176	17	12	1	0	0
	Nonmetal SUBTOTAL (All Occupations)	**5,165**	**3,640**	**780**	**513**	**196**	**29**	**7**
Stone	Drillers	707	423	149	90	35	8	2
	Stone Cutting Operators	1,969	618	423	548	280	77	23
	Operators of Large Powered Haulage Equipment	3,223	2,443	456	243	75	5	1
	Conveyor Operators	44	23	10	8	2	1	0
	Crushing Equipment and Plant Operators	2,764	1,582	606	386	164	22	4
	Kiln, Mill, and Concentrator Workers	308	219	42	31	11	3	2
	Operators of Small Powered Haulage Equipment	404	228	87	67	18	4	0
	Packaging Equipment Operators	508	393	57	25	22	6	5
	Truck Loading Station Tenders	113	85	11	14	3	0	0
	Mobile Workers	4,778	2,860	946	635	285	38	14
	Miners in Other Occupations	597	419	100	54	23	1	0

Table C1-2: Sample Count Distribution of Respirable Crystalline Silica Exposure in the Metal/Nonmetal (MNM) Industry from 2005 to 2019, by Commodity and Occupational Category

Commodity	Occupation	Number of Samples	Sample Counts in ISO Concentration Ranges, µg/m³					
			≤ 25	> 25 to ≤ 50	> 50 to ≤ 100	> 100 to ≤ 250	> 250 to ≤ 500	> 500
	Stone SUBTOTAL (All Occupations)	**15,415**	**9,293**	**2,887**	**2,101**	**918**	**165**	**51**
Crushed Limestone	Drillers	670	535	64	46	16	5	4
	Stone Cutting Operators	143	50	30	34	19	8	2
	Operators of Large Powered Haulage Equipment	5,522	4,613	564	254	82	7	2
	Conveyor Operators	24	17	3	2	2	0	0
	Crushing Equipment and Plant Operators	3,593	2,650	537	304	80	17	5
	Kiln, Mill, and Concentrator Workers	162	146	10	6	0	0	0
	Operators of Small Powered Haulage Equipment	162	114	24	16	7	1	0
	Packaging Equipment Operators	270	240	17	11	2	0	0
	Truck Loading Station Tenders	122	110	6	5	1	0	0
	Mobile Workers	3,931	2,831	593	344	128	21	14
	Miners in Other Occupations	585	502	46	26	6	4	1
	Crushed Limestone SUBTOTAL (All Occupations)	**15,184**	**11,808**	**1,894**	**1,048**	**343**	**63**	**28**
Sand and Gravel	Drillers	169	99	35	22	8	3	2
	Stone Cutting Operators	243	64	48	79	32	12	8
	Operators of Large Powered Haulage Equipment	6,676	4,891	1,127	502	133	20	3
	Conveyor Operators	87	41	25	7	11	2	1
	Crushing Equipment and Plant Operators	3,994	2,004	1,014	625	288	53	10

Table C1-2: Sample Count Distribution of Respirable Crystalline Silica Exposure in the Metal/Nonmetal (MNM) Industry from 2005 to 2019, by Commodity and Occupational Category

Commodity	Occupation	Number of Samples	Sample Counts in ISO Concentration Ranges, µg/m³					
			≤ 25	> 25 to ≤ 50	> 50 to ≤ 100	> 100 to ≤ 250	> 250 to ≤ 500	> 500
	Kiln, Mill, and Concentrator Workers	442	132	117	118	45	20	10
	Operators of Small Powered Haulage Equipment	269	114	69	51	24	6	5
	Packaging Equipment Operators	724	169	188	229	107	22	9
	Truck Loading Station Tenders	155	59	32	39	22	2	1
	Mobile Workers	4,450	2,341	988	675	343	75	28
	Miners in Other Occupations	1,297	936	198	105	37	16	5
	Sand and Gravel SUBTOTAL (All Occupations)	**18,506**	**10,850**	**3,841**	**2,452**	**1,050**	**231**	**82**
	MNM OVERALL	**57,769**	**37,397**	**10,148**	**6,685**	**2,798**	**553**	**188**

Notes:
a. Personal samples were collected using ISO-compliant sampling equipment and calculated as an 8-hour time-weighted average (8-hour TWA). Samples were collected using an air flow rate of 1.7 L/min and reported as 8-hour TWAs. See notes in Summary table C2-1 for additional details.
b. Source: MSHA MSIS respirable crystalline silica data for the MNM industry, January 1, 2005, through December 31, 2019 (version 20220812). All samples were of sufficient mass to be analyzed for respirable crystalline silica.

Table C1-3: Percentage Distribution of Respirable Crystalline Silica Exposure in the Metal/Nonmetal (MNM) Industry from 2005 to 2019, by Commodity and Occupational Category

Commodity	Occupation	Number of Samples	Percentage (%) of Samples in ISO Concentration Ranges, µg/m3						
			≤ 25	> 25 to ≤ 50	> 50 to ≤ 100	> 100 to ≤ 250	> 250 to ≤ 500	> 500	Total
Metal	Drillers	352	62.5%	21.0%	11.9%	3.7%	0.6%	0.3%	100%
	Stone Cutting Operators	10	10.0%	20.0%	30.0%	40.0%	0.0%	0.0%	100%
	Operators of Large Powered Haulage Equipment	673	62.9%	21.1%	11.9%	3.9%	0.3%	0.0%	100%

Table C1-3: Percentage Distribution of Respirable Crystalline Silica Exposure in the Metal/Nonmetal (MNM) Industry from 2005 to 2019, by Commodity and Occupational Category

Commodity	Occupation	Number of Samples	Percentage (%) of Samples in ISO Concentration Ranges, µg/m3						
			≤ 25	> 25 to ≤ 50	> 50 to ≤ 100	> 100 to ≤ 250	> 250 to ≤ 500	> 500	Total
	Conveyor Operators	29	41.4%	27.6%	13.8%	13.8%	3.4%	0.0%	100%
	Crushing Equipment and Plant Operators	628	27.5%	22.8%	26.3%	18.3%	4.1%	1.0%	100%
	Kiln, Mill, and Concentrator Workers	467	59.1%	21.2%	14.6%	3.9%	1.1%	0.2%	100%
	Operators of Small Powered Haulage Equipment	38	78.9%	13.2%	2.6%	2.6%	0.0%	2.6%	100%
	Packaging Equipment Operators	88	68.2%	9.1%	12.5%	9.1%	1.1%	0.0%	100%
	Truck Loading Station Tenders	21	61.9%	23.8%	4.8%	9.5%	0.0%	0.0%	100%
	Mobile Workers	1,004	49.8%	22.6%	16.3%	8.2%	2.4%	0.7%	100%
	Miners in Other Occupations	189	51.9%	17.5%	16.9%	9.5%	2.1%	2.1%	100%
	Metal SUBTOTAL (All Occupations)	**3,499**	**51.6%**	**21.3%**	**16.3%**	**8.3%**	**1.9%**	**0.6%**	**100%**
Nonmetal	Drillers	194	74.2%	14.9%	6.7%	3.6%	0.5%	0.0%	100%
	Stone Cutting Operators	81	71.6%	9.9%	7.4%	7.4%	2.5%	1.2%	100%
	Operators of Large Powered Haulage Equipment	922	83.3%	10.2%	4.1%	2.1%	0.3%	0.0%	100%
	Conveyor Operators	31	87.1%	12.9%	0.0%	0.0%	0.0%	0.0%	100%
	Crushing Equipment and Plant Operators	586	65.5%	18.4%	11.6%	3.8%	0.5%	0.2%	100%
	Kiln, Mill, and Concentrator Workers	423	69.0%	19.1%	9.5%	2.1%	0.2%	0.0%	100%
	Operators of Small Powered Haulage Equipment	237	70.0%	12.7%	13.1%	4.2%	0.0%	0.0%	100%
	Packaging Equipment Operators	1,390	58.1%	19.9%	15.1%	6.0%	0.6%	0.3%	100%
	Truck Loading Station Tenders	42	83.3%	9.5%	4.8%	2.4%	0.0%	0.0%	100%
	Mobile Workers	1,053	74.3%	12.3%	8.8%	3.6%	0.9%	0.1%	100%

Table C1-3: Percentage Distribution of Respirable Crystalline Silica Exposure in the Metal/Nonmetal (MNM) Industry from 2005 to 2019, by Commodity and Occupational Category

Commodity	Occupation	Number of Samples	Percentage (%) of Samples in ISO Concentration Ranges, µg/m3						
			≤ 25	> 25 to ≤ 50	> 50 to ≤ 100	> 100 to ≤ 250	> 250 to ≤ 500	> 500	Total
	Miners in Other Occupations	206	85.4%	8.3%	5.8%	0.5%	0.0%	0.0%	100%
	Nonmetal SUBTOTAL (All Occupations)	**5,165**	**70.5%**	**15.1%**	**9.9%**	**3.8%**	**0.6%**	**0.1%**	**100%**
Stone	Drillers	707	59.8%	21.1%	12.7%	5.0%	1.1%	0.3%	100%
	Stone Cutting Operators	1,969	31.4%	21.5%	27.8%	14.2%	3.9%	1.2%	100%
	Operators of Large Powered Haulage Equipment	3,223	75.8%	14.1%	7.5%	2.3%	0.2%	0.0%	100%
	Conveyor Operators	44	52.3%	22.7%	18.2%	4.5%	2.3%	0.0%	100%
	Crushing Equipment and Plant Operators	2,764	57.2%	21.9%	14.0%	5.9%	0.8%	0.1%	100%
	Kiln, Mill, and Concentrator Workers	308	71.1%	13.6%	10.1%	3.6%	1.0%	0.6%	100%
	Operators of Small Powered Haulage Equipment	404	56.4%	21.5%	16.6%	4.5%	1.0%	0.0%	100%
	Packaging Equipment Operators	508	77.4%	11.2%	4.9%	4.3%	1.2%	1.0%	100%
	Truck Loading Station Tenders	113	75.2%	9.7%	12.4%	2.7%	0.0%	0.0%	100%
	Mobile Workers	4,778	59.9%	19.8%	13.3%	6.0%	0.8%	0.3%	100%
	Miners in Other Occupations	597	70.2%	16.8%	9.0%	3.9%	0.2%	0.0%	100%
	Stone SUBTOTAL (All Occupations)	**15,415**	**60.3%**	**18.7%**	**13.6%**	**6.0%**	**1.1%**	**0.3%**	**100%**
Crushed Limestone	Drillers	670	79.9%	9.6%	6.9%	2.4%	0.7%	0.6%	100%
	Stone Cutting Operators	143	35.0%	21.0%	23.8%	13.3%	5.6%	1.4%	100%
	Operators of Large Powered Haulage Equipment	5,522	83.5%	10.2%	4.6%	1.5%	0.1%	0.0%	100%
	Conveyor Operators	24	70.8%	12.5%	8.3%	8.3%	0.0%	0.0%	100%
	Crushing Equipment and Plant Operators	3,593	73.8%	14.9%	8.5%	2.2%	0.5%	0.1%	100%

Table C1-3: Percentage Distribution of Respirable Crystalline Silica Exposure in the Metal/Nonmetal (MNM) Industry from 2005 to 2019, by Commodity and Occupational Category

Commodity	Occupation	Number of Samples	Percentage (%) of Samples in ISO Concentration Ranges, µg/m3						
			≤ 25	> 25 to ≤ 50	> 50 to ≤ 100	> 100 to ≤ 250	> 250 to ≤ 500	> 500	Total
	Kiln, Mill, and Concentrator Workers	162	90.1%	6.2%	3.7%	0.0%	0.0%	0.0%	100%
	Operators of Small Powered Haulage Equipment	162	70.4%	14.8%	9.9%	4.3%	0.6%	0.0%	100%
	Packaging Equipment Operators	270	88.9%	6.3%	4.1%	0.7%	0.0%	0.0%	100%
	Truck Loading Station Tenders	122	90.2%	4.9%	4.1%	0.8%	0.0%	0.0%	100%
	Mobile Workers	3,931	72.0%	15.1%	8.8%	3.3%	0.5%	0.4%	100%
	Miners in Other Occupations	585	85.8%	7.9%	4.4%	1.0%	0.7%	0.2%	100%
	Crushed Limestone SUBTOTAL (All Occupations)	**15,184**	**77.8%**	**12.5%**	**6.9%**	**2.3%**	**0.4%**	**0.2%**	**100%**
Sand and Gravel	Drillers	169	58.6%	20.7%	13.0%	4.7%	1.8%	1.2%	100%
	Stone Cutting Operators	243	26.3%	19.8%	32.5%	13.2%	4.9%	3.3%	100%
	Operators of Large Powered Haulage Equipment	6,676	73.3%	16.9%	7.5%	2.0%	0.3%	0.0%	100%
	Conveyor Operators	87	47.1%	28.7%	8.0%	12.6%	2.3%	1.1%	100%
	Crushing Equipment and Plant Operators	3,994	50.2%	25.4%	15.6%	7.2%	1.3%	0.3%	100%
	Kiln, Mill, and Concentrator Workers	442	29.9%	26.5%	26.7%	10.2%	4.5%	2.3%	100%
	Operators of Small Powered Haulage Equipment	269	42.4%	25.7%	19.0%	8.9%	2.2%	1.9%	100%
	Packaging Equipment Operators	724	23.3%	26.0%	31.6%	14.8%	3.0%	1.2%	100%
	Truck Loading Station Tenders	155	38.1%	20.6%	25.2%	14.2%	1.3%	0.6%	100%
	Mobile Workers	4,450	52.6%	22.2%	15.2%	7.7%	1.7%	0.6%	100%
	Miners in Other Occupations	1,297	72.2%	15.3%	8.1%	2.9%	1.2%	0.4%	100%
	Sand and Gravel SUBTOTAL (All Occupations)	**18,506**	**58.6%**	**20.8%**	**13.2%**	**5.7%**	**1.2%**	**0.4%**	**100%**

Table C1-3: Percentage Distribution of Respirable Crystalline Silica Exposure in the Metal/Nonmetal (MNM) Industry from 2005 to 2019, by Commodity and Occupational Category

Commodity	Occupation	Number of Samples	Percentage (%) of Samples in ISO Concentration Ranges, µg/m3						
			≤ 25	> 25 to ≤ 50	> 50 to ≤ 100	> 100 to ≤ 250	> 250 to ≤ 500	> 500	Total
	MNM OVERALL	**57,769**	**64.7%**	**17.6%**	**11.6%**	**4.8%**	**1.0%**	**0.3%**	**100%**

Notes:

a. Personal samples were collected using ISO-compliant sampling equipment and calculated as an 8-hour time-weighted average (8-hour TWA). Samples were collected using an air flow rate of 1.7 L/min and reported as 8-hour TWAs. See notes in Summary table C2-1 for additional details.

b. Source: MSHA MSIS respirable crystalline silica data for the MNM industry, January 1, 2005, through December 31, 2019 (version 20220812). All samples were of sufficient mass to be analyzed for respirable crystalline silica.

Attachment 2: Tables for Coal

Table C2-1: Summary of Respirable Crystalline Silica Exposure in the Coal Industry from 2016 to 2021, by Location and Occupational Category

Location	Occupation	Number of Samples	ISO Concentration (8-hour TWA, µg/m³)		
			Mean	Median	Max
Underground	Continuous Mining Machine Operators (Underground)	9,910	24.6	18.5	390.5
	Operators of Large Powered Haulage Equipment (Underground)	21,777	17.7	13.6	476.8
	Longwall Workers (Underground)	3,176	32.9	22.2	453.4
	Roof Bolters (Underground)	14,306	26.5	20.9	778.6
	Underground Miners (Underground)	3,926	15.7	11.1	324.0
	Underground OVERALL (All Occupations)	**53,095**	**22.1**	**16.0**	**778.6**
Surface	Drillers (Surface)	1,762	36.5	20.9	747.8
	Operators of Large Powered Haulage Equipment (Surface)	5,313	19.9	9.9	721.9
	Crusher Operators (Surface)	631	9.6	6.2	117.0
	Mobile Workers (Surface)	2,326	12.6	8.6	288.3
	Surface OVERALL (All Occupations)	**10,032**	**20.5**	**11.1**	**747.8**
	COAL OVERALL	**63,127**	**21.9**	**16.0**	**778.6**

Notes: Summary of personal samples presented as ISO 8-hour TWA concentrations. The proposed permissible exposure limit (PEL) for all mines is 50 µg/m³ as an 8-hour time-weighted average (8-hour TWA) sample collected according to the ISO standard 7708:1995: *Air Quality—Particle Size Fraction Definitions for Health-Related Sampling*.

a. The compliance samples summarized in this table were collected by MSHA inspectors for the entire duration of each miner's work shift using sampling equipment with an air flow rate of 2 L/min, with results reported as MRE TWA concentrations. For this rulemaking analysis, MSHA recalculated the samples as ISO-equivalent 8-hour TWA concentrations, comparable to the proposed PEL (since samples were not collected using an ISO-compliant sampling method). The procedure to calculate an ISO-equivalent concentration from an MRE TWA sample concentration involves normalizing the sample concentration to an 8-hour TWA and applying the empirically derived conversion factor of 0.857 recommended by NIOSH (1995a) using the following equation:

b. ISO 8-hour TWA concentration = $(MRE\ TWA\ in\ \mu g/m^3)\ x\ \frac{(original\ sampling\ time)}{(480\ minutes)}\ x\ 0.857$

Table C2-1: Summary of Respirable Crystalline Silica Exposure in the Coal Industry from 2016 to 2021, by Location and Occupational Category

Location	Occupation	Number of Samples	ISO Concentration (8-hour TWA, µg/m³)		
			Mean	Median	Max

c. Where: both concentrations (ISO 8-hour TWA and MRE TWA) are concentrations presented as µg/m³; sampling time in minutes.
d. When the mass of respirable crystalline silica collected was too small to be reliably detected by the laboratory, a mass of 1.5 µg (1/2 the limit of detection) was assumed and used to calculate sample results.
e. Source: MSHA MSIS respirable crystalline silica data for the Coal Industry, August 1, 2016, through July 31, 2021 (version 20220617). All samples were of sufficient mass to be analyzed for respirable crystalline silica.

Table C2-2: Sample Count Distribution of Respirable Crystalline Silica Exposure in the Coal Industry from 2016 to 2021, by Location and Occupational Category

Location	Occupation	Number of Samples	Sample Counts in ISO Concentration Ranges, 8-hour TWA, µg/m³						
			≤ 25 µg/m³	> 25 to ≤ 50 µg/m³	> 50 to ≤ 85.7 µg/m³	> 85.7 to ≤ 100 µg/m³	> 100 to ≤ 250 µg/m³	> 250 to ≤ 500 µg/m³	> 500 µg/m³
Underground	Continuous Mining Machine Operators (Underground)	9,910	6,750	2,366	572	67	144	11	0
	Operators of Large Powered Haulage Equipment (Underground)	21,777	17,938	3,110	576	51	95	7	0
	Longwall Workers (Underground)	3,176	1,767	857	356	62	125	9	0
	Roof Bolters (Underground)	14,306	8,768	4,194	1,093	106	141	3	1
	Underground Miners (Underground)	3,926	3,396	398	96	11	22	3	0
	Underground OVERALL (All Occupations)	**53,095**	**38,619**	**10,925**	**2,693**	**297**	**527**	**33**	**1**
Surface	Drillers (Surface)	1,762	1,019	422	180	30	90	17	4
	Operators of Large Powered Haulage Equipment (Surface)	5,313	4,268	627	219	45	132	18	4
	Crusher Operators (Surface)	631	588	28	13	1	1	0	0
	Mobile Workers (Surface)	2,326	2,102	164	45	3	11	1	0
	Surface OVERALL (All Occupations)	**10,032**	**7,977**	**1,241**	**457**	**79**	**234**	**36**	**8**
	COAL OVERALL	**63,127**	**46,596**	**12,166**	**3,150**	**376**	**761**	**69**	**9**

Notes:
a. Personal samples presented in terms of ISO concentrations, normalized to 8-hour time-weighted averages (TWAs). The samples were originally collected for the entire duration of each miner's work shift, using an air flow rate of 2 L/min. See notes in Summary table C1-1 for additional details.
b. Source: MSHA MSIS respirable crystalline silica data for the coal industry, August 1, 2016, through July 31, 2021 (version 20220617). All samples were of sufficient mass to be analyzed for respirable crystalline silica.

Table C2-3: Percentage Distribution of Respirable Crystalline Silica Exposure in the Coal Industry from 2016 to 2021, by Location and Occupational Category

Location	Occupation	Number of Samples	Percentage (%) of Samples in ISO Concentration Ranges, 8-hour TWA, µg/m³							Total
			≤ 25	> 25 to ≤ 50	> 50 to ≤ 85.7	> 85.7 to ≤ 100	> 100 to ≤ 250	> 250 to ≤ 500	> 500	
Underground	Continuous Mining Machine Operators (Underground)	9,910	68.1%	23.9%	5.8%	0.7%	1.5%	0.1%	0%	100%
	Operators of Large Powered Haulage Equipment (Underground)	21,777	82.4%	14.3%	2.6%	0.2%	0.4%	<0.1%	0%	100%
	Longwall Workers (Underground)	3,176	55.6%	27%	11.2%	2%	3.9%	0.3%	0%	100%
	Roof Bolters (Underground)	14,306	61.3%	29.3%	7.6%	0.7%	1%	<0.1%	<0.1%	100%
	Underground Miners (Underground)	3,926	86.5%	10.1%	2.4%	0.3%	0.6%	0.1%	0%	100%
	Underground OVERALL (All Occupations)	**53,095**	**72.7%**	**20.6%**	**5.1%**	**0.6%**	**1%**	**0.1%**	**<0.1%**	**100%**
Surface	Drillers (Surface)	1,762	57.8%	24%	10.2%	1.7%	5.1%	1%	0.2%	100%
	Operators of Large Powered Haulage Equipment (Surface)	5,313	80.3%	11.8%	4.1%	0.8%	2.5%	0.3%	0.1%	100%
	Crusher Operators (Surface)	631	93.2%	4.4%	2.1%	0.2%	0.2%	0%	0%	100%
	Mobile Workers (Surface)	2,326	90.4%	7.1%	1.9%	0.1%	0.5%	<0.1%	0%	100%
	Surface OVERALL (All Occupations)	**10,032**	**79.5%**	**12.4%**	**4.6%**	**0.8%**	**2.3%**	**0.4%**	**0.1%**	**100%**
	COAL OVERALL	**63,127**	**73.8%**	**19.3%**	**5%**	**0.6%**	**1.2%**	**0.1%**	**<0.1%**	**100%**

Notes:
a. Personal samples presented in terms of ISO concentrations, normalized to 8-hour time-weighted averages (TWAs). The samples were originally collected for the entire duration of each miner's work shift, using an air flow rate of 2 L/min. See notes in Summary table C1-1 for additional details.
b. Source: MSHA MSIS respirable crystalline silica data for the coal industry, August 1, 2016, through July 31, 2021 (version 20220617). All samples were of sufficient mass to be analyzed for respirable crystalline silica.

Attachment 3: Coal Job Codes

The complete list of job codes that are found in IAS, as of March 11, 2022, are included below, with Table C3-1 listing job codes for coal miners. For coal, the first digit of the job code identifies where the work is taking place. For example, codes starting with 0 represent jobs that occur at the underground face of the mine. Job codes that start with 6 were added in 2020.

0 – Underground Section Workers (Face)

1 – General Underground (Non-Face)

2 – Underground Transportation (Non-Face)

3 – Surface

4 – Supervisory and Staff

5 – MSHA – State

6 – Shaft and Slope Sinking

Table C3-1 Coal Job Codes	
Job Code	**Occupation / Activity**
Underground Section Workers (Face)	
000	Area
001	Belt Man/Conveyor Man
002	Electrician
003	Electrician Helper
004	Mechanic
005	Mechanic Helper
006	Rock Duster
007	Blaster/Shooter/Shotfirer
008	Stopping Builder/Ventilation Man/Mason
009	Supply Man
010	Auger (Jack Setter) (Intake Side)
011	Wireman
012	Roof Bolter (Twin Head) (Intake Side)
013	Shuttle Car Operator (Off Standard Side)
014	Roof Bolter (Twin Head) (Return Side)
015	Fan Attendant
016	Laborer
017	Auger (Timberman) (Return Side)

Table C3-1 Coal Job Codes	
Job Code	**Occupation / Activity**
018	Auger (Timberman) (Intake Side)
019	Roof Bolter (Mounted) (Intake Side)
031	Shotfirer Helper
032	Brattice Man
033	Coal Drill Helper
034	Coal Drill Operator
035	Continuous Miner Helper
036	Continuous Miner Operator
037	Cutting Machine Helper
038	Cutting Machine Operator
039	Hand Loaders
040	Headgate Operator
041	Jack Setter (Longwall)
042	Loading Machine Helper
043	Loading Machine Operator
044	Longwall Operator (Tailgate Side)
045	Rockman
046	Roof Bolter (Single Head)
047	Roof Bolter Helper (Single Head)
048	Roof Bolter (Mounted) (Return Side)

Table C3-1 Coal Job Codes	
Job Code	**Occupation / Activity**
049	Section Foreman
050	Shuttle Car Operator (Standard Side)
051	Stall Driver
052	Tailgate Operator
053	Utility Man
054	Scoop Car Operator
055	Auger (Jack Setter) (Return Side)
060	Longwall (Return-Side Face Worker)
061	Longwall (Return-Side Fixed)
064	Longwall Operator (Headgate Side)
070	Auger Operator
071	Auger Helper
072	Mobile Bridge Operator
073	Shuttle Car Operator (Off Standard)
074	Tractor Operator/Motorman
General Underground (Non-Face)	
101	Belt Man/Conveyor Man
102	Electrician
103	Electrician Helper
104	Mechanic
105	Mechanic Helper
106	Rock Duster
108	Stopping Builder/Ventilation Man/Mason
109	Supply Man
110	Timberman
111	Wireman
112	Belt Vulcanizer
113	Cleanup Man
114	Coal Sampler
115	Fan Attendant
116	Laborer
117	Rodman
118	Oiler/Greaser
119	Welder
122	Coal Dump Operator
123	Transit Man
146	Roof Bolter
149	Bullgang Foreman/Labor Foreman
154	Belt Cleaner
155	Chainman
156	Rock Driller
157	Pumper

Table C3-1 Coal Job Codes	
Job Code	**Occupation / Activity**
158	Rock Machine Operator
159	Water Line Man
160	Shopman
Underground Transportation (Non-Face)	
201	Belt Man/Conveyor Man
216	Trackman
220	Cager
221	Hoistman
240	Loader Head/Roscoe Operator
250	Shuttle Car Operator
261	Battery Station Operator
262	Brakeman/Roperider
263	Track Foreman
265	Dispatcher
269	Motorman
276	Driver
277	Buggy Pusher
Surface	
301	Conveyor Operator
302	Electrician
303	Electrician Helper
304	Mechanic
305	Mechanic Helper
306	Welder (Non-Shop)
307	Blaster/Shooter/Shotfirer
308	Mason
309	Supply Man
310	Scrapper Operator
311	Wireman
312	Belt Vulcanizer
313	Cleanup Man
314	Coal Sampler
315	Fan Attendant
316	Laborer/Blacksmith
317	Rodman
318	Oiler/Greaser
319	Welder (Shop)
320	Cage Attendant/Cager
321	Hoist Engineer/Operator
322	Coal Strip Operator
323	Transit Man
324	Backhoe Operator
325	Diester Table Operator
326	Forklift Operator
327	Pumper

Table C3-1 Coal Job Codes	
Job Code	**Occupation / Activity**
328	Utility Man
329	Vacuum Filter Operator
330	Face Worker-Shaft/Slope Sinking
331	Clam Operator
333	Coal Drill Helper
334	Coal Drill Operator
340	Boom Operator
341	Belt Man/Conveyor Man
342	Bit Sharpener
343	Car Trimmer/Car Loader
344	Car Shake-Out Operator
345	Crusher Attendant
347	Froth Cell Operator
348	Machinist
349	Rotary Dump Operator
350	Shuttle Car Operator
351	Scoop Operator
352	Steel Worker
354	Sweeper Operator
355	Chainman
356	Rock Driller
357	Washer Operator
358	Water Circuit Operator
359	Self-Propelled Compactor Operator
360	Shopman Repair Cars
362	Brakeman
365	Dispatcher
366	Waterboy
367	Coal Shovel Operator
368	Bulldozer Operator
369	Motorman/Locomotive Operator
370	Auger Operator
371	Auger Helper
372	Barge Attendant
373	Car Dropper
374	Cleaning Plant Operator
375	Road Grader Operator
376	Coal Truck Driver
377	Road Roller Operator
378	Crane Operator/Dragline Operator
379	Dryer Operator
380	Fine Coal Plant Operator
381	Hoist Operator Helper
382	Highlift Operator/Front End Loader

Table C3-1 Coal Job Codes	
Job Code	**Occupation / Activity**
383	Highwall Drill Helper
384	Highwall Drill Operator
385	Lampman
386	Refuse Truck Driver/Backfill Truck Drive
387	Rotary Bucket Excavator Operator
388	Scalper-Screen Operator
390	Silo Operator
391	Stripping Shovel Operator
392	Tipple Operator
393	Weighman
394	Carpenter
395	Water Truck Operator
396	Watchman
397	Yard Engine Operator
398	Groundman
Supervisory And Staff	
402	Master Electrician
404	Master Mechanic
414	Dust Sampler
418	Maintenance Foreman
423	Surveyor
430	Assist Mine Foreman/Assist Mine Manager
449	Mine Foreman/Mine Manager
456	Engineers (Electricity/Ventilation/Minin
462	Fire Boss Pre-Shift Examiner
464	Inspector
481	Superintendent
489	Outside Foreman
494	Preparation Plant Foreman
495	Safety Director
496	Union Representative
497	Clerk/Timekeeper
MSHA – State	
590	Education Specialist
591	Mineral Industrial Safety Officer
592	Mine Safety Instructor
593	Safety Representative
594	Training Specialist
Shaft and Slope Sinking	
602	Electrician
604	Mechanic
607	Blaster/Shooter/Shot Firer
609	Supply Person

Table C3-1 Coal Job Codes	
Job Code	**Occupation / Activity**
612	(Intake) Twin Head Roof Bolter
614	(Return) Twin Head Roof Bolter
616	Laborer
631	Blaster/Shooter/Shot Firer Helper
632	Ventilation Worker
635	Continuous Miner Operator Helper
636	Continuous Miner Operator
646	Single Head Roof Bolter
647	Single Head Roof Bolter Helper
649	Foreman
650	(Standard Side) Shuttle Car Operator
654	Scoop Car Operator/Mucker
656	Rock Driller
673	(Off Standard Side) Shuttle Car Operator

Attachment 4: MNM Job Codes

The complete list of job codes that are found in IAS, as of March 11, 2022, are included below with Table C4-1 outlining job codes for MNM miners.

Table C4-1 MNM Job Codes	
Job Code	**Occupation / Activity**
028	Scoop Tram Operator
029	Mucking Machine Operator
030	Slusher
032	Brattice Man
034	Diamond Drill Operator
035	Continuous Miner Helper
036	Continuous Miner Operator
037	Cutting Machine Helper
038	Cutting Machine Operator
039	Hand Loader (Load Only)
041	Jacksetter
043	Gathering Arm Loader Operator
045	Hangup Man, Chute Blaster
046	Rock Bolter, Roof Bolter
048	Roof Bolter Mounted
053	Utility Man
057	Stope Miner
058	Drift Miner
059	Raise Miner
079	Crusher Operator, Crusher Worker, Pan-Feeder Operator
134	Jet-Piercing Channeler Operator
154	Belt Cleaner, Belt Picker
179	Ball, Rod Or Pebble Mill Operator
216	Track Man; Track Gang
234	Jet-Piercing Drill Operator
261	Battery Station Operator
279	Hammer Mill Operator
331	Clam-Shell Operator
334	Wagon Drill Operator
342	Bit Grinder; Bit Sharpener
344	Car Shake-Out Operator
352	Iron Worker, Metal Worker
367	Shovel Operator
368	Bulldozer Operator
372	Barge Attendant, Boat Operator, Dredge Operator

Table C4-1 MNM Job Codes	
Job Code	**Occupation / Activity**
375	Road Grader Operator
376	Truck Driver
378	Mobile Crane Operator
379	Dryer Operator, Kiln Operator
385	Lampman
387	Rotary Bucket Excavator Operator
388	Scalper-Screen Operator
389	Forklift Operator
392	Toplander, Skip Dumper, Tipple Operator
393	Weighman, Scale Man
394	Carpenter
397	Yard Engineer Operator
399	Dimension Stone Cutter And Polisher; Rock Sawer
413	Janitor
416	Salvage Crew
420	Aerial Tram Operator
434	Churn Drill Operator
456	Engineer (Electrical, Ventilation, Mining, Etc.)
479	Hydrating Plant Operator
488	Dry Screening Plant Operator
513	Building Repair And Maintenance
514	Laboratory Technician
516	Tamping Machine Operator
534	Jacking Or Stoper Drill Operator
579	Slurry, Mixing Or Pumping Operations Worker
588	Sizing And Washing Operations Worker
601	Conveyor Belt Crew
602	Electrician
603	Electrician Helper
604	Mechanic
607	Jackhammer Operator, Chipping Hammer Operator
608	Mason
609	Supply Man, Nipper

Table C4-1 MNM Job Codes	
Job Code	**Occupation / Activity**
612	Belt Vulcanizer
613	Cleanup Man
614	Sampler, Dust Sampler
616	Laborer, Bullgang
618	Greaser, Oiler
619	Welder (Welding, Cutting, Brazing, Hard Surfacing, Soldering)
622	Dump Operator
623	Surveyor, Transit Man
634	Rotary (Electrical Or Hydraulic) Drill Operator
649	Administrative, Supervisory, Management Personnel
660	Machinist
663	Shaft Miner, Shaft Sinker
668	Tractor Operator
669	Bin Puller; Truck Loader
673	Leaching Operations Worker
674	Warehouseman; Supply Handler
678	Dragline Operator
679	Flotation Mill Operator; Concentrator Operator
682	Scraper-Loader Operator
706	Shotcrete Man, Gunite Man
708	Ventilation Crew
710	Ground Control (Wood And Steel), Timberman
716	Cement Man, Concrete Worker
726	Grizzley Man, Grizzley Tender
728	Complete Load/Haul/Dump Cycle
734	Rotary (Pneumatic) Drill Operator
739	Hand Trimmer (Load And Dump)
747	Scaling (Hand)
750	Shuttle Car Operator (Electrical)
759	Raise Borer Operator
763	Shaft Repairer
765	Sandfiller (Dry Operations)
766	Sandfiller (Wet Operations)
778	Backhoe Operator
779	Pelletizing Operations Worker
782	Front-End Loader Operator
804	Plumber, Pipe Fitter, Millwright

Table C4-1 MNM Job Codes	
Job Code	**Occupation / Activity**
807	Powder Gang, Powderman, Powder Monkey, Shooter, Shotfitter, Blaster
825	Bobcat Operator
833	Drill Helper, Chuck Tender
847	Scaling (Mechanical)
850	Ramcar Operator
878	Overhead Crane Operator
879	Bagging Or Packaging Operations Worker
894	Painter
920	Cager, Cage Attendant, Station Attendant
921	Hoist Operator
930	Skip Tender
934	Jumbo Percussion Drill Operator
950	Shuttle Car Operator (Electrical)
962	Trip Rider, Swamper
969	Motorman
979	Packaging Operations Worker

Attachment 5. Examples of Job Code Pocket Cards

Inspectors previously received pocket-sized job code cards for use in filling out forms with the correct job code. Now, a drop-down menu in IAS is used to select the codes. Table C5-1 contains Underground Coal Mining Occupation Codes from Coal Job Code Cards used by MESA between 1973 and 1977. Table C5-2 contains Surface Occupation Codes from Coal Job Codes used by MESA between 1973 and 1977.

Coal Job Code Cards, Underground Coal Mining Occupation Codes

Table C5-1 Coal Job Code Cards (MESA, 1973-1977) Underground Coal Mining Occupation Codes	
Job Code	**Occupation / Activity**
Section Workers (Face)	
071	Auger Helper
070	Auger Operator
031	Beater
001	Belt Man/Conveyor Man
007	Blaster
032	Brattice Man
013	Cleanup Man
033	Coal Drill Helper
034	Coal Drill Operator
035	Continuous Miner Helper
036	Continuous Miner Operator
037	Cutting Machine Helper
038	Cutting Machine Operator
002	Electrician
003	Electrician Helper
015	Fan Attendant
039	Hand Loaders
040	Headgate Operator
010	Jack Setter (Auger – intake side)
055	Jack Setter (Auger – return side)
041	Jack Setter (Longwall)
016	Laborer
042	Loading Machine Helper
043	Loading Machine Operator
008	Mason
004	Mechanic
005	Mechanic Helper

Table C5-1 Coal Job Code Cards (MESA, 1973-1977) Underground Coal Mining Occupation Codes	
Job Code	**Occupation / Activity**
010	Prepman
006	Rock Duster
045	Rockman
046	Roof Bolter
047	Roof Bolter Helper
048	Roof Bolter Mounted
054	Scoop Car Operator
049	Section Foreman
044	Sheer Operator/Plow Operator Longwall
007	Shooter
031	Shotfire Helper
007	Shotfirer
050	Shuttle Car Operator
051	Stall Driver
008	Stopping Builder
009	Supply Man
052	Tailgate Operator
010	Timberman
053	Utility Man
008	Ventilation Man
011	Wireman
General Underground (Non-Face)	
154	Belt Cleaner
101	Belt Man/Conveyor Man
112	Belt Vulcanizer
149	Bullgang Foreman
155	Chainman
113	Cleanup Man
122	Coal Dump Operator

Table C5-1 Coal Job Code Cards (MESA, 1973-1977) Underground Coal Mining Occupation Codes	
Job Code	**Occupation / Activity**
114	Coal Sampler
102	Electrician
103	Electrician Helper
115	Fan Attendant
118	Greaser
149	Labor Foreman
116	Laborer
108	Mason
104	Mechanic
105	Mechanic Helper
118	Oiler
157	Pumper
156	Rock Driller
106	Rock Duster
158	Rock Machine Operator
117	Rodman
146	Roof Bolter
160	Shopman
108	Stopping Builder
109	Supply Man

Table C5-1 Coal Job Code Cards (MESA, 1973-1977) Underground Coal Mining Occupation Codes	
Job Code	**Occupation / Activity**
110	Timberman
123	Transmit Man
108	Ventilation Man
159	Water Line Man
119	Welder
111	Wireman
Underground Transportation (Non-Face)	
261	Battery Station Operator
201	Belt Man/Conveyor Man
262	Brakeman
277	Buggy Pusher
220	Cager
265	Dispatcher
276	Driver
221	Hoistman
240	Leader Head Operator
269	Motorman
262	Rope Rider
240	Roscoe Operator
250	Shuttle Car Operator
216	Trackman

Coal Job Code Cards, Surface Occupation Codes

Table C5-2 Coal Job Code Cards (MESA, 1973-1977) Surface Occupation Codes	
Job Code	**Occupation / Activity**
100	*203(b) Miner
370	Auger Operator
371	Auger Helper
372	Barge Attendant
312	Belt Vulcanizer
307	Blaster
368	Bulldozer Operator
340	Boom Operator
362	Brakeman
320	Cage Attendant/Cager
373	Car Dropper
394	Carpenter
355	Chainman
331	Clam Operator
374	Cleaning Plant Operator

Table C5-2 Coal Job Code Cards (MESA, 1973-1977) Surface Occupation Codes	
Job Code	**Occupation / Activity**
313	Cleanup Man
333	Coal Drill Helper
334	Coal Drill Operator
322	Coal Strip Operator
314	Coal Sampler
367	Coal Shovel Operator
376	Coal Truck Driver
301	Conveyor Operator
378	Crane Operator
365	Dispatcher
378	Dragline Operator
379	Dryer Operator
302	Electrician
303	Electrician Helper
315	Fan Attendant

Table C5-2 Coal Job Code Cards (MESA, 1973-1977) Surface Occupation Codes	
Job Code	**Occupation / Activity**
380	Fine Coal Plant Operator
318	Greaser
398	Groundman
382	Highlift Operator
383	Highwall Drill Helper
384	Highwall Drill Operator
321	Hoist Engineer/Operator
381	Hoist Operator Helper
316	Laborer Blacksmith
385	Lampman
308	Mason
304	Mechanic
305	Mechanic Helper
369	Motorman
318	Oiler
310	Pan Scraper Operator
386	Refuse Truck Driver
375	Road Grader Operator
356	Rock Driller
317	Rodman
387	Rotary Bucket Excavator Operator
388	Scalper-Screen Operator
360	Shopman Repair Care
307	Shooter
307	Shotfirer
350	Shuttle Car Operator
390	Silo Operator
391	Stripping Shovel Operator
309	Supply Man
392	Tipple Operator
323	Transmit Man
396	Watchman

Table C5-2 Coal Job Code Cards (MESA, 1973-1977) Surface Occupation Codes	
Job Code	**Occupation / Activity**
366	Waterboy
395	Water Truck Operator
393	Weighman
319	Welder (Shop) Blacksmith
311	Wireman
397	Yard Engine Operator
Supervisory and Staff	
430	Assistant Mine Foreman/Assistant Mine Manager
497	Clerk
414	Dust Sampler
456	Engineers (Electricity, Ventilation, Mining, etc.)
462	Fire Boss Pre-Shift Examiner
464	Inspector
418	Maintenance Foreman
402	Master Electrician
404	Master Mechanic
449	Mine Foreman/Mine Manager
489	Outside Foreman
494	Preparation Plant Foreman
495	Safety Director
481	Superintendent
423	Surveyor
497	Timekeeper
496	Union Representative
MESA – State	
590	Education Specialist
591	Mineral Industry Safety Officer
592	Mine Safety Instructor
593	Safety Representative
594	Training Specialist

MNM Job Code Cards (1997)

Table C5-3 includes MNM Job Codes from a MNM Job Code Card printed in 1997 by the GPO and which referenced a 1981 MSHA form (MSHA Form 4000-50, Sept. 1981).

Table C5-3 MNM Job Code Cards (1997)	
Job Code	**Occupation / Activity**
Development and Production	

Table C5-3 MNM Job Code Cards (1997)	
Job Code	**Occupation / Activity**
607	Jackhammer Operator; Chipping Hammer Operator
807	Powder Gang; Powderman; Power Monkey; Shooter; Shotfirer; Blaster
609	Supply Man; Nipper
710	Ground Control (wood and steel); Timberman
216	Track Man; Track Gang
516	Tamping Machine Operator
833	Drill Helper; Chuck Tender
034	Diamond Drill Operator
134	Jet-Piercing Channeler Operator
234	Jet-Piercing Drill Operator
334	Wagon Drill Operator
434	Churn Drill Operator
534	Jackleg or Stoper Drill Operator
634	Rotary (electric or hydraulic) Drill Operator
734	Rotary (pneumatic) Drill Operator
934	Jumbo Percussion Drill Operator
035	Continuous Miner Helper
036	Continuous Miner Operator
037	Cutting Machine Helper
038	Cutting Machine Operator
045	Hangup Man; Chute Blaster
046	Rock Bolter; Roof Bolter
747	Scaling (hand)
847	Scaling (mechanical)
048	Roof Bolter Mounted
053	Utility Man
057	Stope Miner
058	Drift Miner
059	Raise Miner
759	Raise Borer Operator
663	Shaft Miner; Shaft Sinking
765	Sandfiller (dry operations)
766	Sandfiller (wet operations)
399	Dimension Stone Cutter and Polisher; Rock Sawer
Ore/Mineral Processing	
673	Leaching Operations Worker
079	Crusher Operator; Crusher Worker; Pan-Feeder Operator
179	Ball, Rod, or Pebble Mill Operator

Table C5-3 MNM Job Code Cards (1997)	
Job Code	**Occupation / Activity**
279	Hammer Mill Operator
379	Dryer Operator; Kiln Operator
479	Hydrating Plant Operator
579	Slurry, Mixing or Pumping Operations Worker
679	Flotation Mill Operator; Concentrator Operator
779	Pelletizing Operations Worker
879	Bagging or Packaging Operations Worker
388	Scalper-Screen Operator
488	Dry Screening Plant Operator
588	Sizing and Washing Operations Worker
Load/Haul/Dump	
601	Conveyor Belt Crew
420	Aerial Tram Operator
920	Cager; Cage Attendant; Station Attendant
921	Hoist Operator
622	Dump Operator
825	Bobcat Operator
726	Grizzly Man; Grizzly Tender
028	Scoop-Tram Operator
728	Complete Load/Haul/Dump Cycle
029	Mucking Machine Operator
030	Slusher Operator
930	Skip Tender
331	Clam-Shell Operator
039	Hand Loader (load only)
739	Hand Trammer (load and dump)
043	Gathering Arm Loader Operator
344	Car Shake-Out Operator
750	Shuttle Car Operator (diesel)
850	Ramcar Operator
950	Shuttle Car Operator (electric)
154	Belt Cleaner; Belt Picker
962	Trip Rider; Swamper
367	Shovel Operator
368	Bulldozer Operator
668	Tractor Operator
669	Bin Puller; Truck Loader
969	Motorman
372	Barge Attendant; Boat Operator; Dredge Operator
376	Truck Driver

Table C5-3 MNM Job Code Cards (1997)	
Job Code	**Occupation / Activity**
378	Mobile Crane Operator
678	Dragline Operator
778	Backhoe Operator
878	Overhead Crane Operator
682	Scraper-Loader Operator
782	Front-End Loader Operator
387	Rotary Bucket Excavator Operator
389	Forklift Operator
392	Toplander; Skip Dumper; Tipple Operator
393	Weighman; Scale Man
397	Yard Engine Operator
Maintenance	
602	Electrician
603	Electrician Helper
604	Mechanic
804	Plumber; Pipe Fitter; Millwright
706	Shotcrete Man; Gunite Man
608	Mason
708	Ventilation Crew
612	Belt Vulcanizer
513	Building Repair and Maintenance
613	Cleanup Man
416	Salvage Crew
616	Laborer; Bullgang

Table C5-3 MNM Job Code Cards (1997)	
Job Code	**Occupation / Activity**
716	Cement Man; Concrete Worker
618	Greaser; Oiler
619	Welder (welding, cutting, brazing, hard surfacing, soldering)
032	Brattice Man
041	Jacksetter
342	Bit Grinder; Bit Sharpener
352	Iron Worker; Metal Worker
660	Machinist
261	Battery Station Operator
763	Shaft Repairer
375	Road Grader Operator
385	Lampman
394	Carpenter
894	Painter
Miscellaneous	
413	Janitor
514	Laboratory Technician
614	Sampler; Dust Sampler
623	Surveyor; Transmit Man
649	Administrative, Supervisory, Management Personnel
456	Engineer (electrical, ventilation, mining, etc.); Technical Services
674	Warehouseman; Supply Handler

List of Subjects

30 CFR Part 56

Chemicals, Electric power, Explosives, Fire prevention, Hazardous substances, Incorporation by reference, Metal and nonmetal mining, Mine safety and health, Noise control, Reporting and recordkeeping requirements, Surface mining.

30 CFR Part 57

Chemicals, Electric power, Explosives, Fire prevention, Gases, Hazardous substances, Incorporation by reference, Metal and nonmetal mining, Mine safety and health, Noise control, Radiation protection, Reporting and recordkeeping requirements, Underground mining.

30 CFR Part 60

Coal, Incorporation by reference, Metal and nonmetal mining, Medical surveillance, Mine safety and health, Respirable crystalline silica, Reporting and recordkeeping requirements, Surface mining, Underground mining.

30 CFR Part 70

Coal, Mine safety and health, Reporting and recordkeeping requirements, Respirable dust, Underground coal mines.

30 CFR Part 71

Coal, Mine safety and health, Reporting and recordkeeping requirements, Surface coal mines, Underground coal mines.

30 CFR Part 72

Coal, Health standards, Incorporation by reference, Mine safety and health, Training, Underground mining.

30 CFR Part 75

Coal, Mine safety and health, Reporting and recordkeeping requirements, Underground coal mines, Ventilation.

30 CFR Part 90

Coal, Mine safety and health, Reporting and recordkeeping requirements, Respirable dust.

Christopher J. Williamson

Assistant Secretary of Labor
for Mine Safety and Health.

For the reasons discussed in the preamble, the Mine Safety and Health Administration is proposing to amend 30 CFR subchapters K, M, and O as follows:

Subchapter K-Metal and Nonmetal Mine Safety and Health

PART 56–SAFETY AND HEALTH STANDARDS-SURFACE METAL AND NONMETAL MINES

1. The authority citation for part 56 continues to read as follows:

Authority: 30 U.S.C. 811.

Subpart D–Air Quality and Physical Agents

2. Amend § 56.5001 by revising paragraph (a) to read as follows:

§ 56.5001 Exposure limits for airborne contaminants.

*****

(a) Except as provided in paragraph (b) of this section and in part 60 of this chapter, the exposure to airborne contaminants shall not exceed, on the basis of a time weighted average, the threshold limit values adopted by the American Conference of Governmental Industrial Hygienists, as set forth and explained in the 1973 edition of the Conference's publication, entitled "TLV's Threshold Limit Values for Chemical Substances in Workroom Air Adopted by ACGIH for 1973," pages 1 through 54. This publication is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Mine Safety and Health Administration (MSHA) and at the National Archives and Records Administration (NARA). Contact MSHA at: MSHA's Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, VA 22202-5450; 202-693-9440; or at any MSHA Metal and Nonmetal Mine

Safety and Health District Office. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations.html or email fr.inspection@nara.gov. The material may be obtained from American Conference of Governmental Industrial Hygienists, 1330 Kemper Meadow Drive, Attn: Customer Service, Cincinnati, OH 45240; www.acgih.org.

*****

3. Amend § 56.5005 by revising the introductory text and paragraphs (b) and (c) to read as follows:

§ 56.5005 Control of exposure to airborne contaminants.

Control of employee exposure to harmful airborne contaminants shall be, insofar as feasible, by prevention of contamination, removal by exhaust ventilation, or by dilution with uncontaminated air. However, where accepted engineering control measures have not been developed or when necessary by the nature of work involved (for example, while establishing controls or occasional entry into hazardous atmospheres to perform maintenance or investigation), employees may work for reasonable periods of time in concentrations of airborne contaminants exceeding permissible levels if they are protected by appropriate respiratory protective equipment. Whenever respiratory protective equipment is used, its selection, fitting, maintenance, cleaning, training, supervision, and use shall meet the following minimum requirements:

*****

(b) Approved respirators shall be selected, fitted, cleaned, used, and maintained in accordance with the requirements, as applicable, of ASTM F3387-19. ASTM F3387-19, Standard Practice for Respiratory Protection approved August 1, 2019, is incorporated by reference into this section with the approval of the Director of the Federal Register under 5

U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Mine Safety and Health Administration (MSHA) and at the National Archives and Records Administration (NARA). Contact MSHA at: MSHA's Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, VA 22202-5450; 202-693-9440; or any Mine Safety and Health Enforcement District Office. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations.html or email fr.inspection@nara.gov. The material may be obtained from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959; www.astm.org/.

(c) When respiratory protection is used in atmospheres immediately dangerous to life or health (IDLH), the presence of at least one other person with backup equipment and rescue capability shall be required in the event of failure of the respiratory equipment.

PART 57–SAFETY AND HEALTH STANDARDS-UNDERGROUND METAL AND NONMETAL MINES

4. The authority citation for part 57 continues to read as follows:

Authority: 30 U.S.C. 811.

Subpart D–Air Quality, Radiation, Physical Agents, and Diesel Particulate Matter

5. Amend § 57.5001 by revising paragraph (a) to read as follows:

§ 57.5001 Exposure limits for airborne contaminants.

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(a) Except as provided in paragraph (b) of this section and in part 60 of this chapter, the exposure to airborne contaminants shall not exceed, on the basis of a time weighted average, the threshold limit values adopted by the American Conference of Governmental Industrial Hygienists, as set forth and explained in the 1973 edition of the Conference's publication, entitled “TLV's Threshold Limit Values for Chemical Substances in Workroom Air Adopted by

ACGIH for 1973," pages 1 through 54. Excursions above the listed thresholds shall not be of a greater magnitude than is characterized as permissible by the Conference. This publication is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Mine Safety and Health Administration (MSHA) and at the National Archives and Records Administration (NARA). Contact MSHA at: MSHA's Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, VA 22202-5450; 202-693-9440; or any MSHA Metal and Nonmetal Mine Safety and Health District Office. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations.html or email fr.inspection@nara.gov. The material may be obtained from American Conference of Governmental Industrial Hygienists by writing to 1330 Kemper Meadow Drive, Attn: Customer Service, Cincinnati, OH 45240; www.acgih.org.

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6. Amend § 57.5005 by revising the introductory text and paragraphs (b) and (c) to read as follows:

§ 57.5005 Control of exposure to airborne contaminants.

Control of employee exposure to harmful airborne contaminants shall be, insofar as feasible, by prevention of contamination, removal by exhaust ventilation, or by dilution with uncontaminated air. However, where accepted engineering control measures have not been developed or when necessary by the nature of work involved (for example, while establishing controls or occasional entry into hazardous atmospheres to perform maintenance or investigation), employees may work for reasonable periods of time in concentrations of airborne contaminants exceeding permissible levels if they are protected by appropriate respiratory protective equipment. Whenever respiratory protective equipment is used, its selection, fitting,

maintenance, cleaning, training, supervision, and use shall meet the following minimum requirements:

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(b) Approved respirators shall be selected, fitted, cleaned, used, and maintained in accordance with the requirements, as applicable, of ASTM F3387-19. ASTM F3387-19, Standard Practice for Respiratory Protection approved August 1, 2019, is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Mine Safety and Health Administration (MSHA) and at the National Archives and Records Administration (NARA). Contact MSHA at: MSHA's Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, VA 22202-5450; 202-693-9440; or any Mine Safety and Health Enforcement District Office. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations.html or email fr.inspection@nara.gov. The material may be obtained from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959; www.astm.org/.

(c) When respiratory protection is used in atmospheres immediately dangerous to life or health (IDLH), the presence of at least one other person with backup equipment and rescue capability shall be required in the event of failure of the respiratory equipment.

Subchapter M-Uniform Mine Health Regulations

7. Add part 60 to subchapter M to read as follows:

PART 60–RESPIRABLE CRYSTALLINE SILICA

Sec.
60.1 Scope; effective date.
60.2 Definitions.
60.10 Permissible exposure limit (PEL).
60.11 Methods of compliance.

60.12 Exposure monitoring.
60.13 Corrective actions.
60.14 Respiratory protection.
60.15 Medical surveillance for metal and nonmetal miners.
60.16 Recordkeeping requirements.
60.17 Severability.

Authority: 30 U.S.C. 811, 813(h) and 957.

§ 60.1 Scope; effective date.

This part sets forth mandatory health standards for each surface and underground metal, nonmetal, and coal mine subject to the Federal Mine Safety and Health Act of 1977, as amended. Requirements regarding medical surveillance for metal and nonmetal miners are also included. The provisions of this part are effective [date 120 days after publication of the final rule].

§ 60.2 Definitions.

The following definitions apply in this part:

Action level means an airborne concentration of respirable crystalline silica of 25 micrograms per cubic meter of air ($\mu g/m^3$) for a full-shift exposure, calculated as an 8-hour time-weighted average (TWA).

Objective data means information, such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance, demonstrating miner exposure to respirable crystalline silica associated with a particular product or material or a specific process, task, or activity. The data must reflect mining conditions closely resembling or with a higher exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the operator's current operations.

Respirable crystalline silica means quartz, cristobalite, and/or tridymite contained in airborne particles that are determined to be respirable by a sampling device designed to meet the characteristics for respirable-particle-size-selective samplers that conform to the International

Organization for Standardization (ISO) 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related Sampling.

Specialist means an American Board-Certified Specialist in Pulmonary Disease or an American Board-Certified Specialist in Occupational Medicine.

§ 60.10 Permissible exposure limit (PEL).

The mine operator shall ensure that no miner is exposed to an airborne concentration of respirable crystalline silica in excess of 50 μg/m^3 for a full-shift exposure, calculated as an 8-hour TWA.

§ 60.11 Methods of compliance.

(a) The mine operator shall install, use, and maintain feasible engineering controls, supplemented by administrative controls when necessary, to keep each miner's exposure at or below the PEL, except as specified in § 60.14.

(b) Rotation of miners shall not be considered an acceptable administrative control used for compliance with this part.

§ 60.12 Exposure monitoring.

(a) *Baseline sampling.* (1) The mine operator shall perform baseline sampling within the first 180 days after [date 120 days after publication of the final rule] to assess the full shift, 8-hour TWA exposure of respirable crystalline silica for each miner who is or may reasonably be expected to be exposed to respirable crystalline silica.

(2) The mine operator is not required to conduct periodic sampling under paragraph (b) of this section if the baseline sampling indicates that miner exposures are below the action level and if the conditions in either paragraph (a)(2)(i) or (ii) of this section are met:

(i) One of the following sources from within the preceding 12 months of baseline sampling indicates that miner exposures are below the action level:

(A) Sampling conducted by the Secretary; or

(B) Mine operator sampling conducted in accordance with paragraphs (f) and (g) of this section; or

(C) Objective data.

(ii) Subsequent sampling that is conducted within 3 months after the baseline sampling indicates that miner exposures are below the action level.

(b) *Periodic sampling.* Where the most recent sampling indicates that miner exposures are at or above the action level but at or below the PEL, the mine operator shall sample within 3 months of that sampling and continue to sample within 3 months of the previous sampling until two consecutive samplings indicate that miner exposures are below the action level.

(c) *Corrective actions sampling.* Where the most recent sampling indicates that miner exposures are above the PEL, the mine operator shall sample after corrective actions taken pursuant to § 60.13 until the sampling indicates that miner exposures are at or below the PEL.

(d) *Semi-annual evaluation.* At least every 6 months after [date one year after the effective date of the final rule], mine operators shall evaluate any changes in production, processes, engineering or administrative controls, or other factors that may reasonably be expected to result in new or increased respirable crystalline silica exposures. Once the evaluation is completed, the mine operator shall:

(1) Make a record of the evaluation and the date of the evaluation; and

(2) Post the record on the mine bulletin board and, if applicable, by electronic means, for the next 31 days.

(e) *Post-evaluation sampling.* If the mine operator determines as a result of the semi-annual evaluation under paragraph (d) of this section that miners may be exposed to respirable crystalline silica at or above the action level, the mine operator shall perform sampling to assess the full shift, 8-hour TWA exposure of respirable crystalline silica for each miner who is or may reasonably be expected to be at or above the action level.

(f) *Sampling requirements*. (1) Sampling shall be performed for the duration of a miner's regular full shift and during typical mining activities.

(2) The full-shift, 8-hour TWA exposure for such miners shall be measured based on:

(i) Personal breathing-zone air samples for metal and nonmetal operations; or

(ii) Occupational environmental samples collected in accordance with § 70.201(c) or (b) or § 90.201(b) of this chapter for coal operations.

(3) Where several miners perform the same tasks on the same shift and in the same work area, the mine operator may sample a representative fraction (at least two) of these miners to meet the requirements in paragraphs (a) through (e) of this section. In sampling a representative fraction of miners, the mine operator shall select the miners who are expected to have the highest exposure to respirable crystalline silica.

(4) The mine operator shall use respirable-particle-size-selective samplers that conform to ISO 7708:1995 to determine compliance with the PEL. ISO 7708:1995, Air Quality—Particle Size Fraction Definitions for Health-Related Sampling, Edition 1, 1995-04, is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Mine Safety and

Health Administration (MSHA) and at the National Archives and Records Administration (NARA). Contact MSHA at: MSHA's Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, VA 22202-5450; 202-693-9440; or any Mine Safety and Health Enforcement District Office. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations.html or email fr.inspection@nara.gov. The material may be obtained from the International Organization for Standardization (ISO), CP 56, CH–1211 Geneva 20, Switzerland; phone: + 41 22 749 01 11; fax: + 41 22 733 34 30; website: www.iso.org.

(g) *Methods of sample analysis*. (1) The mine operator shall use a laboratory that is accredited to ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories" with respect to respirable crystalline silica analyses, where the accreditation has been issued by a body that is compliant with ISO/IEC 17011 "Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies."

(2) The mine operator shall ensure that the laboratory evaluates all samples using respirable crystalline silica analytical methods specified by MSHA, the National Institute for Occupational Safety and Health (NIOSH), or the Occupational Safety and Health Administration (OSHA).

(h) *Sampling records*. For each sample taken pursuant to paragraphs (a) through (e) of this section, the mine operator shall make a record of the sample date, the occupations sampled, and the concentrations of respirable crystalline silica and respirable dust, and post the record and the laboratory report on the mine bulletin board and, if applicable, by electronic means, for the next 31 days, upon receipt.

§ 60.13 Corrective actions.

(a) If any sampling indicates that a miner's exposure exceeds the PEL, the mine operator shall:

(1) Make approved respirators available to affected miners before the start of the next work shift in accordance with § 60.14;

(2) Ensure that affected miners wear respirators properly for the full shift or during the period of overexposure until miner exposures are at or below the PEL; and

(3) Immediately take corrective actions to lower the concentration of respirable crystalline silica to at or below the PEL.

(4) Once corrective actions have been taken, the mine operator shall:

(i) Conduct sampling pursuant to § 60.12(c); and

(ii) Take additional or new corrective actions until sampling indicates miner exposures are at or below the PEL.

(b) The mine operator shall make a record of corrective actions and the dates of the corrective actions under paragraph (a) of this section.

§ 60.14 Respiratory protection.

(a) *Temporary non-routine use of respirators*. The mine operator shall use respiratory protection as a temporary measure in accordance with paragraph (c) of this section. Miners must use respirators when working in concentrations of respirable crystalline silica above the PEL while:

(1) Engineering control measures are being developed and implemented; or

(2) It is necessary by the nature of work involved.

(b) *Miners unable to wear respirators*. Upon written determination by a physician or other licensed health care professional (PLHCP) that an affected miner is unable to wear a respirator, the miner shall be temporarily transferred either to work in a separate area of the same mine or to an occupation at the same mine where respiratory protection is not required.

(1) The affected miner shall continue to receive compensation at no less than the regular rate of pay in the occupation held by that miner immediately prior to the transfer.

(2) The affected miner may be transferred back to the miner's initial work area or occupation when temporary non-routine use of respirators under paragraph (a) of this section is no longer required.

(c) *Respirator*y *protection requirements*. (1) Affected miners shall be provided with a NIOSH-approved atmosphere-supplying respirator or NIOSH-approved air-purifying respirator equipped with the following:

(i) Particulate protection classified as 100 series under 42 CFR part 84; or

(ii) Particulate protection classified as High Efficiency "HE" under 42 CFR part 84.

(2) Approved respirators shall be selected, fitted, used, and maintained in accordance with the requirements, as applicable, of ASTM F3387-19. ASTM F3387-19, Standard Practice for Respiratory Protection approved August 1, 2019, is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Mine Safety and Health Administration (MSHA) and at the National Archives and Records Administration (NARA). Contact MSHA at: MSHA's Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, VA 22202-5450; 202-693-9440; or any Mine Safety and Health Enforcement

District Office. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations.html or email fr.inspection@nara.gov. The material may be obtained from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959; www.astm.org/.

§ 60.15 Medical surveillance for metal and nonmetal miners.

(a) *Medical surveillance*. Each operator of a metal and nonmetal mine shall provide to each miner periodic medical examinations performed by a physician or other licensed health care professional (PLHCP) or specialist, as defined in § 60.2, at no cost to the miner.

(1) Medical examinations shall be provided at frequencies specified in this section.

(2) Medical examinations shall include:

(i) A medical and work history, with emphasis on: past and present exposure to respirable crystalline silica, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including diagnoses and symptoms of respiratory disease (e.g., shortness of breath, cough, wheezing); history of tuberculosis; and smoking status and history;

(ii) A physical examination with special emphasis on the respiratory system;

(iii) A chest X-ray (a single posteroanterior radiographic projection or radiograph of the chest at full inspiration recorded on either film (no less than 14 x 17 inches and no more than 16 x 17 inches) or digital radiography systems), classified according to the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified B Reader; and

(iv) A pulmonary function test to include forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1) and FEV_1/FVC ratio, administered by a spirometry technician with a current certificate from a NIOSH-approved Spirometry Program Sponsor.

(b) *Voluntary medical examinations.* Each mine operator shall provide the opportunity to have the medical examinations specified in paragraph (a) of this section at least every 5 years to all miners employed at the mine. The medical examinations shall be available during a 6-month period that begins no less than 3.5 years and not more than 4.5 years from the end of the last 6-month period.

(c) *Mandatory medical examinations.* For each miner who begins work in the mining industry for the first time, the mine operator shall provide medical examinations specified in paragraph (a) of this section as follows:

(1) An initial medical examination no later than 30 days after beginning employment;

(2) A follow-up medical examination no later than 3 years after the initial examination in paragraph (c)(1) of this section; and

(3) A follow-up medical examination conducted by a specialist no later than 2 years after the examinations in paragraph (c)(2) of this section if the chest X-ray shows evidence of pneumoconiosis or the spirometry examination indicates evidence of decreased lung function.

(d) *Medical examinations results*. The results of medical examinations or tests made pursuant to this section shall be provided only to the miner, and at the request of the miner, to the miner's designated physician.

(e) *Written medical opinion*. The mine operator shall obtain a written medical opinion from the PLHCP or specialist within 30 days of the medical examination. The written opinion shall contain only the following:

(1) The date of the medical examination;

(2) A statement that the examination has met the requirements of this section; and

(3) Any recommended limitations on the miner’s use of respirators.

(f) *Written medical opinion records.* The mine operator shall maintain a record of the written medical opinions received from the PLHCP or specialist under paragraph (e) of this section.

§ 60.16 Recordkeeping requirements.

(a) Table 1 to this paragraph (a) lists the records the mine operator shall retain and their retention period.

(1) Evaluation records made under § 60.12(d) shall be retained for at least 2 years from the date of each evaluation.

(2) Sampling records made under § 60.12(h) shall be retained for at least 2 years from the sample date.

(3) Corrective action records made under § 60.13(b) shall be retained for at least 2 years from the date of each corrective action. These records must be stored with the records of related sampling under § 60.12(h).

(4) Written determination records received from a PLHCP under § 60.14(b) shall be retained for the duration of the miner's employment plus 6 months.

(5) Written medical opinion records received from a PLHCP or specialist under § 60.15(f) shall be retained for the duration of the miner's employment plus 6 months.

Table 1 to Paragraph (a) –Recordkeeping Requirements		
Record	**Section References**	**Retention period**
1. Evaluation records	§ 60.12(d)	At least 2 years from date of each evaluation.
2. Sampling records	§ 60.12(h)	At least 2 years from sample date.
3. Corrective action records	§ 60.13(b)	At least 2 years from date of each corrective action.
4. Written determination records received from a PLHCP	§ 60.14(b)	Duration of miner's employment plus 6 months.
5. Written medical opinion records received from a PLHCP or specialist	§ 60.15(f)	Duration of miner's employment plus 6 months.

(b) Upon request from an authorized representative of the Secretary, from an authorized representative of miners, or from miners, mine operators shall promptly provide access to any record listed in this section.

§ 60.17 Severability.

Each section of this part, as well as sections in 30 CFR parts 56, 57, 70, 71, 72, 75, and 90 that address respirable crystalline silica or respiratory protection, is separate and severable from the other sections and provisions. If any provision of this subpart is held to be invalid or unenforceable by its terms, or as applied to any person, entity, or circumstance, or is stayed or enjoined, that provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from these sections and shall not affect the remainder thereof.

Subchapter O-Coal Mine Safety and Health

PART 70—MANDATORY HEALTH STANDARDS—UNDERGROUND COAL MINES

8. The authority citation for part 70 continues to read as follows:

Authority: 30 U.S.C. 811, 813(h), 957.

Subpart A–General

§ 70.2 [Amended]

9. Amend § 70.2 by removing the definition of "Quartz".

Subpart B—Dust Standards

§ 70.101 [Removed and Reserved]

10. Remove and reserve § 70.101.

Subpart C–Sampling Procedures

11. Amend § 70.205 by revising paragraph (c) to read as follows:

§ 70.205 Approved sampling devices; operation; air flowrate.

*****

(c) If using a CPDM, the person certified in sampling shall monitor the dust concentrations and the sampling status conditions being reported by the sampling device at mid-shift or more frequently as specified in the approved mine ventilation plan to assure: The sampling device is in the proper location and operating properly; and the work environment of the occupation or DA being sampled remains in compliance with the standard at the end of the shift. This monitoring is not required if the sampling device is being operated in an anthracite coal mine using the full box, open breast, or slant breast mining method.

§ 70.206 [Removed and Reserved]

12. Remove and reserve § 70.206.

§ 70.207 [Removed and Reserved]

13. Remove and reserve § 70.207.

14. Amend § 70.208 by:

a. Removing and reserving paragraph (c);

b. Revising paragraphs (d), (e) introductory text, (e)(2), (f), (g), (h) introductory text, (h)(2), (i) introductory text, and (i)(1); and

c. Adding table 1.

The revisions and addition read as follows:

§ 70.208 Quarterly sampling; mechanized mining units.

*****

(d) If a normal production shift is not achieved, the DO or ODO sample for that shift may be voided by MSHA. However, any sample, regardless of production, that exceeds the standard by at least 0.1 mg/m^3 shall be used in the determination of the equivalent concentration for that occupation.

(e) When a valid representative sample taken in accordance with this section meets or exceeds the ECV in table 1 to this section that corresponds to the particular sampling device used, the operator shall:

*****

(2) Immediately take corrective action to lower the concentration of respirable dust to at or below the respirable dust standard; and

*****

(f) Noncompliance with the standard is demonstrated during the sampling period when:

(1) Three or more valid representative samples meet or exceed the ECV in table 1 to this section that corresponds to the particular sampling device used; or

(2) The average for all valid representative samples meets or exceeds the ECV in table 1 to this section that corresponds to the particular sampling device used.

(g)(1) Unless otherwise directed by the District Manager, upon issuance of a citation for a violation of the standard involving a DO in an MMU, paragraph (a)(1) of this section shall not

apply to the DO in that MMU until the violation is abated and the citation is terminated in accordance with paragraphs (h) and (i) of this section.

(2) Unless otherwise directed by the District Manager, upon issuance of a citation for a violation of the standard involving a type of ODO in an MMU, paragraph (a)(2) of this section shall not apply to that ODO type in that MMU until the violation is abated and the citation is terminated in accordance with paragraphs (h) and (i) of this section.

(h) Upon issuance of a citation for violation of the standard, the operator shall take the following actions sequentially:

*****

(2) Immediately take corrective action to lower the concentration of respirable coal mine dust to at or below the standard; and

*****

(i) A citation for a violation of the standard shall be terminated by MSHA when:

(1) Each of the five valid representative samples is at or below the standard; and

*****

Table 1 to § 70.208– Excessive Concentration Values (ECV) based on a Single Sample, Three Samples, or the Average of Five or Fifteen Full-Shift CMDPSU/CPDM Concentration Measurements.			
Section	**Samples**	**ECV (mg/m^3)**	
		CMDPSU	**CPDM**
70.208 (e)	70.100(a) - Single sample	1.79	1.70
	70.100(b) - Single sample	0.74	0.57
70.208(f)(1)	70.100(a) - 3 or more samples	1.79	1.70
	70.100(b) - 3 or more samples	0.74	0.57
70.208(f)(2)	70.100(a) - 5 sample average	1.63	1.59
	70.100(b) - 5 sample average	0.61	0.53
70.208(f)(2)	70.100(a) - 15 sample average	1.58	1.56
	70.100(b) - 15 sample average	0.57	0.52
70.208(i)(1)	70.100(a) - Each of 5 samples	1.79	1.70
	70.100(b) - Each of 5 samples	0.74	0.57

15. Amend § 70.209 by:

a. Removing and reserving paragraph (b);

b. Revising paragraphs (c) introductory text, (c)(2), (d), (e), (f) introductory text, (f)(2), (g) introductory text, and (g)(1); and

c. Adding table 1.

The revisions and addition read as follows:

§ 70.209 Quarterly sampling; designated areas.

*****

(c) When a valid representative sample taken in accordance with this section meets or exceeds the ECV in table 1 to this section that corresponds to the particular sampling device used, the operator shall:

*****

(2) Immediately take corrective action to lower the concentration of respirable dust to at or below the respirable dust standard; and

*****

(d) Noncompliance with the standard is demonstrated during the sampling period when:

(1) Two or more valid representative samples meet or exceed the ECV in table 1 to this section that corresponds to the particular sampling device used; or

(2) The average for all valid representative samples meets or exceeds the ECV in table 1 to this section that corresponds to the particular sampling device used.

(e) Unless otherwise directed by the District Manager, upon issuance of a citation for a violation of the standard, paragraph (a) of this section shall not apply to that DA until the violation is abated and the citation is terminated in accordance with paragraphs (f) and (g) of this section.

(f) Upon issuance of a citation for a violation of the standard, the operator shall take the following actions sequentially:

*****

(2) Immediately take corrective action to lower the concentration of respirable coal mine dust to at or below the standard; and

*****

(g) A citation for a violation of the standard shall be terminated by MSHA when:

(1) Each of the five valid representative samples is at or below the standard; and

*****

Table 1 to § 70.209 - Excessive Concentration Values (ECV) based on a Single Sample, Two Samples, or the Average of Five or Fifteen Full-Shift CMDPSU/CPDM Concentration Measurements.			
Section	**Samples**	**ECV (mg/m^3)**	
		CMDPSU	**CPDM**
70.209 (c)	70.100(a) - Single sample	1.79	1.70
	70.100(b) - Single sample	0.74	0.57
70.209(d)(1)	70.100(a) - 2 or more samples	1.79	1.70
	70.100(b) - 2 or more samples	0.74	0.57
70.209(d)(2)	70.100(a) - 5 sample average	1.63	1.59
	70.100(b) - 5 sample average	0.61	0.53
70.209(d)(2)	70.100(a) - 15 sample average	1.58	1.56
	70.100(b) - 15 sample average	0.57	0.52
70.209(g)(1)	70.100(a) - Each of 5 samples	1.79	1.70
	70.100(b) - Each of 5 samples	0.74	0.57

Table 70-1 to Subpart C of Part 70 [Removed]

16. Remove table 70-1 to subpart C of part 70.

Table 70-2 to Subpart C of Part 70 [Removed]

17. Remove table 70-2 to subpart C of part 70.

PART 71—MANDATORY HEALTH STANDARDS—SURFACE COAL MINES AND SURFACE WORK AREAS OF UNDERGROUND COAL MINES

18. The authority citation for part 71 continues to read as follows:

Authority: 30 U.S.C. 811, 813(h), 957.

Subpart A–General

§ 71.2 [Amended]

19. Amend § 71.2 by removing the definition of “Quartz”.

Subpart B—Dust Standards

§ 71.101 [Removed and Reserved]

20. Remove and reserve § 71.101.

Subpart C–Sampling Procedures

21. Amend § 71.205 by revising paragraph (c) to read as follows:

§ 71.205 Approved sampling devices; operation; air flowrate.

*****

(c) If using a CPDM, the person certified in sampling shall monitor the dust concentrations and the sampling status conditions being reported by the sampling device at mid-shift or more frequently as specified in the approved respirable dust control plan, if applicable, to assure: The sampling device is in the proper location and operating properly; and the work environment of the occupation being sampled remains in compliance with the standard at the end of the shift.

22. Amend § 71.206 by:

a. Removing and reserving paragraph (b);

b. Revising paragraphs (e), (g), (h) introductory text, (h)(2), (i), (j), (k) introductory text, (k)(2), and (l);

c. Removing tables 71-1 and 71-2;

d. Revising paragraphs (m) and (n); and

e. Adding table 1.

The revisions and addition read as follows:

§ 71.206 Quarterly sampling; designated work positions.

*****

(e) Each DWP sample shall be taken on a normal work shift. If a normal work shift is not achieved, the respirable dust sample shall be transmitted to MSHA with a notation by the person certified in sampling on the back of the dust data card stating that the sample was not taken on a normal work shift. When a normal work shift is not achieved, the sample for that shift may be voided by MSHA. However, any sample, regardless of whether a normal work shift was achieved, that exceeds the standard by at least 0.1 mg/m^3 shall be used in the determination of the equivalent concentration for that occupation.

*****

(g) Upon notification from MSHA that any valid representative sample taken from a DWP to meet the requirements of paragraph (a) of this section exceeds the standard, the operator shall, within 15 calendar days of notification, sample that DWP each normal work shift until five valid representative samples are taken. The operator shall begin sampling on the first normal work shift following receipt of notification.

(h) When a valid representative sample taken in accordance with this section meets or exceeds the excessive concentration value (ECV) in table 1 to this section that corresponds to the particular sampling device used, the mine operator shall:

*****

(2) Immediately take corrective action to lower the concentration of respirable coal mine dust to at or below the standard; and

*****

(i) Noncompliance with the standard is demonstrated during the sampling period when:

(1) Two or more valid representative samples meet or exceed the ECV in table 1 to this section that corresponds to the particular sampling device used; or

(2) The average for all valid representative samples meets or exceeds the ECV in table 1 to this section that corresponds to the particular sampling device used.

(j) Unless otherwise directed by the District Manager, upon issuance of a citation for a violation of the standard, paragraph (a) of this section shall not apply to that DWP until the violation is abated and the citation is terminated in accordance with paragraphs (k) and (l) of this section.

(k) Upon issuance of a citation for violation of the standard, the operator shall take the following actions sequentially:

*****

(2) Immediately take corrective action to lower the concentration of respirable coal mine dust to at or below the standard; and

*****

(l) A citation for violation of the standard shall be terminated by MSHA when the equivalent concentration of each of the five valid representative samples is at or below the standard.

(m) The District Manager may designate for sampling under this section additional work positions at a surface coal mine and at a surface work area of an underground coal mine where a concentration of respirable dust exceeding 50 percent of the standard has been measured by one or more MSHA valid representative samples.

(n) The District Manager may withdraw from sampling any DWP designated for sampling under paragraph (m) of this section upon finding that the operator is able to maintain continuing compliance with the standard. This finding shall be based on the results of MSHA and operator valid representative samples taken during at least a 12-month period.

Table 1 to § 71.206 - Excessive Concentration Values (ECV) based on a Single Sample, Two Samples, or the Average of Five Full-Shift CMDPSU/CPDM Concentration Measurements.			
Section	**Samples**	**ECV (mg/m^3)**	
		CMDPSU	**CPDM**
71.206(h)	Single sample	1.79	1.70
71.206(i)(1)	2 or more samples	1.79	1.70
71.206(i)(2)	5 sample average	1.63	1.59
71.206(l)	Each of 5 samples	1.79	1.70

Subpart D—Respirable Dust Control Plans

23. Amend § 71.300 by revising paragraph (a) introductory text to read as follows:

§ 71.300 Respirable dust control plan; filing requirements.

(a) Within 15 calendar days after the termination date of a citation for violation of the standard, the operator shall submit to the District Manager for approval a written respirable dust control plan applicable to the DWP identified in the citation. The respirable dust control plan and revisions thereof shall be suitable to the conditions and the mining system of the coal mine and shall be adequate to continuously maintain respirable dust to at or below the standard at the DWP identified in the citation.

*****

24. Amend § 71.301 by revising paragraph (a)(1) to read as follows:

§ 71.301 Respirable dust control plan; approval by District Manager and posting.

(a) ***

(1) The respirable dust control measures would be likely to maintain concentrations of respirable coal mine dust at or below the standard; and

*****

PART 72—HEALTH STANDARDS FOR COAL MINES

25. The authority citation for part 72 continues to read as follows:

Authority: 30 U.S.C. 811, 813(h), 957.

Subpart E—Miscellaneous

26. Revise § 72.710 to read as follows:

§ 72.710 Selection, fit, use, and maintenance of approved respirators.

Approved respirators shall be selected, fitted, used, and maintained in accordance with the provisions of a respiratory protection program consistent with the requirements, as applicable, of ASTM F3387-19. ASTM F3387-19, Standard Practice for Respiratory Protection approved August 1, 2019, is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Mine Safety and Health Administration (MSHA) and at the National Archives and Records Administration (NARA). Contact MSHA at: MSHA's Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, VA 22202-5450; 202-693-9440; or any Mine Safety and Health Enforcement District Office. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations.html or email fr.inspection@nara.gov. The material may be obtained from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959; www.astm.org/.

27. Revise § 72.800 to read as follows:

§ 72.800 Single, full-shift measurement of respirable coal mine dust.

The Secretary will use a single, full-shift measurement of respirable coal mine dust to determine the average concentration on a shift since that measurement accurately represents atmospheric conditions to which a miner is exposed during such shift. Noncompliance with the respirable dust standard, in accordance with this subchapter, is demonstrated when a single, full-shift measurement taken by MSHA meets or exceeds the applicable ECV in table 1 to § 70.208, table 1 to § 70.209, table 1 to § 71.206, or table 1 to § 90.207 of this chapter that corresponds to the particular sampling device used. Upon issuance of a citation for a violation of the standard, and for MSHA to terminate the citation, the mine operator shall take the specified actions in this subchapter.

PART 75—MANDATORY SAFETY STANDARDS—UNDERGROUND COAL MINES

28. The authority citation for part 75 continues to read as follows:

Authority: 30 U.S.C. 811, 813(h), 957.

Subpart D—Ventilation

29. Amend § 75.350 by:

a. Revising paragraph (b)(3)(i);

b. Removing paragraph (b)(3)(ii); and

c. Redesignating (b)(3)(iii) as (b)(3)(ii).

The revision reads as follows:

§ 75.350 Belt air course ventilation.

*****

(b)***

(3)***

(i) The average concentration of respirable dust in the belt air course, when used as a section intake air course, shall be maintained at or below 0.5 milligrams per cubic meter of air (mg/m^3).

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PART 90—MANDATORY HEALTH STANDARDS—COAL MINERS WHO HAVE EVIDENCE OF THE DEVELOPMENT OF PNEUMOCONIOSIS

30. The authority citation for part 90 continues to read as follows:

Authority: 30 U.S.C. 811, 813(h), 957.

Subpart A-General

31. Amend § 90.2 by revising the definition of "Part 90 miner" and removing the definition of "Quartz".

The revision reads as follows:

§ 90.2 Definitions.

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Part 90 miner. A miner employed at a coal mine who has exercised the option under the old section 203(b) program (36 FR 20601 preview citation details, October 27, 1971), or under § 90.3 to work in an area of a mine where the average concentration of respirable dust in the mine atmosphere during each shift to which that miner is exposed is continuously maintained at or below the standard, and who has not waived these rights.

*****

32. Amend § 90.3 by revising paragraph (a) to read as follows:

§ 90.3 Part 90 option; notice of eligibility; exercise of option.

(a) Any miner employed at a coal mine who, in the judgment of the Secretary of HHS, has evidence of the development of pneumoconiosis based on a chest X-ray, read and classified in the manner prescribed by the Secretary of HHS, or based on other medical examinations shall be afforded the option to work in an area of a mine where the average concentration of respirable dust in the mine atmosphere during each shift to which that miner is exposed is continuously maintained at or below the standard. Each of these miners shall be notified in writing of eligibility to exercise the option.

*****

Subpart B—Dust Standards, Rights of Part 90 Miners

§ 90.101 [Removed and Reserved]

33. Remove and reserve § 90.101.

34. Amend § 90.102 by revising paragraph (a) to read as follows:

§ 90.102 Transfer; notice.

(a) Whenever a Part 90 miner is transferred in order to meet the standard, the operator shall transfer the miner to an existing position at the same coal mine on the same shift or shift rotation on which the miner was employed immediately before the transfer. The operator may transfer a Part 90 miner to a different coal mine, a newly created position or a position on a different shift or shift rotation if the miner agrees in writing to the transfer. The requirements of this paragraph do not apply when the respirable dust concentration in a Part 90 miner's work

position complies with the standard but circumstances, such as reductions in workforce or changes in operational status, require a change in the miner's job or shift assignment.

*****

35. Amend § 90.104 by revising paragraph (a)(2) to read as follows:

§ 90.104 Waiver of rights; re-exercise of option.

(a) ***

(2) Applying for and accepting a position in an area of a mine which the miner knows has an average respirable dust concentration exceeding the standard; or

*****

Subpart C–Sampling Procedures

36. Amend § 90.205 by revising paragraph (c) to read as follows:

§ 90.205 Approved sampling devices; operation; air flowrate.

*****

(c) If using a CPDM, the person certified in sampling shall monitor the dust concentrations and the sampling status conditions being reported by the sampling device at mid-shift or more frequently as specified in the approved respirable dust control plan, if applicable, to assure: The sampling device is in the proper location and operating properly; and the work environment of the Part 90 miner being sampled remains in compliance with the standard at the end of the shift. This monitoring is not required if the sampling device is being operated in an anthracite coal mine using the full box, open breast, or slant breast mining method.

37. Amend § 90.206 by revising paragraphs (b) and (c) to read as follows:

§ 90.206 Exercise of option or transfer sampling.

*****

(b) Noncompliance with the standard shall be determined in accordance with § 90.207(d).

(c) Upon issuance of a citation for a violation of the standard, the operator shall comply with § 90.207(f).

38. Amend § 90.207 by:

a. Removing and reserving paragraph (b);

b. Revising paragraphs (c) introductory text, (c)(2), (d), (e), (f) introductory text, (f)(2) introductory text, (f)(2)(ii), and (g);

c. Removing tables 90-1 and 90-2; and

d. Adding table 1.

The revisions and addition read as follows:

§ 90.207 Quarterly sampling.

*****

(c) When a valid representative sample taken in accordance with this section meets or exceeds the ECV in table 1 to this section corresponding to the particular sampling device used, the mine operator shall:

*****

(2) Immediately take corrective action to lower the concentration of respirable coal mine dust to below the standard; and

*****

(d) Noncompliance with the standard is demonstrated during the sampling period when:

(1) Two or more valid representative samples meet or exceed the ECV in table 1 to this section that corresponds to the particular sampling device used; or

(2) The average for all valid representative samples meets or exceeds the ECV in table 1 to this section that corresponds to the particular sampling device used.

(e) Unless otherwise directed by the District Manager, upon issuance of a citation for a violation of the standard, paragraph (a) of this section shall not apply to that Part 90 miner until the violation is abated and the citation is terminated in accordance with paragraphs (f) and (g) of this section.

(f) Upon issuance of a citation for a violation of the standard, the operator shall take the following actions sequentially:

*****

(2) Immediately take corrective action to lower the concentration of respirable dust to below the standard. If the corrective action involves:

*****

(ii) Transferring the Part 90 miner to another work position at the mine to meet the standard, the operator shall comply with § 90.102 and then sample the affected miner in accordance with § 90.206(a).

*****

(g) A citation for a violation of the standard shall be terminated by MSHA when the equivalent concentration of each of the five valid representative samples is below the standard.

Table 1 to § 90.207 - Excessive Concentration Values (ECV) based on a Single Sample, Two Samples, or the Average of Five Full-Shift CMDPSU/CPDM Concentration Measurements.			
Section	**Samples**	**ECV (mg/m^3)**	
		CMDPSU	**CPDM**
90.207(c)	Single sample	0.74	0.57
90.207(d)(1)	2 or more samples	0.74	0.57
90.207(d)(2)	5 sample average	0.61	0.53
90.207(g)	Each of 5 samples	0.74	0.57

Subpart D-Respirable Dust Control Plans

39. Amend § 90.300 by revising paragraphs (a) and (b)(3) to read as follows:

§ 90.300 Respirable dust control plan; filing requirements.

(a) If an operator abates a violation of the standard by reducing the respirable dust level in the position of the Part 90 miner, the operator shall submit to the District Manager for approval a written respirable dust control plan for the Part 90 miner in the position identified in the citation within 15 calendar days after the citation is terminated. The respirable dust control plan and revisions thereof shall be suitable to the conditions and the mining system of the coal mine and shall be adequate to continuously maintain respirable dust below the standard for that Part 90 miner.

(b) ***

(3) A detailed description of how each of the respirable dust control measures used to continuously maintain concentrations of respirable coal mine dust below the standard; and

*****

40. Amend § 90.301 by revising paragraphs (a)(1) and (b) to read as follows:

§ 90.301 Respirable dust control plan; approval by District Manager; copy to part 90 miner.

(a) ***

(1) The respirable dust control measures would be likely to maintain concentrations of respirable coal mine dust below the standard; and

*****

(b) MSHA may take respirable dust samples to determine whether the respirable dust control measures in the operator's plan effectively maintain concentrations of respirable coal mine dust below the standard.

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