AMERICAN PUBLIC HEALTH ASSOCIATION
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January 27, 2013

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Occupational Safety and Health
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

SUBMITTED VIA: Regulations.gov

SUBJECT: Occupational Safety and Health Administration (OSHA)
Docket #: OSHA-2010-0034
Occupational Exposure to Respirable Silica

Dear Dr. Michaels:

I write on behalf of the American Public Health Association, a diverse community of public health professionals who champion the health of all people and communities, to express our strong support for OSHA's proposal to protect silica-exposed workers. APHA has long called on OSHA to prevent silica-related disease by adopting the exposure limits recommended by the National Institute for Occupational Safety and Health; requiring exposure and medical monitoring, including surveillance for tuberculosis; and restricting the use of silica for abrasive blasting.[1] We are pleased that we now have the opportunity to provide comments on this important proposed rule. The following will also form the basis of our testimony for the public hearing scheduled to begin in March.

Health Effects and Significance of Risk

APHA recognizes that OSHA has thoroughly reviewed and evaluated the peer-reviewed literature on the health effects associated with exposure to respirable crystalline silica. OSHA's quantitative risk assessment is sound. The agency has relied on the best available evidence and acted appropriately in giving greater weight to those studies with the most robust designs and statistical analyses.

In an appendix to this letter, we point to a number of additional papers that have been published in the peer-reviewed literature since OSHA's "Review of Health Effects Literature and Preliminary Quantitative Risk Assessment" was completed. These studies add to the evidence on the adverse health effects associated with respirable silica exposure, as already demonstrated by OSHA's risk assessment.

[1] American Public Health Association, Prevention of Silicosis, policy statement 9512, adopted 1995.

Risk Assessment

APHA concurs with OSHA's assessment of the scientific evidence and its conclusion that exposure to respirable crystalline silica at the current permissible exposure limit is associated with malignant and non-malignant respiratory disease, as well as renal disease. We note with concern, however, the evidence from OSHA's risk assessment that workers exposed to the proposed permissible exposure limit of 50 ug/m^3 will continue to face a significant risk of disease. This lifetime excess risk of disease includes six, to as many as 26, deaths per 1,000 from lung cancer; 32 deaths per 1,000 from renal disease; and as many as 43 deaths per 1,000 from non-malignant respiratory disease. Given the substantial excess risk that will exist after a 50 ug/m^3 PEL is implemented, secondary means to protect workers' health are clearly warranted. Our recommendations are offered below.

Permissible Exposure Limit (1910.1053 (c) / 1926.1053(c))

We support OSHA's decision to establish a new, more protective permissible exposure limit of 50 ug/m^3. OSHA's risk assessment indicates that a lower PEL is warranted. We note that the 50 ug/m^3 level was recommended in 1974 by the National Institute for Occupational Safety and Health, and that the American Thoracic Society, the American College of Occupational and Environmental Medicine, and the Association of Environmental and Occupational Clinics support it as well.

Action Level (1910.1053(b) / 1926.1053(b))

An OSHA standard to protect silica-exposed workers can be considered a form of primary prevention. That is, its goal is to prevent workers from developing silica-related disease. To the extent a protective PEL is determined not to be feasible, strong secondary prevention measures are vitally important. Secondary prevention measures, such as exposure monitoring and surveillance, do not prevent disease, but may allow for early detection and medical intervention to limit or eliminate progression.

We concur with OSHA's proposal for exposure monitoring requirements when silica exposures are at or above an action level of 25 ug/m^3. We recommend, however, that for workers employed in general industry, exposure to silica that exceeds the AL for 30 or more days a year should trigger the rule's medical surveillance provisions. Given the excess risk of disease for workers exposed at (and even below) the AL, this secondary prevention measure is appropriate and necessary, and is consistent with other OSHA health standard (e.g., lead, chromium, cadmium, methylene chloride) in which medical surveillance requirements are triggered by exposures above the AL.

Regulated Areas (1910.1053(e) / 1926.1053(e))

OSHA's rule should include a requirement for the employer to post a warning sign at each regulated area. This requirement would be consistent with OSHA's other health standards that address toxic substances. The warning sign should include, at a minimum, the following information (in languages appropriate for all workers at the worksite):

DANGER
SILICA DUST
CAUSES DAMAGE TO LUNGS

CARCINOGEN: MAY CAUSE LUNG CANCER
AUTHORIZED PERSONNEL ONLY

When applicable, the warning sign should note that respiratory protection and protective clothing are required.

Methods to Control Respirable Silica (1926.1053(f)(2))

In the proposed standard for the construction industry, we recommend a modification to Table 1, "Exposure Control Methods for Selected Construction Operations." OSHA should modify the rule to indicate that Table 1 will be amended periodically (e.g., every five years) to reflect improvements in control technology. New dust control technology could be evaluated by NIOSH, and if deemed by NIOSH to be effective and feasible, OSHA would publish a direct final rule to adopt a revised Table 1. As Ashford and colleagues wrote, new regulation can spur market innovation.[2]

In addition, and with respect to Question 63 (at page FR 56290), we urge OSHA to prohibit the use of silica sand for abrasive blasting. In 1992, NIOSH issued a Hazard Alert with the notation: "WARNING! Abrasive blasting with sands containing crystalline silica can cause serious or fatal respiratory disease."[3] In the document, NIOSH recommends: "Prohibit silica sand (or other substances containing more than 1% crystalline silica) as an abrasive blasting material and substitute less hazardous materials." Safer alternatives to silica sand are feasible and available. OSHA's website lists more than 25 alternatives to silica sand for abrasive blasting.[4] We refer OSHA to the rulemaking petition it received in April 2009 calling for a prohibition on the use of silica in abrasive blasting.[5] The petition offers the following information:

> "Many countries have banned the use of silica sand in abrasive blasting including Great Britain (in 1949), Germany, Sweden and Belgium. These industrialized nations have demonstrated that the abrasive blasting process can be carried on effectively without the use of sand. The U.S. Navy, the Air Force, the U.S. Coast Guard, and twenty-three state Departments of Transportation have banned the use of silica in abrasive blasting."

Hierarchy of Controls to Protect Silica-Exposed Workers

We support the long-standing public health policy on the primacy of engineering controls to address occupational hazards. Requiring employers to follow the hierarchy of controls is the most effective way to protect workers from silica exposure.

We strongly disagree with commenters who insist OSHA should allow the use of respirators to protect silica-exposed workers. These commenters fail to recognize or acknowledge the reasons

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[2] Ashford NA, Ayers C, Stone RF. Using regulation to change the market for innovation. Harvard Environmental Law Review. Summer 1985, 419-466.
[3] U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health. Preventing Silicosis and Deaths From Sandblasting, Publication Number 92-102, 1992.
[4] OSHA. Taking Action to Prevent Against Silica. https://www.osha.gov/dsg/etools/silica/protect_against/protect_against.html.
[5] International Safety Equipment Association and Risk and Insurance Management Society. Petition for Expedited Rulemaking to Amend Regulations at 29 CFR 1910.94, April 28, 2009. Available at: http://www.safetyequipment.org/userfiles/File/SilicaPetition.pdf.

respirators are unreliable as the first line of defense for respirable silica. These factors include special responsibilities for employers, such as: (1) ensuring that the respirators are individually selected and fitted for each worker; (2) ensuring workers who wear respirators are refitted periodically; (3) ensuring that respirators are worn properly each and every time; and (4) ensuring respirators are maintained precisely as directed by the manufacturer, and replaced accordingly. Moreover, if employers fail to provide the required medical examinations to assess workers' fitness to wear respiratory protection, workers are at risk of suffering harm. We agree with OSHA that in too many workplaces, employers are unable to diligently and consistently meet these requirements.

In addition, workers offer their own reasons why respirators should not be the primary means of protection from silica dust. They report that (1) it is difficult to breathe, especially when engaged in heavy physical labor, while wearing a respirator; (2) wearing a respirator, instead of controlling the dust at its source, means co-workers in close proximity are still exposed to silica dust; (3) respirators are uncomfortable to wear, especially when working in a hot environment; and (4) it is difficult to communicate with co-workers when wearing a respirator, which can compromise safety.

Outreach

With respect to Question 23 (at page FR 56287), we agree it is important for OSHA to develop and make available materials to employers on the provisions of the standards. In addition, the materials should indicate that retaliating against a worker for asking questions or raising concerns about silica exposure is a prohibited practice.

We urge OSHA to develop materials written specifically for workers who are exposed or potentially exposed to respirable silica. The materials should (1) explain the health effects of silica exposure; (2) explain provisions of the rule in terms of what their employers are required to do, including requirements for training; and (3) describe measures workers could take if their employers are failing to comply with the rule.

Medical Surveillance (1910.1053(h) / 1926.1053 (h))

We agree with the majority of the medical surveillance requirements and find the addition of the non-mandatory Appendix A to be particularly helpful. We recommend that OSHA's provisions for medical surveillance should be amended in the following ways:

Based on OSHA's risk assessment and on the additional information published since OSHA's thorough review of health outcomes, APHA strongly recommends requiring medical surveillance for workers exposed at or above the action level.

With respect to specific questions raised by OSHA, while we agree that it is appropriate to accept a previously conducted medical surveillance examination as the baseline examination, the examination should have been conducted within one year of hire (not three years).
To provide a robust baseline and to strengthen opportunities for reviewing exposures and health outcomes, the initial follow-up examination should be conducted within 12 – 18 months of the baseline, to include pulmonary function testing and clinician examination. The potential hazard to the worker from frequent x-ray examinations is radiation, and it is appropriate to reduce this risk by eliminating radiographic examination from periodic examinations occurring less than

three years from the accepted baseline. However, medical examinations should provide a fail-safe mechanism to identify disease in the event that exposure control has failed.

As OSHA notes, very high levels of respirable silica exposure may result in acute silicosis, a rapidly progressive disease that can cause death well before a three year follow up examination.[6] Although implementation of the standard is expected to eliminate this outcome, decades of experience with other OSHA standards, such as the lead standard, demonstrate that excessive exposures may nevertheless occur if employers fail to comply with the rule. The public health goal of medical surveillance is to identify instances in which exposures have produced early adverse outcomes with the explicit goal of providing the feedback loop to identify and remediate problems with exposure. Physical examination and spirometric pulmonary function testing are safe, provide the worker with the opportunity to discuss symptoms and work practices with clinicians, and should allow clinicians to identify instances of high-level overexposure. In the event the clinician identifies signs or symptoms of concern, radiographic testing can be ordered. The reduced interval for the first follow-up examination also gives the worker an additional opportunity to discuss any concerns about exposures, symptoms, or respirator use.

Subsequent to the first follow-up examination, the proposed periodicity of three years is appropriate, with the clarification that workers are able to request to see a clinician if there is a concern about shortness of breath, excessive exposure levels, or ability to use respiratory protection.

With respect to the definition of a physician or other licensed health care professional, deletion of the phrase "or be delegated the responsibility to provide" would clarify that the responsible clinician should be licensed for independent practice. We believe that the PLHCP should have training and experience in clinical and in population/preventive health, in managing and interpreting group surveillance information, and in the care and management of respiratory illness. It should be noted that different members of the health team may provide different required services through referral or other arrangements, but that the designated PLHCP should have responsibility for program oversight and coordination.

A PLHCP's written opinion should only be provided to the employee, not the employer. The employee's health record must be considered confidential. The employee must have the right to determine when, or if, to share the PLHCP's written opinion with his or her employer. The only health information that a PLHCP should report to an employer concerns the employee's fitness to wear a respirator.

The baseline testing requirement for latent tuberculosis is appropriate. If skin testing is conducted, two-step testing should be performed with the second test performed approximately a week following the initial test to identify latent TB. The risks posed by silica exposure for potential reactivation of even remotely acquired latent tuberculosis or atypical mycobacterial infections should warrant referral for evaluation for both initial and "boosted" positive results. As noted in the non-mandatory medical appendix, the presence of radiographic evidence of silicosis may warrant periodic TB testing as well as appropriate referral for the management of positive results. Appropriate referral should include public health as well as respiratory and/or infectious disease expertise.

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[6] Marchiori E, Souza CA, et al. Silicoproteinosis: high-resolution CT findings in 13 patients. AJR Am J Roentgenol, 189 (2007), pp. 1402–1406.

The recommendations of the U.S. Preventive Services Task Force for screening individuals at high risk of lung cancer have recently been released and are available at http://www.uspreventiveservicestaskforce.org/uspstf/uspslung.htm. We recommend that OSHA reserve the ability to require lung cancer screening pending the formal adaptation of this recommendation to specify relevant levels and duration of silica exposure and other carcinogens. Programs involving radiographic testing should target only the relatively few workers reaching appropriate risk levels and should use appropriate protocols, quality control mechanisms, and low-dose radiation exposure equipment to minimize the potential for adverse effects from screening. Workers should have the ability to opt out of screening after signing declination forms following individual clinical counseling.

We believe the use of "equivalent diagnostic studies" (CT or HRCT) for routine medical surveillance should be discouraged both because of cost and because of the radiation exposure involved. However, the examining clinician should be able to obtain such studies for diagnostic purposes, in which case the study should be accepted in lieu of obtaining an additional chest x-ray that would not add to the clinical information. As discussed above, the standard of care now includes low-dose CT scans for lung cancer surveillance for high-risk populations, and this recommendation should be adapted for workers with long-duration, high-dose silica exposure.

Medical Removal Protection

OSHA's final silica standard for general industry and shipyards must include provisions for medical removal protection for workers who have evidence of respiratory disease. Workers should have the right to be transferred to a less dusty job (i.e., a job in the same workplace with exposures below the AL) at no loss of pay, consistent with the Federal Coal Mine Health and Safety Act of 1969 and NIOSH regulations at 42 CFR 37.7. Workers would be able to exercise this right at a time of their choosing by providing the employer with a written medical determination of silica-related impairment by a PLHCP. OSHA should explicitly state in the regulatory text that discriminating against a worker for exercising this right is a prohibited practice and will be deemed a violation of the standard.

We appreciated the opportunity to provide comments on this vitally important proposed occupational health standard. We wish to reserve the right to elaborate or amend our comments during the post-hearing comment period.

Sincerely,

Georges Benjamin, MD
Executive Director

Appendix to Comments submitted by
The American Public Health Association

The following are papers published in the peer-reviewed literature in the time period following completion of OSHA's preliminary "Review of Health Effects Literature and Preliminary Quantitative Risk Assessment."

Silicosis, Chronic Obstructive Pulmonary Disease, Cardiovascular Disease

Pérez-Alonso A, Córdoba-Doña JA, et al. Outbreak of silicosis in Spanish quartz conglomerate workers. Int J Occup Environ Med. 20154;20(1):26–32.

A study investigating an outbreak of silicosis among workers involved in the manufacture, finishing, and installation of quartz conglomerate countertops, used mainly in kitchens. Three sentinel cases from the industry were identified in 2009. A subsequent investigation of about 200 exposed workers from 12 small businesses identified a total of 46 cases of silicosis. The median age of the workers with silicosis was 33 years.

Dumavibhat N, Matsui T, Hoshino E, et al. Radiographic progression of silicosis among Japanese tunnel workers in Kochi. J Occup Health. 2013;55(3):142-8.

A retrospective cohort study investigating the radiographic progression of silicosis among 65 tunnel workers. The authors report that 86 percent of the workers, who had no further silica exposure, experienced a progression of disease from a category 1 or 2 to a category 4 in a mean of less than 15 years, controlling for smoking and age.

Möhner M, Kersten N, Gellissen J. Chronic obstructive pulmonary disease and longitudinal changes in pulmonary function due to occupational exposure to respirable quartz. Occup Environ Med. 2013 Jan;70(1):9-14.

A cohort study among uranium miners examining the effects of long-term exposure to respirable silica and loss of pulmonary function as well as development of chronic obstructive pulmonary disease (COPD). The authors report: significant longitudinal reductions in FEV_1 and FEV_1/FVC ratio with silica exposure among smokers and nonsmokers; and, the risk for COPD stage I increases (OR 1.81 per 100 ug/m^3) with each year of cumulative exposure to respirable silica.

Kramer MR, Blanc PD, Fireman E, et al. Artificial stone silicosis: disease resurgence among artificial stone workers. Chest. 2012 Aug;142(2):419-24.

This study examined the work history of 25 patients with silicosis referred between 1997 and 2010 to a clinic for possible lung transplants. All of the patients were exposed to respirable silica through dry cutting of artificial, decorative stone product containing silica and used for kitchen countertops and bathroom fixtures. The authors report 0.68 cases of silicosis would have been expected in the clinic's registry, but 10 cases were observed (IR= 14.6; 95% CI, 7.02-26.8).

Chen W, Liu Y, Wang H, et al. Long-term exposure to silica dust and risk of total and cause-specific mortality in Chinese workers: a cohort study. PLoS Med. 2012;9(4):e1001206.

The study examined the mortality of 74,040 individuals exposed to silica in metal mining and pottery making. Among workers exposed to respirable silica concentrations equal to or lower than 100 ug/m^3, elevated standardized mortality ratios were observed for ischemic heart disease (1.65, 1.35-1.99) and pneumoconiosis (11.01, 7.67-14.95), controlling for smoking and other potential confounders.

Lung Cancer

Kachuri L, Villeneuve PJ, Parent ME, et al. Occupational exposure to crystalline silica and the risk of lung cancer in Canadian men. Int J Cancer. 2013 Nov 22. doi: 10.1002/ijc.28629.

This study investigated the relationship between silica exposure and lung cancer and the combined effects of cigarette smoking and silica exposure on lung cancer risk. The authors report that an increasing duration of silica exposure at any concentration was associated with a significant trend in lung cancer risk, relative to those unexposed to silica dust. They indicate their findings concur with previous research on lung cancer risk associated with silica exposure, independent from smoking and exposure to diesel emissions.

Autoimmune Disorders

Gómez-Puerta JA, Gedmintas L, Costenbader KH. The association between silica exposure and development of ANCA-associated vasculitis: systematic review and meta-analysis. Autoimmun Rev. 2013 Oct;12(12):1129-35.

This paper offers a review of the literature and a meta-analysis on silica exposure and anti-neutrophil cytoplasmic antibody-associated vasculitis (AAV). The authors and report that while there was moderate heterogeneity among the studies reviewed, there was still adequate evidence to conclude that silica exposure was associated with more than two times higher risk for developing AAV.

Miller FW, Alfredsson L, Costenbader KH, et al. Epidemiology of environmental exposures and human autoimmune diseases: findings from a National Institute of Environmental Health Sciences Expert Panel Workshop. J Autoimmun. 2012 Dec;39(4):259-71.

An expert panel convened by the National Institute of Environmental Health Sciences conducted a literature review on the role of certain environmental exposures and autoimmune disorders. The authors report a consensus on the positive association of silica exposure and autoimmune disease.

Makol A, Reilly MJ, Rosenman KD. Prevalence of connective tissue disease in silicosis (1985-2006) – a report from the state of Michigan surveillance system for silicosis. Am J Ind Med. 2011 Apr;54(4):255-62.

An analysis of 790 medical records of patients with silicosis from the State of Michigan was conducted to assess the presence of connective tissue disease. The authors report a two- to eight-fold risk for rheumatoid arthritis and systemic lupus erythematosus, and a greater than 24-fold risk for scleroderma and anti-neutrophil cytoplasmic antibody-associated vasculitis.

Chronic Kidney Disease

Vupputuri S, Parks CG, Nylander-French LA, et al. Occupational silica exposure and chronic kidney disease. Ren Fail. 2012;34(1):40-6.

The case-control study examined the association between silica exposure and chronic kidney disease (CKD). The authors report a statistically significant exposure-response association of increasing CKD risk with increasing duration of silica exposure (OR=1.37, 95% CI: 1.02, 1.85).