AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE

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ACOEM Comments on Proposed OSHA Silica Rule

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Docket No. OSHA-2010-0034
U.S. Department of Labor
Room N-2625
200 Constitution Avenue, NW
Washington, DC 20210

To Whom It May Concern:

The American College of Occupational and Environmental Medicine (ACOEM) welcomes the opportunity to comment on the Notice of Proposed Rulemaking — Occupational Exposure to Respirable Crystalline Silica. These comments were prepared by an ACOEM Presidential Task Force on the proposed rule and include input from the ACOEM Board of Directors and other ACOEM members.

BACKGROUND AND GENERAL COMMENTS

The American College of Occupational and Environmental Medicine (ACOEM) applauds the renewed efforts of the U.S. Occupational Safety and Health Administration (OSHA) to revise the standard for exposure to crystalline silica and to improve protection for workers in the many industries where silica is a hazard. ACOEM recognizes that the proposed revision of the permissible exposure limit (PEL) represents an important step forward in achieving adequate protection for silica-exposed workers, while observing that conformance to the proposed standard will not eliminate the risk of silica-related disease.

ACOEM fully supports the adoption and implementation of OSHA's proposed silica standard as an important measure for protecting working men and women in this country, one which should reduce the occurrence of lung disease, cancer, other illnesses, and deaths related to silica exposure. The proposed standard is well documented and clear and should serve as a model for future OSHA standards. The medical surveillance requirements likewise reflect thoughtful deliberation and, for the most part, are appropriate and in accord with good practice in occupational medicine. In particular, ACOEM recognizes and applauds each of the following:

• The thoroughness of the OSHA health effects literature review and risk assessment;

• The inclusion of the nonmandatory appendix (Appendix A, Medical Surveillance Guidelines) as an important measure to assist the evaluating clinician in the appropriate implementation of the medical surveillance portion of the standard. We concur with OSHA's objective for this guideline document, which is to ensure that the medical surveillance examinations are performed using established and defined procedures that should lead to accurate, consistent, and timely health monitoring while, at the same time, providing clinicians with adequate flexibility to tailor approaches to specific circumstances.

• The acknowledgment by OSHA that, while the proposed PEL will result in a substantial reduction in mortality and morbidity from silica-associated illnesses compared to the current PEL, material impairment to health nevertheless will occur at levels of exposure below the proposed PEL.

• The newly included requirement for baseline testing for latent tuberculosis infection (LTBI) as part of medical surveillance, which acknowledges the increased morbidity and mortality associated with the activation of tuberculosis caused by silica exposure and the attendant risks not only to individual workers but also potentially to their families and communities. The combination of silicosis and tuberculosis can have severe consequences for the worker.[1] Recognition of tuberculosis infection is important for the medical management of the affected worker and also has public health implications for others in the same workplace.

• The request for scientific input regarding alternative approaches to medical surveillance testing.

We concur that, as documented by the scientific information from the OSHA risk assessment and from epidemiology studies, there remains a continuing and significant risk to health from silica exposure, even with conformance to the newly proposed PEL:

• There is a well-documented excess risk of disease, including lung cancer, for working lifetime exposures at and below the proposed PEL, as documented in tables VI-1 and VI-2 of the section, "VI. Summary of OSHA's Preliminary Quantitative Risk Assessment" (see *Federal Register*, Vol. 78, No. 177, pp. 56320-21).

• This assessment is further strengthened by a peer-reviewed paper, including the findings from an epidemiologic study of a large cohort of Chinese workers and an associated risk assessment, which was published subsequent to the conduct of the OSHA literature review. This paper documents that, in order to reduce the excess lifetime risk of lung cancer to the level generally considered acceptable by U.S. OSHA (0.1% or 1 in a 1000), the exposure level would need to be less than 40 µg/m3, i.e., below the proposed PEL of 50 µg/m3.[2]

RECOMMENDATIONS

Based upon this information, we respectfully submit the following recommendations, which will ultimately enhance the protections afforded by the standard:

Recommendations Regarding Air Sampling and Hazard Assessment of the Workplace

We understand that there may be technological limitations that, at present, affect the precision of measurements of silica air concentrations when at or below the action level (AL) and the feasibility of control to these concentrations in certain job tasks. We anticipate that the proposed rule will drive advances in this area but agree that current technology is sufficient to support the proposed rule. We look forward to future developments that will allow documentation of exposure below the proposed PEL and reductions of the PEL, when appropriate.

The current OSHA proposal requires that workplace sampling be done that is representative of the exposures for each potentially exposed worker. Thus, although not all employees may have participated in personal sampling, we recommend that representative exposure results should be available for each covered individual, based upon the results for workers who are similarly exposed.

We recommend that OSHA consider more precisely specifying the type (and periodicity of collection) of industrial hygiene data and other relevant information (such as work processes, production rates, and dust control parameters) that would be required to assure representative exposure measurements adequate to document an employer's conformance to the proposed standard. Testing at sufficiently frequent intervals is important, because of the recognized variability in sampling results over time. Monitoring should be repeated after introduction of a change in work processes or practices that may potentially increase exposure.

ACOEM concurs with the implication of OSHA specifications that medical surveillance must consider the individual's work practices and relevant exposures. ACOEM maintains that it is essential that the examining clinician be provided with the most precise and specific information available on potential workplace hazards. This information should include the actual measured personal and area exposure results for the examinee and for workers with similar exposures over the preceding 5-year period.

Recommendations Regarding Chemical Substitution

ACOEM suggests that OSHA endorse the use of alternative materials to silica when feasible and when the substitute has been demonstrated to be safe in short- and long-term inhalation toxicology studies.[3] OSHA appears to support this approach. On page 56453, in section XVI. Summary and Explanation of the Standards, it states: "OSHA considers substitution to be an ideal control measure if it replaces a toxic material in the work environment with a non-toxic material, thus eliminating the risk of adverse health effects." We suggest that OSHA include this recommended approach in the body of the standard. Further, we suggest that OSHA request from NIOSH a periodic assessment that evaluates such substitutes, to determine which have been found to be safe, based upon the results of inhalational toxicity and epidemiologic studies.

Recommendations Regarding Medical Surveillance

Trigger for Conduct of Medical Surveillance

The OSHA proposed rule indicates that the trigger for medical surveillance would be exposure above the proposed PEL of 50 µg/m3 for 30 days or more per year. Because adverse health effects will occur with prolonged exposure at the PEL, ACOEM strongly recommends that the trigger should be exposure above the action level of 25 µg/m3 for 30 days or more per year. Of note, many other current OSHA standards similarly specify the trigger for medical surveillance at exposure levels at or above the action level, such as the Lead Standard (1910.1025).

Frequency of Medical Surveillance

OSHA has proposed a required testing frequency of every 3 years. The required frequency of testing should reflect the potential for and intensity of worker exposures, the recognized toxicity of the substance, and the level of confidence in established monitoring and preventive measures. ACOEM recognizes that serious and irreversible lung injury can occur from some workplace exposures after even short-term exposures.[4] ACOEM recommends that OSHA specify that all workers with potential occupational exposure to silica above the action level be provided the first follow-up surveillance examination 18 months after the baseline examination. The 18-month examination should include all the required elements ***except*** a chest radiograph. The purposes of this interval examination are: 1) to detect symptoms that could be associated with acute silicosis, a rare but very serious condition; and 2) to establish a more useful spirometry baseline, because accelerated declines in lung function have been demonstrated during the first 18 months of very dusty work.[5] Subsequently, ACOEM concurs that a minimum frequency for medical monitoring of 3 years is reasonable. If spirometry quality is adequate, changes in the test results over periods of as little as 2-3 years can provide good diagnostic value in detecting individuals who are at risk of important long-term functional declines.[6] It should also be emphasized that OSHA specifies a minimum frequency for medical examinations and that the examining clinician may recommend that spirometry be performed more frequently, perhaps every 1-2 years, e.g., in circumstances when exposure monitoring results are not available or if exposures are documented to be above the PEL.

ACOEM recommends that, if a surveillance examination appointment is missed, OSHA should make it clear that it is not acceptable practice for 6 years to elapse without surveillance. Instead, a repeat examination should be scheduled within 6 months.

Recommendations for Components of Medical Surveillance

Physical Examination

The OSHA proposed silica standard states that "a physical exam provides for a more comprehensive medical evaluation than that required by the ASTM standards." ACOEM endorses this requirement. Although symptoms and medical histories may be recorded on standard forms, the requirement for a physical examination provides the employee direct contact with a qualified clinician and thus an important opportunity to ask questions about controlling exposures and to discuss any symptoms or health concerns (such symptoms may suggest the presence of an illness such as a rheumatologic or kidney disorder that can also arise from silica exposures). As stated above, ACOEM maintains that it is essential that the examining clinician be provided with the most precise and specific information available on potential workplace hazards, including the measured personal and area exposure results for the examinee and for workers with similar exposures.

Imaging Procedures

Regarding the chest X-ray interpretation, OSHA recommends that: "A 12-point profusion scale is employed, in which the B reader gives a first choice and then a second choice profusion rating." ACOEM endorses this recommended approach. According to the International Labour Office (ILO) system for classifying chest radiographs for pneumoconiosis, the first profusion score indicates the level of profusion on the ILO standard radiograph which was judged by the reader to best match the concentration of small pneumoconiotic opacities on the examined worker's chest radiograph. The second profusion category indicates if another ILO profusion category was also seriously considered but ultimately rejected. OSHA proposes use of 1/0 as the cutoff for abnormality on the chest radiograph. This is logically consistent, because a 1/0 profusion score indicates that the reader concluded that the worker's radiograph most closely matches the ILO 1/1 standard, and the reader considered, but ultimately rejected, that the radiograph was normal (0/0). Although studies have demonstrated that chest x-rays classified as 0/1 are associated with elevated worker dust exposures,[7] ACOEM agrees that use of the 1/0 cutoff in silica-exposed workers is reasonable and consistent with both the ILO classification guidelines[8] and current practice in other federal health surveillance activities.[9]

OSHA suggested that computed tomography (CT) or high resolution computed tomography (HRCT) scans could be considered "equivalent diagnostic studies" under paragraph (h)(2)(iii) of the proposed standard. However, although standardized approaches to assessment of CT scans for pneumoconiosis have been published,[10] they have not yet been widely accepted and applied for interpreting and reporting the results of CT or HRCT scans. Furthermore, although the U.S. Preventive Services Task Force (USPSTF) has recently recommended the use of low-dose computed tomography for screening certain individuals (smokers) at high risk of lung cancer, they have not made a specific recommendation for screening based upon occupational exposure to silica (although they acknowledge that occupational or environmental carcinogen exposures affect risk).[11,12] We recognize that there is currently some scientific support for considering the use of CT scans in screening as several studies have demonstrated that interstitial abnormalities may be identifiable on the CT scan when the standard 2-dimensional imaging of the chest is not clearly abnormal.[13] However, until further study and recommendations from authoritative bodies such as the ILO fully support the use of CT or HRCT scans in the classification of radiographic images for pneumoconioses, ACOEM recommends that these scans not be used as "equivalent diagnostic studies" in medical surveillance, because the risks, costs, benefits, and recommended procedure and methods for image capture and interpretation have not been adequately specified.

ACOEM recognizes that CT or HRCT scans can and should be utilized as part of follow-up medical evaluations for those individuals with abnormal chest X-rays when clinically indicated. There are generally accepted indications for chest CT and HRCT in the work-up of patients with respiratory symptoms or abnormal 2-dimensional chest X-rays.

Spirometry

ACOEM endorses OSHA's proposal to require spirometry as part of the baseline medical examination. Unlike radiographs, spirometry detects abnormal loss of lung function. The cited literature provides documentation that silica exposure can result in important loss of lung function even in the absence of identifiable abnormalities on chest x-rays. Recent studies among working U.S. coal miners showed that abnormal lung function was three times more prevalent than pneumoconiotic opacities on chest x-rays.[14] Improved methods for testing and interpretation permit earlier detection of disease processes.[15] Although declines in function can occur from both workplace exposures and non-occupational causes, early recognition of lung function loss permits assessment of employee lung health and initiation of protective interventions before the onset of severe symptoms and disability, irrespective of the cause or causes.

To assure a uniform interpretation of spirometry, ACOEM recommends that OSHA include a reference in the non-mandatory medical appendix to the predicted normal values, as was done for the Cotton Dust Standard 1910.1043.[16]

Role and Scope of Medical Surveillance
ACOEM emphasizes that findings from medical surveillance examinations alone do not constitute a diagnosis of a disease, in the absence of an appropriate diagnostic medical evaluation. Medical surveillance is intended to trigger an appropriate medical evaluation that can detect early disease, so that preventive interventions may be initiated to modify the course of the illness and prevent serious impairment.

ACOEM recommends that OSHA should clarify the multiple roles/objectives of medical surveillance and suggests that this standard presents an opportunity to do so. Medical surveillance is a key component of occupational health protection. Surveillance serves two functions: 1) a public health function, by allowing early detection of inadequate control measures so that employers have the opportunity to correct them in time to protect other workers; and 2) identification of relevant health abnormalities in the individual worker to permit timely follow-up medical evaluations and initiation of treatment, improved exposure control, or medical removal, as necessary. It is therefore necessary and appropriate that the draft silica standard both articulate and advance a clear concept of surveillance, especially in light of OSHA's acknowledgement that some workers will experience silica-related health effects from exposures at the proposed PEL.

In order to clarify and advance surveillance within the context of this standard, ACOEM recommends that OSHA include a monitoring system complementary to workplace evaluations. By analogy to the NIOSH Refractory Ceramic Fiber (RCF) Criteria Document,[17] this requirement would include periodic (e.g., every 3-6 years) program evaluations, which would consist of a formal written assessment of relevant health abnormalities associated with workplace exposures, tied to job assignment and work station, noting the presence of dust controls and documenting work practices. For all workplaces with at least five exposed employees, aggregated de-identified test results should be analyzed by qualified occupational health professionals (which for this purpose would include epidemiologists) for patterns that indicate the possible association of health effects with workplace exposures. This approach will also assist in assessing the adequacy of protection afforded by the proposed PEL. Written descriptions of the methods and results of these should be available for review by employees at any time and should be produced during authorized workplace inspections.

ACOEM, an organization of more than 4,000 occupational physicians and other health care professionals, provides leadership to promote optimal health and safety of workers, workplaces, and environments.

Thank you for your consideration of our comments. Please do not hesitate to contact me or Dr. Michael Fischman, the Chair of ACOEM's Silica Task Force, at 925-283-2366, should you have any questions.

Sincerely,

Ronald R. Loeppke, MD, MPH, FACOEM
President
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17. "1.11.2.7 Evaluation Employers shall evaluate their medical monitoring programs as follows:
Periodically have standardized medical screening data aggregated and evaluated by an epidemiologist or other knowledgeable person to identify patterns of worker health that may be linked to work activities and practices requiring additional primary preventive efforts. Combine routine aggregate assessments of medical screening data with evaluations of exposure monitoring data to identify needed changes in work areas or exposure conditions." [NIOSH, Criteria for a Recommended Standard: Occupational Exposure to Refractory Ceramic Fibers, http://www.cdc.gov/niosh/docs/2006-123/pdfs/2006-123Ch1.pdf.]