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The Honorable Christopher J. Williamson
Assistant Secretary of Labor for Mine Safety and Health
Mine Safety and Health Administration
U.S. Department of Labor
201 12th St South, Suite 401
Arlington, VA 22202-5450

RE: Comments on Proposed “Lowering Miners’ Exposure to Respirable Crystalline Silica and Improving Respiratory Protection” (Respirable Crystalline Silica) Rule [Docket No. MSHA-2023-0001] (RIN 1219-AB36)

Dear Assistant Secretary Williamson,

The American College of Occupational and Environmental Medicine ([ACOEM](https://www.acoem.org)) appreciates this opportunity to comment upon the Mine Safety and Health Administration’s (MSHA) proposed rule, *Lowering Miners’ Exposure to Respirable Crystalline Silica and Improving Respiratory Protection* (Respirable Crystalline Silica).¹ Founded in 1916, ACOEM is the nation’s largest medical society dedicated to promoting employee health through preventive medicine, clinical care, research, and education. The College represents Occupational and Environmental Medicine (OEM) physicians and other healthcare professionals devoted to preventing and managing occupational injuries and exposures.

ACOEM strongly supports MSHA’s proposed standard to expand protections against silica exposure to all miners in surface and underground metal and non-metal mines. ACOEM applauds the outstanding background health information and the risk assessment provided in the MSHA document and would like to highlight some of the information already provided:

- While the proposed PEL of 50 mcg/M3 is a significant improvement, MSHA’s risk assessment demonstrates that it allows continued mortality risks from silicosis, lung cancer, and other disease outcomes higher than the 1 in 1000 lifetime risk established by the Supreme Court. The details on the likely residual risk, even at the improved PEL (50 mcg/cu m), are nicely tabulated in Table VI-6 on page 151, and even with this improved PEL, MNM miners will still face an excess mortality risk of about 1/800 after a working lifetime, of which about a third is excess cancer risk. Technical challenges in measurement and dust control may preclude a lower PEL, but OSHA has considered technology-forcing in the past for its cotton dust standard, and MSHA may wish to consider that. At a minimum, it should recognize the need to revisit the PEL in the future.
- The proposal recognizes the importance of lung cancer in its risk assessment. Significant information supporting the use of low-dose CT scans to improve mortality through early detection has been modified for working populations and should be included.

¹ 89 Fed. Reg. 44852 (July 13, 2023).

ACOEM provides additional comments through responses to the specific questions listed by MSHA:

Health Effects

1) 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.

ACOEM applauds MSHA's helpful review of the medical and epidemiologic literature on the health effects of silica exposure. Since OSHA's comprehensive summary of the medical literature in its preamble to the 2016 revisions to the silica standard, there has been an explosion of new information about the molecular basis for silica's adverse effects,² including information about the metabolic pathways responsible for fibrosis and myelofibrosis.^{3,4,5} We have also seen much more refined methods for studying the effects of inhaled respirable crystalline silica in animal models,^{6,7,8} with important implications for risk assessment, dust control, respirator selection, and management of early manifestations of silicosis,⁹ including possible risk factors for progressive massive fibrosis.¹⁰ All of these findings highlight the hazards posed by respirable silica. ACOEM stresses that this new information only adds to the urgency of establishing and enforcing the proposed standard.

² Wei Wang, Yuhui Yu, Shuangshuang Wu, Lingli Sang, Xiaohui Wang, Anni Qiu, Xiaoqiao Yu, Jingzhi Li, Lu Zhang, Min Yi, Huiting Zheng, Yuexia Gao, Jing Xiao, Yihua Lu, Liying Jiang, Yulong Lian, Xun Zhuang, Tian Tian, Minjie Chu (2018). The rs2609255 polymorphism in the FAM13A gene is reproducibly associated with silicosis susceptibility in a Chinese population. *Gene* 661: 196-201.

Marco Chilosi, Venerino Poletti, Alberto Zamò, Maurizio Lestani, Licia Montagna, Paola Piccoli, Serena Pedron, Manuela Bertaso, Aldo Scarpa, Bruno Murer, Alessandra Cancellieri, Roberta Maestro, Gianpietro Semenzato, Claudio Doglioni (2003). Aberrant Wnt/ β -Catenin Pathway Activation in Idiopathic Pulmonary Fibrosis. *Am J Pathology* 162:1495-1502.

³ Chanda D, Otoupalova E, Smith SR, Volckaert T, De Langhe SP, Thannickal VJ. (2019). Developmental pathways in the pathogenesis of lung fibrosis. *Mol Asp Med* 65:56–69.

⁴ Feng F, Li N, Cheng P, Zhang H, Wang H, Wang Y, et al. Tanshinone IIA attenuates silica-induced pulmonary fibrosis via inhibition of TGF- β 1-Smad signaling pathway. *Biomed Pharmacother*. 2020;121:109586.

⁵ Wu Q, Jiao B, Gui W, Zhang Q, Wang F, Han L. Long non-coding RNA SNHG1 promotes fibroblast-to-myofibroblast transition during the development of pulmonary fibrosis induced by silica particles exposure. *Ecotoxicol Environ Saf*. 2021;228:112938.

⁶ Chen, J, Yao, Y, Su, X, et al. Comparative RNA-Seq transcriptome analysis on silica induced pulmonary inflammation and fibrosis in mice silicosis model. *J Appl Toxicol*. 2018; 38: 773–782.

⁷ Juan LI, Wu YAO, Jian Yong HOU, Lin ZHANG, Lei BAO, Hui Ting CHEN, Di WANG, Zhong Zheng YUE, Yi Ping LI, Miao ZHANG, Xing Hao YU, Jian Hui ZHANG, Ya Qian QU, Chang Fu HAO (2018). The Role of Fibrocyte in the Pathogenesis of Silicosis, *Biomedical and Environmental Sciences*. 31: 311-6.

⁸ Zhuji Cao, Meiyue Song, Ying Liu, Junling Pang, Zhaoguo Li, Xianmei Qi, Ting Shu, Baicun Li, Dong Wei, Jingyu Chen, Bolun Li, Jing Wang, Chen Wang (2020). A novel pathophysiological classification of silicosis models provides some new insights into the progression of the disease. *Ecotoxicology and Environmental Safety*. 202:110834

⁹ Multiple studies; see, for example: Peruzzi, CP et al. (2022). Occupational exposure to crystalline silica and peripheral biomarkers: An update. *Journal of Applied Toxicology*, 42(1):87–102.

Guo J, Yang Z, Jia Q, Bo C, Shao H, Zhang Z. Pirfenidone inhibits epithelial-mesenchymal transition and pulmonary fibrosis in the rat silicosis model. *Toxicol Lett*. 2019;300:59–66.

Jia, Yangmin, et al. (2022). "Chinese medicinal plant *Polygonum cuspidatum* ameliorates silicosis via suppressing the Wnt/ β -catenin pathway" *Open Chemistry* 20: 1601-1611.

Huang H, Chen M, Liu F, Wu H, Wang J, Chen J, et al. (2019). N-acetylcysteine therapeutically protects against pulmonary fibrosis in a mouse model of silicosis. *Biosci Rep*. 39(7):BSR20190681

Pang X, Shao L, Nie X, Yan H, Li C, Yeo AJ, et al. (2021). Emodin attenuates silica-induced lung injury by inhibition of inflammation, apoptosis and epithelial-mesenchymal transition. *Int Immunopharmacol*. 91:107277.

Yang T et al. (2016) Emodin suppresses silica-induced lung fibrosis by promoting Sirt1 signaling via direct contact. *Mol Med Rep*. 14(5):4643–9.

¹⁰ Wang W, et al., (2018). The rs2609255 polymorphism in the FAM13A gene is reproducibly associated with silicosis susceptibility in a Chinese population. *Gene* 661: 196-201.

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.

ACOEM recommends a very broad scope – any mine where exposure to respiratory crystalline silica above the Action Level is anticipated for 10 or more days per year, consistent with the OSHA silica standards.

Proposed Permissible Exposure Limit

13) MSHA seeks the views and recommendations of stakeholders on the proposed PEL (50 µg/m³ for a full-shift exposure, calculated as an 8-hour TWA). 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.

As noted above, ACOEM endorses the proposed PEL as a temporary measure given current technological constraints but urges lowering the PEL to the proposed Action Level (25 µg/m³) in the future.

14) MSHA is proposing a PEL of 50 ug/m³ and an action level of 25 µg/m³ for respirable crystalline silica exposure. Which proposed requirements should be triggered by exposure at, above, or below the proposed action level?

ACOEM endorses ALL standard safety measures when exposures exceed the Action Level (training, housekeeping, record-keeping, medical surveillance), and endorses the use of the hierarchy of controls (all feasible engineering and administrative controls – except job rotation—plus respirators with standard Assigned Protection Factors (APF) for exposures over the Action Level).

Methods of Compliance

15) MSHA requests comments on the proposed prohibition against rotation of miners as an administrative control.

ACOEM strongly endorses this prohibition.

16) MSHA requests comments on the proposed requirement that mine operators must install, use, and maintain feasible engineering and administrative controls to keep miners' 18 exposures to respirable crystalline silica below the proposed PEL.

ACOEM strongly endorses the standard hierarchy of controls.

Proposed Exposure Monitoring

19) 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.

Given the increased vulnerability of temporary workers, ACOEM strongly opposes any reduction in protections for this population.

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.

ACOEM strongly endorses this requirement, as well as continuing to require repeat representative air sampling whenever there is a change in work process that might affect exposure levels.

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.

ACOEM does NOT support this waiver, given the variability inherent in mining.

Proposed Medical Surveillance for Metal and Nonmetal Miners

32) MSHA is proposing to require medical surveillance for MNM (metal and non-metal) 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?

ACOEM strongly endorses medical surveillance for any worker whose silica exposures exceed the Action Level and recommends the initial follow-up examination take place within 18 months with periodic examinations every 3 years after that. Operators should be required to offer the examinations to miners at no cost.

33) 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. Should the plan requirements

be extended to MNM operators? 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.

ACOEM recognizes the importance of quality control, which NIOSH approval provides. However, if this requirement creates a bottleneck for implementation, ACOEM would instead recommend requiring employers to contract with qualified "supervising" physicians for these exams, with the requirement that the supervising physician be board certified in pulmonary disease or occupational medicine, or another American Board of Medical Specialties (ABMS) discipline with the requisite experience in silica surveillance. Any worker with findings suggestive of silicosis should be referred for evaluation by a physician with specific expertise in diagnosis of pneumoconioses as defined by board certification in pulmonary disease, occupational medicine, or documented equivalence. Findings include ILO $\geq 0/1$, abnormal spirometry, or dyspnea.

At present, we are concerned that there is an inadequate supply and geographic maldistribution of NIOSH-approved facilities for medical examinations.

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.

Although still necessary for medical surveillance, recent studies about the inter-rater reliability of B-readings^{11,12} and other studies of advancing silicosis have found that chest x-rays and spirograms alone, even when accompanied by a thorough history and physical, are very insensitive in detecting even moderate levels of silicosis.¹³ ACOEM strongly recommends use of low-dose CT (LDCT) scans for workers with suspected silicosis. We recommend that workers with at least 3 to 5 years of silica exposure who have a suggestive pattern of lung symptoms (cough and decreased exercise tolerance) combined with suspicious findings on chest-ray or spirometry, should be offered LDCT, at the discretion of the examining physician.

ACOEM further recommends offering referral at no cost to workers aged 50 or older who have at least 20 years of exposure and any current or previous smoking deemed

¹¹ Halldin CN, Petsonk EL, Laney AS. Validation of the International Labour Office Digitized Standard Images for Recognition and Classification of Radiographs of Pneumoconiosis. *Academic radiology*. 2014;21(3):305-311.

¹² Muller JG et al (2008). Variability in Interpretation among B-Readers in the U.S. Navy Asbestos Medical Surveillance Program, *Military Medicine*, Volume 173: 375-380.

¹³ Hoy RF, Dimitriadis C, Abramson M, et al. (2023). Prevalence and risk factors for silicosis among a large cohort of stone benchtop industry workers. *Occupational and Environmental Medicine* 80:439-446.

significant by a physician to centers experienced in the use of LDCT for lung cancer screening.¹⁴

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.

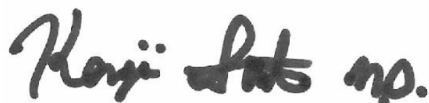
With high levels of exposure, acute and accelerated silicosis can occur well within five years of exposure.¹⁵ ACOEM recommends a second exam within 18 months of the baseline exam as a fail-safe for underperforming mines. After that, subsequent exams should take place every three years or at the discretion of the examining physician. Persons known to have silicosis (B-read 1/0 or worse, or significant findings on LDCT) should have a follow-up exam at least annually.

Conclusion

ACOEM is prepared and willing to work with MSHA to develop and implement this proposed rule. This action by MSHA is timely and necessary, as there is no question that increasing numbers of miners, particularly young miners, are suffering and dying of severe lung disease due to their work in the mines. Both the causes of and solutions to this epidemic are known. It is time for MSHA to fulfill its mission to ensure safe, healthful workplaces for U.S. miners and prevent needless illness and deaths.

On behalf of ACOEM, I would like to reiterate our support for the proposed rule and thank you for your leadership on this critical issue. Please do not hesitate to contact Dane Farrell (Dane@cascadeassociates.net), ACOEM's Government Affairs Representative, with any questions.

Sincerely,



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President

American College of Occupational and Environmental Medicine (ACOEM)

¹⁴ Welch LS, Dement JM, Cranford K, et al. Early detection of lung cancer in a population at high risk due to occupation and smoking. *Occup Environ Med.* 2019;76(3):137-142. doi:10.1136/oemed-2018-105431

¹⁵ Nowak-Pasternak J, Lipińska-Ojrzanowska A, Świątkowska B. Silicosis after short-term exposure. *Occup Med (Lond).* 2023;73(1):33-35. doi:10.1093/occmed/kqac113