



ARMA Health, Safety, &
Environment (HSE)
Committee

OSHA Silica Webinar

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1910.1053 Respirable Crystalline Silica

(a) Scope and application. (1) This section applies to all occupational exposures to respirable crystalline silica, except:

(i) Construction work as defined in 29 CFR 1910.12(b) (occupational exposures to respirable crystalline silica in construction work are covered under 29 CFR 1926.1153);

(ii) Agricultural operations covered under 29 CFR part 1928; and

(iii) Exposures that result from the processing of sorptive clays.

(2) This section does not apply where the employer has objective data demonstrating that employee exposure to respirable crystalline silica will remain below 25 micrograms per cubic meter of air ($25 \mu\text{g}/\text{m}^3$) as an 8-hour time-weighted average (TWA) under any foreseeable conditions.

(3) This section does not apply if the employer complies with 29 CFR 1926.1153 and:

(i) The task performed is indistinguishable from a construction task listed on Table 1 in paragraph (c) of 29 CFR 1926.1153; and

(ii) The task will not be performed regularly in the same environment and conditions.

(b) Definitions. For the purposes of this section the following definitions apply:

Action level means a concentration of airborne respirable crystalline silica of $25 \mu\text{g}/\text{m}^3$, calculated as an 8-hour TWA.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Employee exposure means the exposure to airborne respirable crystalline silica that would occur if the employee were not using a respirator.

High-efficiency particulate air [HEPA] filter means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter.

Objective data means information, such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance, demonstrating employee exposure to respirable crystalline silica associated with a particular product or material or a specific process, task, or activity. The data must reflect workplace conditions closely resembling or with a higher exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Physician or other licensed health care professional [PLHCP] means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (i) of this section.

Regulated area means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of respirable crystalline silica exceeds, or can reasonably be expected to exceed, the PEL.

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 specified in 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.

This section means this respirable crystalline silica standard, 29 CFR 1910.1053.

(c) Permissible exposure limit (PEL). The employer shall ensure that no employee is exposed to an airborne concentration of respirable crystalline silica in excess of $50 \mu\text{g}/\text{m}^3$, calculated as an 8-hour TWA.

(d) Exposure assessment—(1) General. The employer shall assess the exposure of each employee who is or may reasonably be expected to be exposed to respirable crystalline silica at or above the action level in accordance with either the performance option in paragraph (d)(2) or the scheduled monitoring option in paragraph (d)(3) of this section.

(2) Performance option. The employer shall assess the 8-hour TWA exposure for each employee on the basis of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures to respirable crystalline silica.

(3) Scheduled monitoring option. (i) The employer shall perform initial monitoring to assess the 8-hour TWA exposure for each employee on the basis of one or more personal breathing zone air samples that reflect the exposures of employees on each shift, for each job classification, in each work area. Where several employees perform the same tasks on the same shift and in the same work area, the employer may sample a representative fraction of these employees in order to meet this requirement. In representative sampling, the employer shall sample the employee(s) who are expected to have the highest exposure to respirable crystalline silica.

(ii) If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring.

(iii) Where the most recent exposure monitoring indicates that employee exposures are at or above the action level but at or below the PEL, the employer shall repeat such monitoring within six months of the most recent monitoring.

(iv) Where the most recent exposure monitoring indicates that employee exposures are above the PEL, the employer shall repeat such monitoring within three months of the most recent monitoring.

(v) Where the most recent (non-initial) exposure monitoring indicates that employee exposures are below the action level, the employer shall repeat such monitoring within six months of the most recent monitoring until two consecutive measurements, taken 7 or more days apart, are below the action level, at which time the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring, except as otherwise provided in paragraph (d)(4) of this section.

(4) Reassessment of exposures. The employer shall reassess exposures whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional exposures at or above the action level, or when the employer has any reason to believe that new or additional exposures at or above the action level have occurred.

(5) Methods of sample analysis. The employer shall ensure that all samples taken to satisfy the monitoring requirements of paragraph (d) of this section are evaluated by a laboratory that analyzes air samples for respirable crystalline silica in accordance with the procedures in Appendix A to this section.

(6) Employee notification of assessment results. (i) Within 15 working days after completing an exposure assessment in accordance with paragraph (d) of this section, the

employer shall individually notify each affected employee in writing of the results of that assessment or post the results in an appropriate location accessible to all affected employees.

(ii) Whenever an exposure assessment indicates that employee exposure is above the PEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.

(7) Observation of monitoring. (i) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to respirable crystalline silica.

(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required for any workplace hazard, the employer shall provide the observer with protective clothing and equipment at no cost and shall ensure that the observer uses such clothing and equipment.

(e) Regulated areas—(1) Establishment. The employer shall establish a regulated area wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL.

(2) Demarcation. (i) The employer shall demarcate regulated areas from the rest of the workplace in a manner that minimizes the number of employees exposed to respirable crystalline silica within the regulated area.

(ii) The employer shall post signs at all entrances to regulated areas that bear the legend specified in paragraph (j)(2) of this section.

(3) Access. The employer shall limit access to regulated areas to:

(A) Persons authorized by the employer and required by work duties to be present in the regulated area;

(B) Any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring procedures under paragraph (d) of this section; and

(C) Any person authorized by the Occupational Safety and Health Act or regulations issued under it to be in a regulated area.

(4) Provision of respirators. The employer shall provide each employee and the employee's designated representative entering a regulated area with an appropriate respirator in accordance with paragraph (g) of this section and shall require each employee and the employee's designated representative to use the respirator while in a regulated area.

(f) Methods of compliance—(1) Engineering and work practice controls. The employer shall use engineering and work practice controls to reduce and maintain employee exposure to respirable crystalline silica to or below the PEL, unless the employer can demonstrate that such controls are not feasible. Wherever such feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the PEL, the employer shall nonetheless use them to reduce employee exposure to the lowest feasible level and shall supplement them with the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(2) Written exposure control plan. (i) The employer shall establish and implement a written exposure control plan that contains at least the following elements:

(A) A description of the tasks in the workplace that involve exposure to respirable crystalline silica;

(B) A description of the engineering controls, work practices, and respiratory protection used to limit employee exposure to respirable crystalline silica for each task; and

(C) A description of the housekeeping measures used to limit employee exposure to respirable crystalline silica.

(ii) The employer shall review and evaluate the effectiveness of the written exposure control plan at least annually and update it as necessary.

(iii) The employer shall make the written exposure control plan readily available for examination and copying, upon request, to each employee covered by this section, their designated representatives, the Assistant Secretary and the Director.

(3) Abrasive blasting. In addition to the requirements of paragraph (f)(1) of this section, the employer shall comply with other OSHA standards, when applicable, such as 29 CFR 1910.94 (Ventilation), 29 CFR 1915.34 (Mechanical paint removers), and 29 CFR 1915 Subpart I (Personal Protective Equipment), where abrasive blasting is conducted using crystalline silica-containing blasting agents, or where abrasive blasting is conducted on substrates that contain crystalline silica.

(g) Respiratory protection—(1) General. Where respiratory protection is required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph and 29 CFR 1910.134. Respiratory protection is required:

(i) Where exposures exceed the PEL during periods necessary to install or implement feasible engineering and work practice controls;

(ii) Where exposures exceed the PEL during tasks, such as certain maintenance and repair tasks, for which engineering and work practice controls are not feasible;

(iii) During tasks for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL; and

(iv) During periods when the employee is in a regulated area.

(2) Respiratory protection program. Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.

(h) Housekeeping. (1) The employer shall not allow dry sweeping or dry brushing where such activity could contribute to employee exposure to respirable crystalline silica unless wet sweeping, HEPA-filtered vacuuming or other methods that minimize the likelihood of exposure are not feasible.

(2) The employer shall not allow compressed air to be used to clean clothing or surfaces where such activity could contribute to employee exposure to respirable crystalline silica unless:

(i) The compressed air is used in conjunction with a ventilation system that effectively captures the dust cloud created by the compressed air; or

(ii) No alternative method is feasible.

(i) Medical surveillance—(1) General. (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for each employee who will be occupationally exposed to respirable crystalline silica at or above the action level for 30 or more days per year.

(ii) The employer shall ensure that all medical examinations and procedures required by this section are performed by a PLHCP as defined in paragraph (b) of this section.

(2) Initial examination. The employer shall make available an initial (baseline) medical examination within 30 days after initial assignment, unless the employee has received a medical

examination that meets the requirements of this section within the last three years. The examination shall consist of:

(i) A medical and work history, with emphasis on: past, present, and anticipated exposure to respirable crystalline silica, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including signs 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), interpreted and classified according to the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified B Reader;

(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 course;

(v) Testing for latent tuberculosis infection; and

(vi) Any other tests deemed appropriate by the PLHCP.

(3) Periodic examinations. The employer shall make available medical examinations that include the procedures described in paragraph (i)(2) of this section (except paragraph (i)(2)(v)) at least every three years, or more frequently if recommended by the PLHCP.

(4) Information provided to the PLHCP. The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the PLHCP with the following information:

(i) A description of the employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica;

(ii) The employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica;

(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used or will use that equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the employee and currently within the control of the employer.

(5) PLHCP's written medical report for the employee. The employer shall ensure that the PLHCP explains to the employee the results of the medical examination and provides each employee with a written medical report within 30 days of each medical examination performed. The written report shall contain:

(i) A statement indicating the results of the medical examination, including any medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica and any medical conditions that require further evaluation or treatment;

(ii) Any recommended limitations on the employee's use of respirators;

(iii) Any recommended limitations on the employee's exposure to respirable crystalline silica; and

(iv) A statement that the employee should be examined by a specialist (pursuant to paragraph (i)(7) of this section) if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the B Reader, or if referral to a specialist is otherwise deemed appropriate by the PLHCP.

(6) PLHCP's written medical opinion for the employer. (i) The employer shall obtain a written medical opinion from the PLHCP within 30 days of the medical examination. The written opinion shall contain only the following:

(A) The date of the examination;

(B) A statement that the examination has met the requirements of this section; and

(C) Any recommended limitations on the employee's use of respirators.

(ii) If the employee provides written authorization, the written opinion shall also contain either or both of the following:

(A) Any recommended limitations on the employee's exposure to respirable crystalline silica;

(B) A statement that the employee should be examined by a specialist (pursuant to paragraph (i)(7) of this section) if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the B Reader, or if referral to a specialist is otherwise deemed appropriate by the PLHCP.

(iii) The employer shall ensure that each employee receives a copy of the written medical opinion described in paragraph (i)(6)(i) and (ii) of this section within 30 days of each medical examination performed.

(7) Additional examinations. (i) If the PLHCP's written medical opinion indicates that an employee should be examined by a specialist, the employer shall make available a medical examination by a specialist within 30 days after receiving the PLHCP's written opinion.

(ii) The employer shall ensure that the examining specialist is provided with all of the information that the employer is obligated to provide to the PLHCP in accordance with paragraph (i)(4) of this section.

(iii) The employer shall ensure that the specialist explains to the employee the results of the medical examination and provides each employee with a written medical report within 30 days of the examination. The written report shall meet the requirements of paragraph (i)(5) (except paragraph (i)(5)(iv)) of this section.

(iv) The employer shall obtain a written opinion from the specialist within 30 days of the medical examination. The written opinion shall meet the requirements of paragraph (i)(6) (except paragraph (i)(6)(i)(B) and (i)(6)(ii)(B)) of this section.

(j) Communication of respirable crystalline silica hazards to employees—(1) Hazard communication. The employer shall include respirable crystalline silica in the program established to comply with the hazard communication standard (HCS) (29 CFR 1910.1200). The employer shall ensure that each employee has access to labels on containers of crystalline silica and safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (j)(3) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer, lung effects, immune system effects, and kidney effects.

(2) Signs. The employer shall post signs at all entrances to regulated areas that bear the following legend:

DANGER

RESPIRABLE CRYSTALLINE SILICA

MAY CAUSE CANCER

CAUSES DAMAGE TO LUNGS

WEAR RESPIRATORY PROTECTION IN THIS AREA

AUTHORIZED PERSONNEL ONLY

(3) Employee information and training. (i) The employer shall ensure that each employee covered by this section can demonstrate knowledge and understanding of at least the following:

(A) The health hazards associated with exposure to respirable crystalline silica;

(B) Specific tasks in the workplace that could result in exposure to respirable crystalline silica;

(C) Specific measures the employer has implemented to protect employees from exposure to respirable crystalline silica, including engineering controls, work practices, and respirators to be used;

(D) The contents of this section; and

(E) The purpose and a description of the medical surveillance program required by paragraph (i) of this section.

(ii) The employer shall make a copy of this section readily available without cost to each employee covered by this section.

(k) Recordkeeping—(1) Air monitoring data. (i) The employer shall make and maintain an accurate record of all exposure measurements taken to assess employee exposure to respirable crystalline silica, as prescribed in paragraph (d) of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement for each sample taken;

- (B) The task monitored;
- (C) Sampling and analytical methods used;
- (D) Number, duration, and results of samples taken;
- (E) Identity of the laboratory that performed the analysis;
- (F) Type of personal protective equipment, such as respirators, worn by the employees

monitored; and

(G) Name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer shall ensure that exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(2) Objective data. (i) The employer shall make and maintain an accurate record of all objective data relied upon to comply with the requirements of this section.

(ii) This record shall include at least the following information:

- (A) The crystalline silica-containing material in question;
- (B) The source of the objective data;
- (C) The testing protocol and results of testing;
- (D) A description of the process, task, or activity on which the objective data were based;

and

(E) Other data relevant to the process, task, activity, material, or exposures on which the objective data were based.

(iii) The employer shall ensure that objective data are maintained and made available in accordance with 29 CFR 1910.1020.

(3) Medical surveillance. (i) The employer shall make and maintain an accurate record for each employee covered by medical surveillance under paragraph (i) of this section.

(ii) The record shall include the following information about the employee:

(A) Name and social security number;

(B) A copy of the PLHCPs' and specialists' written medical opinions; and

(C) A copy of the information provided to the PLHCPs and specialists.

(iii) The employer shall ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.

(1) Dates. (1) This section is effective June 23, 2016.

(2) Except as provided for in paragraphs (1)(3) and (4) of this section, all obligations of this section commence June 23, 2018.

(3) For hydraulic fracturing operations in the oil and gas industry:

(i) All obligations of this section, except obligations for medical surveillance in paragraph (i)(1)(i) and engineering controls in paragraph (f)(1) of this section, commence June 23, 2018;

(ii) Obligations for engineering controls in paragraph (f)(1) of this section commence June 23, 2021; and

(iii) Obligations for medical surveillance in paragraph (i)(1)(i) commence in accordance with paragraph (1)(4) of this section.

(4) The medical surveillance obligations in paragraph (i)(1)(i) commence on June 23, 2018, for employees who will be occupationally exposed to respirable crystalline silica above the PEL for 30 or more days per year. Those obligations commence June 23, 2020, for employees

who will be occupationally exposed to respirable crystalline silica at or above the action level for 30 or more days per year.

Appendix A to § 1910.1053– Methods of sample analysis

This appendix specifies the procedures for analyzing air samples for respirable crystalline silica, as well as the quality control procedures that employers must ensure that laboratories use when performing an analysis required under 29 CFR 1910.1053 (d)(5). Employers must ensure that such a laboratory:

1. Evaluates all samples using the procedures specified in one of the following analytical methods: OSHA ID-142; NMAM 7500; NMAM 7602; NMAM 7603; MSHA P-2; or MSHA P-7;
2. Is accredited to ANS/ISO/IEC Standard 17025:2005 with respect to crystalline silica analyses by a body that is compliant with ISO/IEC Standard 17011:2004 for implementation of quality assessment programs;
3. Uses the most current National Institute of Standards and Technology (NIST) or NIST traceable standards for instrument calibration or instrument calibration verification;
4. Implements an internal quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error;
5. Characterizes the sample material by identifying polymorphs of respirable crystalline silica present, identifies the presence of any interfering compounds that might affect the analysis, and makes any corrections necessary in order to obtain accurate sample analysis; and
6. Analyzes quantitatively for crystalline silica only after confirming that the sample matrix is free of uncorrectable analytical interferences, corrects for analytical interferences, and uses a method that meets the following performance specifications:

6.1 Each day that samples are analyzed, performs instrument calibration checks with standards that bracket the sample concentrations;

6.2 Uses five or more calibration standard levels to prepare calibration curves and ensures that standards are distributed through the calibration range in a manner that accurately reflects the underlying calibration curve; and

6.3 Optimizes methods and instruments to obtain a quantitative limit of detection that represents a value no higher than 25 percent of the PEL based on sample air volume.

Appendix B to § 1910.1053 – Medical Surveillance Guidelines

Introduction

The purpose of this Appendix is to provide medical information and recommendations to aid physicians and other licensed health care professionals (PLHCPs) regarding compliance with the medical surveillance provisions of the respirable crystalline silica standard (29 CFR 1910.1053). Appendix B is for informational and guidance purposes only and none of the statements in Appendix B should be construed as imposing a mandatory requirement on employers that is not otherwise imposed by the standard.

Medical screening and surveillance allow for early identification of exposure-related health effects in individual employee and groups of employees, so that actions can be taken to both avoid further exposure and prevent or address adverse health outcomes. Silica-related diseases can be fatal, encompass a variety of target organs, and may have public health consequences when considering the increased risk of a latent tuberculosis (TB) infection becoming active. Thus, medical surveillance of silica-exposed employees requires that PLHCPs have a thorough knowledge of silica-related health effects.

This Appendix is divided into seven sections. Section 1 reviews silica-related diseases, medical responses, and public health responses. Section 2 outlines the components of the medical surveillance program for employees exposed to silica. Section 3 describes the roles and responsibilities of the PLHCP implementing the program and of other medical specialists and public health professionals. Section 4 provides a discussion of considerations, including confidentiality. Section 5 provides a list of additional resources and Section 6 lists references. Section 7 provides sample forms for the written medical report for the employee, the written medical opinion for the employer and the written authorization.

1. Recognition of Silica-related Diseases.

1.1. Overview. The term “silica” refers specifically to the compound silicon dioxide (SiO₂). Silica is a major component of sand, rock, and mineral ores. Exposure to fine (respirable size) particles of crystalline forms of silica is associated with adverse health effects, such as silicosis, lung cancer, chronic obstructive pulmonary disease (COPD), and activation of latent TB infections. Exposure to respirable crystalline silica can occur in industry settings such as foundries, abrasive blasting operations, paint manufacturing, glass and concrete product manufacturing, brick making, china and pottery manufacturing, manufacturing of plumbing fixtures, and many construction activities including highway repair, masonry, concrete work, rock drilling, and tuck-pointing. New uses of silica continue to emerge. These include countertop manufacturing, finishing, and installation (Kramer *et al.* 2012; OSHA 2015) and hydraulic fracturing in the oil and gas industry (OSHA 2012).

Silicosis is an irreversible, often disabling, and sometimes fatal fibrotic lung disease. Progression of silicosis can occur despite removal from further exposure. Diagnosis of silicosis requires a history of exposure to silica and radiologic findings characteristic of silica exposure.

Three different presentations of silicosis (chronic, accelerated, and acute) have been defined. Accelerated and acute silicosis are much less common than chronic silicosis. However, it is critical to recognize all cases of accelerated and acute silicosis because these are life-threatening illnesses and because they are caused by substantial overexposures to respirable crystalline silica. Although any case of silicosis indicates a breakdown in prevention, a case of acute or accelerated silicosis implies current high exposure and a very marked breakdown in prevention.

In addition to silicosis, employees exposed to respirable crystalline silica, especially those with accelerated or acute silicosis, are at increased risks of contracting active TB and other infections (ATS 1997; Rees and Murray 2007). Exposure to respirable crystalline silica also increases an employee's risk of developing lung cancer, and the higher the cumulative exposure, the higher the risk (Steenland et al. 2001; Steenland and Ward 2014). Symptoms for these diseases and other respirable crystalline silica-related diseases are discussed below.

1.2. Chronic Silicosis. Chronic silicosis is the most common presentation of silicosis and usually occurs after at least 10 years of exposure to respirable crystalline silica. The clinical presentation of chronic silicosis is:

1.2.1. Symptoms - shortness of breath and cough, although employees may not notice any symptoms early in the disease. Constitutional symptoms, such as fever, loss of appetite and fatigue, may indicate other diseases associated with silica exposure, such as TB infection or lung cancer. Employees with these symptoms should immediately receive further evaluation and treatment.

1.2.2. Physical Examination - may be normal or disclose dry rales or rhonchi on lung auscultation.

1.2.3. Spirometry - may be normal or may show only a mild restrictive or obstructive pattern.

1.2.4. Chest X-ray - classic findings are small, rounded opacities in the upper lung fields bilaterally. However, small irregular opacities and opacities in other lung areas can also occur. Rarely, “eggshell calcifications” in the hilar and mediastinal lymph nodes are seen.

1.2.5. Clinical Course - chronic silicosis in most cases is a slowly progressive disease. Under the respirable crystalline silica standard, the PLHCP is to recommend that employees with a 1/0 category X-ray be referred to an American Board Certified Specialist in Pulmonary Disease or Occupational Medicine. The PLHCP and/or Specialist should counsel employees regarding work practices and personal habits that could affect employees’ respiratory health.

1.3. Accelerated Silicosis. Accelerated silicosis generally occurs within 5-10 years of exposure and results from high levels of exposure to respirable crystalline silica. The clinical presentation of accelerated silicosis is:

1.3.1. Symptoms - shortness of breath, cough, and sometimes sputum production. Employees with exposure to respirable crystalline silica, and especially those with accelerated silicosis, are at high risk for activation of TB infections, atypical mycobacterial infections, and fungal superinfections. Constitutional symptoms, such as fever, weight loss, hemoptysis (coughing up blood), and fatigue may herald one of these infections or the onset of lung cancer.

1.3.2. Physical Examination - rales, rhonchi, or other abnormal lung findings in relation to illnesses present. Clubbing of the digits, signs of heart failure, and cor pulmonale may be present in severe lung disease.

1.3.3. Spirometry - restrictive or mixed restrictive/obstructive pattern.

1.3.4. Chest X-ray - small rounded and/or irregular opacities bilaterally. Large opacities and lung abscesses may indicate infections, lung cancer, or progression to complicated silicosis, also termed progressive massive fibrosis.

1.3.5. Clinical Course - accelerated silicosis has a rapid, severe course. Under the respirable crystalline silica standard, the PLHCP can recommend referral to a Board Certified Specialist in either Pulmonary Disease or Occupational Medicine, as deemed appropriate, and referral to a Specialist is recommended whenever the diagnosis of accelerated silicosis is being considered.

1.4. Acute Silicosis. Acute silicosis is a rare disease caused by inhalation of extremely high levels of respirable crystalline silica particles. The pathology is similar to alveolar proteinosis with lipoproteinaceous material accumulating in the alveoli. Acute silicosis develops rapidly, often, within a few months to less than 2 years of exposure, and is almost always fatal. The clinical presentation of acute silicosis is as follows:

1.4.1. Symptoms - sudden, progressive, and severe shortness of breath. Constitutional symptoms are frequently present and include fever, weight loss, fatigue, productive cough, hemoptysis (coughing up blood), and pleuritic chest pain.

1.4.2. Physical Examination - dyspnea at rest, cyanosis, decreased breath sounds, inspiratory rales, clubbing of the digits, and fever.

1.4.3. Spirometry - restrictive or mixed restrictive/obstructive pattern.

1.4.4. Chest X-ray - diffuse haziness of the lungs bilaterally early in the disease. As the disease progresses, the “ground glass” appearance of interstitial fibrosis will appear.

1.4.5. Clinical Course - employees with acute silicosis are at especially high risk of TB activation, nontuberculous mycobacterial infections, and fungal superinfections. Acute silicosis

is immediately life-threatening. The employee should be urgently referred to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine for evaluation and treatment.

Although any case of silicosis indicates a breakdown in prevention, a case of acute or accelerated silicosis implies a profoundly high level of silica exposure and may mean that other employees are currently exposed to dangerous levels of silica.

1.5. COPD. COPD, including chronic bronchitis and emphysema, has been documented in silica-exposed employees, including those who do not develop silicosis. Periodic spirometry tests are performed to evaluate each employee for progressive changes consistent with the development of COPD. In addition to evaluating spirometry results of individual employees over time, PLHCPs may want to be aware of general trends in spirometry results for groups of employees from the same workplace to identify possible problems that might exist at that workplace. (See Section 2 of this Appendix on Medical Surveillance for further discussion.)

Heart disease may develop secondary to lung diseases such as COPD. A recent study by Liu *et al.* 2014 noted a significant exposure-response trend between cumulative silica exposure and heart disease deaths, primarily due to pulmonary heart disease, such as cor pulmonale.

1.6. Renal and Immune System. Silica exposure has been associated with several types of kidney disease, including glomerulonephritis, nephrotic syndrome, and end stage renal disease requiring dialysis. Silica exposure has also been associated with other autoimmune conditions, including progressive systemic sclerosis, systemic lupus erythematosus, and rheumatoid arthritis. Studies note an association between employees with silicosis and serologic markers for autoimmune diseases, including antinuclear antibodies, rheumatoid factor, and immune complexes (Jalloul and Banks 2007; Shtraichman *et al.* 2015).

1.7. TB and Other Infections. Silica-exposed employees with latent TB are 3 to 30 times more likely to develop active pulmonary TB infection (ATS 1997; Rees and Murray 2007). Although respirable crystalline silica exposure does not cause TB infection, individuals with latent TB infection are at increased risk for activation of disease if they have higher levels of respirable crystalline silica exposure, greater profusion of radiographic abnormalities, or a diagnosis of silicosis. Demographic characteristics, such as immigration from some countries, are associated with increased rates of latent TB infection. PLHCPs can review the latest Centers for Disease Control and Prevention (CDC) information on TB incidence rates and high risk populations online (See Section 5 of this Appendix). Additionally, silica-exposed employees are at increased risk for contracting nontuberculous mycobacterial infections, including Mycobacterium avium-intracellulare and Mycobacterium kansaii.

1.8. Lung Cancer. The National Toxicology Program has listed respirable crystalline silica as a known human carcinogen since 2000 (NTP 2014). The International Agency for Research on Cancer (2012) has also classified silica as Group 1 (carcinogenic to humans). Several studies have indicated that the risk of lung cancer from exposure to respirable crystalline silica and smoking is greater than additive (Brown 2009; Liu et al. 2013). Employees should be counseled on smoking cessation.

2. Medical Surveillance.

PLHCPs who manage silica medical surveillance programs should have a thorough understanding of the many silica-related diseases and health effects outlined in Section 1 of this Appendix. At each clinical encounter, the PLHCP should consider silica-related health outcomes, with particular vigilance for acute and accelerated silicosis. In this Section, the required components of medical surveillance under the respirable crystalline silica standard are reviewed,

along with additional guidance and recommendations for PLHCPs performing medical surveillance examinations for silica-exposed employees.

2.1. History.

2.1.1. The respirable crystalline silica standard requires the following: A medical and work history, with emphasis on: past, present, and anticipated exposure to respirable crystalline silica, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including signs and symptoms of respiratory disease (e.g., shortness of breath, cough, wheezing); history of TB; and smoking status and history.

2.1.2. Further, the employer must provide the PLHCP with the following information:

2.1.2.1. A description of the employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica;

2.1.2.2. The employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica;

2.1.2.3. A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used or will use that equipment; and

2.1.2.4. Information from records of employment-related medical examinations previously provided to the employee and currently within the control of the employer.

2.1.3. Additional guidance and recommendations: A history is particularly important both in the initial evaluation and in periodic examinations. Information on past and current medical conditions (particularly a history of kidney disease, cardiac disease, connective tissue disease, and other immune diseases), medications, hospitalizations and surgeries may uncover health risks, such as immune suppression, that could put an employee at increased health risk

from exposure to silica. This information is important when counseling the employee on risks and safe work practices related to silica exposure.

2.2. Physical Examination.

2.2.1. The respirable crystalline silica standard requires the following: A physical examination, with special emphasis on the respiratory system. The physical examination must be performed at the initial examination and every three years thereafter.

2.2.2. Additional guidance and recommendations: Elements of the physical examination that can assist the PHLCP include: an examination of the cardiac system, an extremity examination (for clubbing, cyanosis, edema, or joint abnormalities), and an examination of other pertinent organ systems identified during the history.

2.3. TB Testing.

2.3.1. The respirable crystalline silica standard requires the following: Baseline testing for TB on initial examination.

2.3.2. Additional guidance and recommendations:

2.3.2.1. Current CDC guidelines (See Section 5 of this Appendix) should be followed for the application and interpretation of Tuberculin skin tests (TST). The interpretation and documentation of TST reactions should be performed within 48 to 72 hours of administration by trained PLHCPs.

2.3.2.2. PLHCPs may use alternative TB tests, such as interferon- γ release assays (IGRAs), if sensitivity and specificity are comparable to TST (Mazurek et al. 2010; Slater et al. 2013). PLHCPs can consult the current CDC guidelines for acceptable tests for latent TB infection.

2.3.2.3. The silica standard allows the PLHCP to order additional tests or test at a greater frequency than required by the standard, if deemed appropriate. Therefore, PLHCPs might perform periodic (e.g., annual) TB testing as appropriate, based on employees' risk factors. For example, according to the American Thoracic Society (ATS), the diagnosis of silicosis or exposure to silica for 25 years or more are indications for annual TB testing (ATS 1997). PLHCPs should consult the current CDC guidance on risk factors for TB (See Section 5 of this Appendix).

2.3.2.4. Employees with positive TB tests and those with indeterminate test results should be referred to the appropriate agency or specialist, depending on the test results and clinical picture. Agencies, such as local public health departments, or specialists, such as a pulmonary or infectious disease specialist, may be the appropriate referral. Active TB is a nationally notifiable disease. PLHCPs should be aware of the reporting requirements for their region. All States have TB Control Offices that can be contacted for further information. (See Section 5 of this Appendix for links to CDC's TB resources and State TB Control Offices.)

2.3.2.5. The following public health principles are key to TB control in the U.S. (ATS-CDC-IDSA 2005):

- (1) Prompt detection and reporting of persons who have contracted active TB;
- (2) Prevention of TB spread to close contacts of active TB cases;
- (3) Prevention of active TB in people with latent TB through targeted testing and treatment; and
- (4) Identification of settings at high risk for TB transmission so that appropriate infection-control measures can be implemented.

2.4. Pulmonary Function Testing.

2.4.1. The respirable crystalline silica standard requires the following: Pulmonary function testing must be performed on the initial examination and every three years thereafter. The required pulmonary function test is spirometry and must include forced vital capacity (FVC), forced expiratory volume in one second (FEV₁), and FEV₁/FVC ratio. Testing must be administered by a spirometry technician with a current certificate from a National Institute for Occupational Health and Safety (NIOSH)-approved spirometry course.

2.4.2. Additional guidance and recommendations: Spirometry provides information about individual respiratory status and can be used to track an employee's respiratory status over time or as a surveillance tool to follow individual and group respiratory function. For quality results, the ATS and the American College of Occupational and Environmental Medicine (ACOEM) recommend use of the third National Health and Nutrition Examination Survey (NHANES III) values, and ATS publishes recommendations for spirometry equipment (Miller *et al.* 2005; Townsend 2011; Redlich *et al.* 2014). OSHA's publication, Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals, provides helpful guidance (See Section 5 of this Appendix). Abnormal spirometry results may warrant further clinical evaluation and possible recommendations for limitations on the employee's exposure to respirable crystalline silica.

2.5. Chest X-ray.

2.5.1. The respirable crystalline silica standard requires the following: A single posteroanterior (PA) 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. A chest X-ray must be performed on the initial examination and every three years thereafter. The chest X-ray must be interpreted and classified according to the

International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified B Reader.

Chest radiography is necessary to diagnose silicosis, monitor the progression of silicosis, and identify associated conditions such as TB. If the B reading indicates small opacities in a profusion of 1/0 or higher, the employee is to receive a recommendation for referral to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine.

2.5.2. Additional guidance and recommendations: Medical imaging has largely transitioned from conventional film-based radiography to digital radiography systems. The ILO Guidelines for the Classification of Pneumoconioses has historically provided film-based chest radiography as a referent standard for comparison to individual exams. However, in 2011, the ILO revised the guidelines to include a digital set of referent standards that were derived from the prior film-based standards. To assist in assuring that digitally-acquired radiographs are at least as safe and effective as film radiographs, NIOSH has prepared guidelines, based upon accepted contemporary professional recommendations (See Section 5 of this Appendix). Current research from Laney et al. 2011 and Halldin et al. 2014 validate the use of the ILO digital referent images. Both studies conclude that the results of pneumoconiosis classification using digital references are comparable to film-based ILO classifications. Current ILO guidance on radiography for pneumoconioses and B-reading should be reviewed by the PLHCP periodically, as needed, on the ILO or NIOSH websites (See Section 5 of this Appendix).

2.6. Other Testing. Under the respirable crystalline silica standards, the PLHCP has the option of ordering additional testing he or she deems appropriate. Additional tests can be ordered on a case-by-case basis depending on individual signs or symptoms and clinical judgment. For example, if an employee reports a history of abnormal kidney function tests, the PLHCP may

want to order a baseline renal function tests (e.g., serum creatinine and urinalysis). As indicated above, the PLHCP may order annual TB testing for silica-exposed employees who are at high risk of developing active TB infections. Additional tests that PLHCPs may order based on findings of medical examinations include, but is not limited to, chest computerized tomography (CT) scan for lung cancer or COPD, testing for immunologic diseases, and cardiac testing for pulmonary-related heart disease, such as cor pulmonale.

3. Roles and Responsibilities.

3.1. PLHCP. The PLHCP designation refers to “an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required” by the respirable crystalline silica standard. The legally permitted scope of practice for the PLHCP is determined by each State. PLHCPs who perform clinical services for a silica medical surveillance program should have a thorough knowledge of respirable crystalline silica-related diseases and symptoms. Suspected cases of silicosis, advanced COPD, or other respiratory conditions causing impairment should be promptly referred to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine.

Once the medical surveillance examination is completed, the employer must ensure that the PLHCP explains to the employee the results of the medical examination and provides the employee with a written medical report within 30 days of the examination. The written medical report must contain a statement indicating the results of the medical examination, including any medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica and any medical conditions that require further evaluation or treatment. In addition, the PLHCP’s written medical report must include

any recommended limitations on the employee's use of respirators, any recommended limitations on the employee's exposure to respirable crystalline silica, and a statement that the employee should be examined by a Board Certified Specialist in Pulmonary Disease or Occupational medicine if the chest X-ray is classified as 1/0 or higher by the B Reader, or if referral to a Specialist is otherwise deemed appropriate by the PLHCP.

The PLHCP should discuss all findings and test results and any recommendations regarding the employee's health, worksite safety and health practices, and medical referrals for further evaluation, if indicated. In addition, it is suggested that the PLHCP offer to provide the employee with a complete copy of their examination and test results, as some employees may want this information for their own records or to provide to their personal physician or a future PLHCP. Employees are entitled to access their medical records.

Under the respirable crystalline silica standard, the employer must ensure that the PLHCP provides the employer with a written medical opinion within 30 days of the employee examination, and that the employee also gets a copy of the written medical opinion for the employer within 30 days. The PLHCP may choose to directly provide the employee a copy of the written medical opinion. This can be particularly helpful to employees, such as construction employees, who may change employers frequently. The written medical opinion can be used by the employee as proof of up-to-date medical surveillance. The following lists the elements of the written medical report for the employee and written medical opinion for the employer. (Sample forms for the written medical report for the employee, the written medical opinion for the employer, and the written authorization are provided in Section 7 of this Appendix.)

3.1.1. The written medical report for the employee must include the following information:

3.1.1.1. A statement indicating the results of the medical examination, including any medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica and any medical conditions that require further evaluation or treatment;

3.1.1.2. Any recommended limitations upon the employee's use of a respirator;

3.1.1.3. Any recommended limitations on the employee's exposure to respirable crystalline silica; and

3.1.1.4. A statement that the employee should be examined by a Board Certified Specialist in Pulmonary Disease or Occupational Medicine, where the standard requires or where the PLHCP has determined such a referral is necessary. The standard requires referral to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine for a chest X-ray B reading indicating small opacities in a profusion of 1/0 or higher, or if the PHLCP determines that referral to a Specialist is necessary for other silica-related findings.

3.1.2. The PLHCP's written medical opinion for the employer must include only the following information:

3.1.2.1. The date of the examination;

3.1.2.2. A statement that the examination has met the requirements of this section; and

3.1.2.3. Any recommended limitations on the employee's use of respirators.

3.1.2.4. If the employee provides the PLHCP with written authorization, the written opinion for the employer shall also contain either or both of the following:

(1) Any recommended limitations on the employee's exposure to respirable crystalline silica; and

(2) A statement that the employee should be examined by a Board Certified Specialist in Pulmonary Disease or Occupational Medicine if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the B Reader, or if referral to a Specialist is otherwise deemed appropriate.

3.1.2.5. In addition to the above referral for abnormal chest X-ray, the PLHCP may refer an employee to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine for other findings of concern during the medical surveillance examination if these findings are potentially related to silica exposure.

3.1.2.6. Although the respirable crystalline silica standard requires the employer to ensure that the PLHCP explains the results of the medical examination to the employee, the standard does not mandate how this should be done. The written medical opinion for the employer could contain a statement that the PLHCP has explained the results of the medical examination to the employee.

3.2. Medical Specialists. The silica standard requires that all employees with chest X-ray B readings of 1/0 or higher be referred to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine. If the employee has given written authorization for the employer to be informed, then the employer shall make available a medical examination by a Specialist within 30 days after receiving the PLHCP's written medical opinion.

3.2.1. The employer must provide the following information to the Board Certified Specialist in Pulmonary Disease or Occupational Medicine:

3.2.1.1. A description of the employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica;

3.2.1.2. The employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica;

3.2.1.3. A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used or will use that equipment; and

3.2.1.4. Information from records of employment-related medical examinations previously provided to the employee and currently within the control of the employer.

3.2.2. The PLHCP should make certain that, with written authorization from the employee, the Board Certified Specialist in Pulmonary Disease or Occupational Medicine has any other pertinent medical and occupational information necessary for the specialist's evaluation of the employee's condition.

3.2.3. Once the Board Certified Specialist in Pulmonary Disease or Occupational Medicine has evaluated the employee, the employer must ensure that the Specialist explains to the employee the results of the medical examination and provides the employee with a written medical report within 30 days of the examination. The employer must also ensure that the Specialist provides the employer with a written medical opinion within 30 days of the employee examination. (Sample forms for the written medical report for the employee, the written medical opinion for the employer and the written authorization are provided in Section 7 of this Appendix.)

3.2.4. The Specialist's written medical report for the employee must include the following information:

3.2.4.1. A statement indicating the results of the medical examination, including any medical condition(s) that would place the employee at increased risk of material impairment to

health from exposure to respirable crystalline silica and any medical conditions that require further evaluation or treatment;

3.2.4.2. Any recommended limitations upon the employee's use of a respirator; and

3.2.4.3. Any recommended limitations on the employee's exposure to respirable crystalline silica.

3.2.5. The Specialist's written medical opinion for the employer must include the following information:

3.2.5.1. The date of the examination; and

3.2.5.2. Any recommended limitations on the employee's use of respirators.

3.2.5.3. If the employee provides the Board Certified Specialist in Pulmonary Disease or Occupational Medicine with written authorization, the written medical opinion for the employer shall also contain any recommended limitations on the employee's exposure to respirable crystalline silica.

3.2.5.4. Although the respirable crystalline silica standard requires the employer to ensure that the Board Certified Specialist in Pulmonary Disease or Occupational Medicine explains the results of the medical examination to the employee, the standard does not mandate how this should be done. The written medical opinion for the employer could contain a statement that the Specialist has explained the results of the medical examination to the employee.

3.2.6. After evaluating the employee, the Board Certified Specialist in Pulmonary Disease or Occupational Medicine should provide feedback to the PLHCP as appropriate, depending on the reason for the referral. OSHA believes that because the PLHCP has the primary relationship with the employer and employee, the Specialist may want to communicate his or her findings to the PLHCP and have the PLHCP simply update the original medical report

for the employee and medical opinion for the employer. This is permitted under the standard, so long as all requirements and time deadlines are met.

3.3. Public Health Professionals. PLHCPs might refer employees or consult with public health professionals as a result of silica medical surveillance. For instance, if individual cases of active TB are identified, public health professionals from state or local health departments may assist in diagnosis and treatment of individual cases and may evaluate other potentially affected persons, including coworkers. Because silica-exposed employees are at increased risk of progression from latent to active TB, treatment of latent infection is recommended. The diagnosis of active TB, acute or accelerated silicosis, or other silica-related diseases and infections should serve as sentinel events suggesting high levels of exposure to silica and may require consultation with the appropriate public health agencies to investigate potentially similarly exposed coworkers to assess for disease clusters. These agencies include local or state health departments or OSHA. In addition, NIOSH can provide assistance upon request through their Health Hazard Evaluation program. (See Section 5 of this Appendix)

4. Confidentiality and Other Considerations.

The information that is provided from the PLHCP to the employee and employer under the medical surveillance section of OSHA's respirable crystalline silica standard differs from that of medical surveillance requirements in previous OSHA standards. The standard requires two separate written communications, a written medical report for the employee and a written medical opinion for the employer. The confidentiality requirements for the written medical opinion are more stringent than in past standards. For example, the information the PLHCP can (and must) include in his or her written medical opinion for the employer is limited to: the date of the examination, a statement that the examination has met the requirements of this section,

and any recommended limitations on the employee's use of respirators. If the employee provides written authorization for the disclosure of any limitations on the employee's exposure to respirable crystalline silica, then the PLHCP can (and must) include that information in the written medical opinion for the employer as well. Likewise, with the employee's written authorization, the PLHCP can (and must) disclose the PLHCP's referral recommendation (if any) as part of the written medical opinion for the employer. However, the opinion to the employer must not include information regarding recommended limitations on the employee's exposure to respirable crystalline silica or any referral recommendations without the employee's written authorization.

The standard also places limitations on the information that the Board Certified Specialist in Pulmonary Disease or Occupational Medicine can provide to the employer without the employee's written authorization. The Specialist's written medical opinion for the employer, like the PLHCP's opinion, is limited to (and must contain): the date of the examination and any recommended limitations on the employee's use of respirators. If the employee provides written authorization, the written medical opinion can (and must) also contain any limitations on the employee's exposure to respirable crystalline silica.

The PLHCP should discuss the implication of signing or not signing the authorization with the employee (in a manner and language that he or she understands) so that the employee can make an informed decision regarding the written authorization and its consequences. The discussion should include the risk of ongoing silica exposure, personal risk factors, risk of disease progression, and possible health and economic consequences. For instance, written authorization is required for a PLHCP to advise an employer that an employee should be referred to a Board Certified Specialist in Pulmonary Disease or Occupational Medicine for evaluation of

an abnormal chest X-ray (B-reading 1/0 or greater). If an employee does not sign an authorization, then the employer will not know and cannot facilitate the referral to a Specialist and is not required to pay for the Specialist's examination. In the rare case where an employee is diagnosed with acute or accelerated silicosis, co-workers are likely to be at significant risk of developing those diseases as a result of inadequate controls in the workplace. In this case, the PLHCP and/or Specialist should explain this concern to the affected employee and make a determined effort to obtain written authorization from the employee so that the PLHCP and/or Specialist can contact the employer.

Finally, without written authorization from the employee, the PLHCP and/or Board Certified Specialist in Pulmonary Disease or Occupational Medicine cannot provide feedback to an employer regarding control of workplace silica exposure, at least in relation to an individual employee. However, the regulation does not prohibit a PLHCP and/or Specialist from providing an employer with general recommendations regarding exposure controls and prevention programs in relation to silica exposure and silica-related illnesses, based on the information that the PLHCP receives from the employer such as employees' duties and exposure levels. Recommendations may include increased frequency of medical surveillance examinations, additional medical surveillance components, engineering and work practice controls, exposure monitoring and personal protective equipment. For instance, more frequent medical surveillance examinations may be a recommendation to employers for employees who do abrasive blasting with silica because of the high exposures associated with that operation.

ACOEM's Code of Ethics and discussion is a good resource to guide PLHCPs regarding the issues discussed in this section (See Section 5 of this Appendix).

5. Resources.

5.1. American College of Occupational and Environmental Medicine (ACOEM):

ACOEM Code of Ethics. Accessed at: <http://www.acoem.org/codeofconduct.aspx>

Raymond, L.W. and Wintermeyer, S. (2006) ACOEM evidenced-based statement on medical surveillance of silica-exposed workers: medical surveillance of workers exposed to crystalline silica. *J Occup Environ Med*, 48, 95-101.

5.2. Center for Disease Control and Prevention (CDC)

Tuberculosis webpage: <http://www.cdc.gov/tb/default.htm>

State TB Control Offices web page: <http://www.cdc.gov/tb/links/tboffices.htm>

Tuberculosis Laws and Policies webpage: <http://www.cdc.gov/tb/programs/laws/default.htm>

CDC. (2013). Latent Tuberculosis Infection: A Guide for Primary Health Care Providers.

Accessed at: <http://www.cdc.gov/tb/publications/ltbi/pdf/targetedltbi.pdf>

5.3. International Labour Organization

International Labour Office (ILO). (2011) Guidelines for the use of the ILO International Classification of Radiographs of Pneumoconioses, Revised edition 2011. Occupational Safety and Health Series No. 22: http://www.ilo.org/safework/info/publications/WCMS_168260/lang--en/index.htm

5.4. National Institute of Occupational Safety and Health (NIOSH)

NIOSH B Reader Program webpage. (Information on interpretation of X-rays for silicosis and a list of certified B-readers). Accessed at:

<http://www.cdc.gov/niosh/topics/chestradiography/breader-info.html>

NIOSH Guideline (2011). Application of Digital Radiography for the Detection and Classification of Pneumoconiosis. NIOSH publication number 2011-198. Accessed at:

<http://www.cdc.gov/niosh/docs/2011-198/>

NIOSH Hazard Review (2002), Health Effects of Occupational Exposure to Respirable Crystalline Silica. NIOSH publication number 2002-129: Accessed at

<http://www.cdc.gov/niosh/docs/2002-129/>

NIOSH Health Hazard Evaluations Programs. (Information on the NIOSH Health Hazard Evaluation (HHE) program, how to request an HHE and how to look up an HHE report).

Accessed at: <http://www.cdc.gov/niosh/hhe/>

5.5. National Industrial Sand Association:

Occupational Health Program for Exposure to Crystalline Silica in the Industrial Sand Industry.

National Industrial Sand Association, 2nd ed. 2010. Can be ordered at:

<http://www.sand.org/silica-occupational-health-program>

5.6. Occupational Safety and Health Administration (OSHA)

Contacting OSHA: http://www.osha.gov/html/Feed_Back.html

OSHA's Clinicians webpage. (OSHA resources, regulations and links to help clinicians navigate

OSHA's web site and aid clinicians in caring for workers.) Accessed at:

<http://www.osha.gov/dts/oom/clinicians/index.html>

OSHA's Safety and Health Topics webpage on Silica. Accessed at:

<http://www.osha.gov/dsg/topics/silicacrystalline/index.html>

OSHA (2013). Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals. (OSHA 3637-03 2013). Accessed at:

<http://www.osha.gov/Publications/OSHA3637.pdf>

OSHA/NIOSH (2011). Spirometry: OSHA/NIOSH Spirometry InfoSheet (OSHA 3415-1-11).

(Provides guidance to employers). Accessed at <http://www.osha.gov/Publications/osha3415.pdf>

OSHA/NIOSH (2011) Spirometry: OSHA/NIOSH Spirometry Worker Info. (OSHA 3418-3-11). Accessed at <http://www.osha.gov/Publications/osha3418.pdf>

5.7. Other

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(This article reviews not only silica and lung cancer but also all the known silica-related health effects. Further, the authors provide guidance to clinicians on medical surveillance of silica-exposed workers and worker counselling on safety practices to minimize silica exposure.)

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Laney, A. S., Petsonk, E. L., and Attfield, M. D. (2011). Intramodality and intermodality comparisons of storage phosphor computed radiography and conventional film-screen radiography in the recognition of small pneumonconiotic opacities. Chest, 140,1574-1580.

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7. Sample Forms.

Three sample forms are provided. The first is a sample written medical report for the employee. The second is a sample written medical opinion for the employer. And the third is a sample written authorization form that employees sign to clarify what information the employee is authorizing to be released to the employer.

WRITTEN MEDICAL REPORT FOR EMPLOYEE

EMPLOYEE NAME: _____

DATE OF EXAMINATION: _____

TYPE OF EXAMINATION:

Initial examination Periodic examination Specialist examination
 Other: _____

RESULTS OF MEDICAL EXAMINATION:

Physical Examination – Normal Abnormal (see below) Not performed
Chest X-Ray – Normal Abnormal (see below) Not performed
Breathing Test (Spirometry) – Normal Abnormal (see below) Not performed
Test for Tuberculosis – Normal Abnormal (see below) Not performed
Other: _____ Normal Abnormal (see below) Not performed

Results reported as abnormal: _____

Your health may be at increased risk from exposure to respirable crystalline silica due to the following:

RECOMMENDATIONS:

No limitations on respirator use
 Recommended limitations on use of respirator: _____
 Recommended limitations on exposure to respirable crystalline silica: _____

Dates for recommended limitations, if applicable: _____ to _____
MM/DD/YYYY MM/DD/YYYY

I recommend that you be examined by a Board Certified Specialist in Pulmonary Disease or Occupational Medicine

Other recommendations*:

Your next periodic examination for silica exposure should be in: 3 years Other: _____
MM/DD/YYYY

Examining Provider: _____ Date: _____
(signature)

Provider Name: _____

Office Address: _____ Office Phone: _____

*These findings may not be related to respirable crystalline silica exposure or may not be work-related, and therefore may not be covered by the employer. These findings may necessitate follow-up and treatment by your personal physician.

Respirable Crystalline Silica standard (§ 1910.1053 or 1926.1153)

WRITTEN MEDICAL OPINION FOR EMPLOYER

EMPLOYER: _____

EMPLOYEE NAME: _____

DATE OF EXAMINATION: _____

TYPE OF EXAMINATION:

Initial examination Periodic examination Specialist examination

Other: _____

USE OF RESPIRATOR:

No limitations on respirator use

Recommended limitations on use of respirator: _____

Dates for recommended limitations, if applicable: _____ to _____
MM/DD/YYYY MM/DD/YYYY

The employee has provided written authorization for disclosure of the following to the employer (if applicable):

This employee should be examined by an American Board Certified Specialist in Pulmonary Disease or Occupational Medicine

Recommended limitations on exposure to respirable crystalline silica: _____

Dates for exposure limitations noted above: _____ to _____
MM/DD/YYYY MM/DD/YYYY

NEXT PERIODIC EVALUATION: 3 years Other: _____
MM/DD/YYYY

Examining Provider: _____
(signature)

Date: _____

Provider Name: _____

Provider's specialty: _____

Office Address: _____

Office Phone: _____

I attest that the results have been explained to the employee.

The following is required to be checked by the Physician or other Licensed Health Care Professional (PLHCP):

I attest that this medical examination has met the requirements of the medical surveillance section of the OSHA Respirable Crystalline Silica standard (§ 1910.1053(h) or 1926.1153(h)).

AUTHORIZATION FOR CRYSTALLINE SILICA OPINION TO EMPLOYER

This medical examination for exposure to crystalline silica could reveal a medical condition that results in recommendations for (1) limitations on respirator use, (2) limitations on exposure to crystalline silica, or (3) examination by a specialist in pulmonary disease or occupational medicine. Recommended limitations on respirator use will be included in the written opinion to the employer. If you want your employer to know about limitations on crystalline silica exposure or recommendations for a specialist examination, you will need to give authorization for the written opinion to the employer to include one or both of those recommendations.

I hereby authorize the opinion to the employer to contain the following information, if relevant (please check all that apply):

Recommendations for limitations on crystalline silica exposure

Recommendation for a specialist examination

OR

I do not authorize the opinion to the employer to contain anything other than recommended limitations on respirator use.

Please read and initial:

____ I understand that if I do not authorize my employer to receive the recommendation for specialist examination, the employer will not be responsible for arranging and covering costs of a specialist examination.

Name (printed)

Signature

Date

OSHA's Crystalline Silica Rule: Stakeholder Participation and Changes to the Standards

OSHA's final rule is the result of extensive review of the scientific evidence on adverse health effects associated with exposure to respirable crystalline silica — analysis of the feasibility of limiting exposures and providing other protective measures and, importantly, substantial input by stakeholders.

Stakeholder involvement in the rulemaking

OSHA's rulemaking process involves significant engagement with stakeholders. Information and comment provided by the public contribute to development of rules that protect workers, are based on the best available evidence, and are feasible for employers.

OSHA obtained input from the public on the silica rule through a variety of methods, including:

Engagement with small businesses.

OSHA obtained input from small business representatives throughout the rulemaking process. OSHA's engagement with small businesses started early with review under the *Small Business Regulatory Enforcement Fairness Act* (SBREFA). The SBREFA panel, including representatives from OSHA, the Small Business Administration's Office of Advocacy, and the Office of Management and Budget, conferred with small entity representatives from general industry, maritime, and construction. The panel's final report includes comments and recommendations to OSHA for the proposed rule, which resulted in many changes to the proposal. Many small businesses submitted comments and participated in the 14 days of public hearings on the proposed rule.

Consultation with advisory committees.

Throughout the rulemaking process, OSHA engaged with the agency's Advisory Committee on Construction Safety and Health, and the Maritime Advisory Committee on Occupational Safety and Health. These diverse committees include representatives of employers, workers, and other stakeholders.

Public comments and public hearings. OSHA published its Notice of Proposed Rulemaking for respirable crystalline silica in the *Federal Register* on September 12, 2013. Interested parties had nearly five months, until February 11, 2014, to submit comments on the proposed rule.

OSHA held 14 days of informal public hearings on the proposed rule in Washington, D.C., from March 18 through April 4, 2014. More than 200 stakeholders testified, including representatives from more than 70 organizations, such as public health groups, trade associations, labor unions, businesses, and workers. OSHA allowed hearing participants until June 3, 2014, to submit additional information and data to the record, and until August 18, 2014, to submit final briefs and arguments.

OSHA received more than 2,000 comments during the pre- and post-hearing public participation period. Hearing transcripts contain more than 4,400 pages of testimony on the proposed rule.

Changes to the proposed standards

The final standards include several major changes from the proposed standards as a result of OSHA's analysis of written comments and testimony on the proposed rule. These changes include:

Scope. The scope of the standards has been revised to exclude tasks that involve low exposures; the standards do not apply where worker exposures to respirable crystalline silica will remain below 25 $\mu\text{g}/\text{m}^3$ as an 8-hour time-weighted average under any foreseeable conditions (employers in general industry and maritime must have evidence to support this exception).

The standard for general industry and maritime does not apply to exposures that result from the processing of sorptive clays (i.e., specific types of clay found in a few geologic deposits in the country that are used in a range of consumer products and industrial applications, such as pet litter and sealants for landfills).

The standard for general industry and maritime also allows employers to comply with the specified exposure control methods in the standard for construction instead of complying with the PEL in certain circumstances.

Specified exposure control methods. The proposed construction standard included Table 1, which lists exposure control methods for common construction tasks. The proposed standard would have required employers following Table 1 to comply with the permissible exposure limit (PEL). Under the final standard, employers who fully and properly implement the exposure control methods for tasks listed on Table 1 of the standard are not subject to the PEL, and are not required to assess worker exposures to silica or comply with other provisions of the standard on use of engineering and work practice controls.

The entries on Table 1 have also been revised extensively to include additional tasks and divide entries for greater specificity; Table 1 now includes 18 entries, as opposed to 13 in the proposed standard. Most notes in the proposed entries were also removed, making Table 1 easier to follow.

Protective clothing. The proposed standards would have required use of protective clothing in some situations. The final standards do not include that requirement.

Housekeeping. The proposed standards would have prohibited use of compressed air, dry sweeping and dry brushing to clean clothing or surfaces contaminated with crystalline silica where such activities could contribute to employee exposure to respirable crystalline silica that exceeds the PEL. The final standards allow for use of compressed air, dry sweeping, and dry brushing where other cleaning methods are not feasible.

Written exposure control plan. The proposed standards did not include a requirement for employers to develop a written exposure control plan. The final standards require employers to develop a written exposure control plan, and the standard for construction requires a competent person to implement the plan.

Regulated areas. OSHA proposed alternatives for employers to limit access to areas where exposure exceeds the PEL.

- The final standard for general industry and maritime requires regulated areas where exposures exceed the PEL. The posting of warning signs at the entrances to regulated areas is also required.
- The final construction standard requires procedures to restrict access to work areas in the written exposure control plan.

Medical surveillance. The proposed rule would have required employers to make medical surveillance available to employees exposed to respirable crystalline silica above the PEL for 30 or more days per year. The final standard for general industry and maritime requires medical surveillance to be made available to employees exposed at or above the action level for 30 or more days per year, and the construction standard requires medical surveillance to be made available to employees required by the standard to use a respirator for 30 or more days per year.

Employers are required to obtain a written medical opinion for the medical examinations provided for under the standards. Unlike the proposal, in the final standards the information in the written medical opinion provided to the employer is limited to the date of the examination; a statement that the examination met the requirements of the standard; and any recommended limitations on the employee's use of respirators. If the employee provides written authorization, the opinion provided to the employer will include any recommended limitations on the employee's exposure, and/or any referral to a specialist.

Dates. The final standards have been revised to allow employers more time to comply with the requirements. Extensions include:

- Compliance with most provisions is required one year after the effective date for construction and two years after the effective date for general industry and maritime employers, instead of 180 days after the effective date for most provisions and one year after the effective date for engineering controls as proposed;
- Hydraulic fracturing operations in the oil and gas industry must comply with most provisions two years after the effective date, but are provided additional time (five years after the effective date) to implement engineering controls to limit exposures to the new PEL; and
- A staggered implementation schedule is set up for medical surveillance requirements in the standard for general industry and maritime.

Additional information

Additional information on OSHA's silica rule can be found at www.osha.gov/silica.

OSHA can provide extensive help through a variety of programs, including technical assistance about effective safety and health programs, workplace consultations, and training and education.

OSHA's On-site Consultation Program offers free and confidential occupational safety and health services to small and medium-sized businesses in all states and several territories across the country, with priority given to high-hazard worksites. On-site consultation services are separate from enforcement and do not result in penalties or citations. Consultants from state agencies or universities work with employers to identify workplace hazards, provide advice on compliance with OSHA standards, and assist in establishing and improving safety and health management systems. To locate the OSHA On-site Consultation Program nearest you, call 1-800-321-OSHA (6742) or visit www.osha.gov/dcsp/smallbusiness.

For more information on this and other health-related issues impacting workers, to report an emergency, fatality, inpatient hospitalization, or to file a confidential complaint, contact your nearest OSHA office, visit www.osha.gov, or call OSHA at 1-800-321-OSHA (6742), TTY 1-877-889-5627.

This is one in a series of informational fact sheets highlighting OSHA programs, policies or standards. It does not impose any new compliance requirements. For a comprehensive list of compliance requirements of OSHA standards or regulations, refer to Title 29 of the Code of Federal Regulations. This information will be made available to sensory-impaired individuals upon request. The voice phone is (202) 693-1999; teletypewriter (TTY) number: (877) 889-5627.

For assistance, contact us. We can help. It's confidential.



www.osha.gov (800) 321-OSHA (6742)



U.S. Department of Labor