

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 PLHCP 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

Steenland, K. and Ward E. (2014). Silica: A lung carcinogen. CA Cancer J Clin, 64, 63-69.

(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.)

6. References.

American Thoracic Society (ATS). Medical Section of the American Lung Association (1997). Adverse effects of crystalline silica exposure. Am J Respir Crit Care Med, 155, 761-765.

American Thoracic Society (ATS), Centers for Disease Control (CDC), Infectious Diseases Society of America (IDSA) (2005). Controlling Tuberculosis in the United States.

Morbidity and Mortality Weekly Report (MMWR), 54(RR12), 1-81. Accessed at:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5412a1.htm>

Brown, T. (2009). Silica exposure, smoking, silicosis and lung cancer – complex interactions. Occupational Medicine, 59, 89-95.

Halldin, C. N., Petsonk, E. L., and Laney, A. S. (2014). Validation of the International Labour Office digitized standard images for recognition and classification of radiographs of pneumoconiosis. Acad Radiol, 21,305-311.

International Agency for Research on Cancer. (2012). Monographs on the evaluation of carcinogenic risks to humans: Arsenic, Metals, Fibers, and Dusts Silica Dust, Crystalline, in the Form of Quartz or Cristobalite. A Review of Human Carcinogens. Volume 100 C. Geneva, Switzerland: World Health Organization.

Jalloul, A. S. and Banks D. E. (2007). Chapter 23. The health effects of silica exposure. In: Rom, W. N. and Markowitz, S. B. (Eds). Environmental and Occupational Medicine, 4th edition. Lippincott, Williams and Wilkins, Philadelphia, 365-387.

Kramer, M. R., Blanc, P. D., Fireman, E., Amital, A., Guber, A., Rahman, N. A., and Shitrit, D. (2012). Artificial stone silicosis: disease resurgence among artificial stone workers. Chest, 142, 419-424.

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 pneumoconiotic opacities. Chest, 140,1574-1580.

Liu, Y., Steenland, K., Rong, Y., Hnizdo, E., Huang, X., Zhang, H., Shi, T., Sun, Y., Wu, T., and Chen, W. (2013). Exposure-response analysis and risk assessment for lung cancer in

relationship to silica exposure: a 44-year cohort study of 34,018 workers. Am J Epi, 178,1424-1433.

Liu, Y., Rong, Y., Steenland, K., Christiani, D. C., Huang, X., Wu, T., and Chen, W. (2014). Long-term exposure to crystalline silica and risk of heart disease mortality. Epidemiology, 25, 689-696.

Mazurek, G. H., Jereb, J., Vernon, A., LoBue, P., Goldberg, S., Castro, K. (2010). Updated guidelines for using interferon gamma release assays to detect Mycobacterium tuberculosis infection – United States. Morbidity and Mortality Weekly Report (MMWR), 59(RR05), 1-25.

Miller, M. R., Hankinson, J., Brusasco, V., Burgos, F., Casaburi, R., Coates, A., Crapo, R., Enright, P., van der Grinten, C. P., Gustafsson, P., Jensen, R., Johnson, D. C., MacIntyre, N., McKay, R., Navajas, D., Pedersen, O. F., Pellegrino, R., Viegi, G., and Wanger, J. (2005).

American Thoracic Society/European Respiratory Society (ATS/ERS) Task Force: Standardisation of Spirometry. Eur Respir J, 26, 319-338.

National Toxicology Program (NTP) (2014). Report on Carcinogens, Thirteenth Edition. Silica, Crystalline (respirable Size). Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service.

<http://ntp.niehs.nih.gov/ntp/roc/content/profiles/silica.pdf>

Occupational Safety and Health Administration/National Institute for Occupational Safety and Health (OSHA/NIOSH) (2012). Hazard Alert. Worker exposure to silica during hydraulic fracturing.

Occupational Safety and Health Administration/National Institute for Occupational Safety and Health (OSHA/NIOSH) (2015). Hazard alert. Worker exposure to silica during countertop manufacturing, finishing, and installation. (OSHA- HA-3768-2015).

Redlich, C. A., Tarlo, S. M., Hankinson, J. L., Townsend, M. C, Eschenbacher, W. L., Von Essen, S. G., Sigsgaard, T., Weissman, D. N. (2014). Official American Thoracic Society technical standards: spirometry in the occupational setting. Am J Respir Crit Care Med; 189, 984-994.

Rees, D. and Murray, J. (2007). Silica, silicosis and tuberculosis. Int J Tuberc Lung Dis, 11(5), 474-484.

Shtraichman, O., Blanc, P. D., Ollech, J. E., Fridel, L., Fuks, L., Fireman, E., and Kramer, M. R. (2015). Outbreak of autoimmune disease in silicosis linked to artificial stone. Occup Med, 65, 444-450.

Slater, M. L., Welland, G., Pai, M., Parsonnet, J., and Banaei, N. (2013). Challenges with QuantiFERON-TB gold assay for large-scale, routine screening of U.S. healthcare workers. Am J Respir Crit Care Med, 188,1005-1010.

Steenland, K., Mannetje, A., Boffetta, P., Stayner, L., Attfield, M., Chen, J., Dosemeci, M., DeKlerk, N., Hnizdo, E., Koskela, R., and Checkoway, H. (2001). International Agency for Research on Cancer. Pooled exposure-response analyses and risk assessment for lung cancer in 10 cohorts of silica-exposed workers: an IARC multicentre study. Cancer Causes Control,12(9):773-84.

Steenland, K. and Ward E. (2014). Silica: A lung carcinogen. CA Cancer J Clin, 64, 63-69.

Townsend, M. C. ACOEM Guidance Statement. (2011). Spirometry in the occupational health setting – 2011 Update. J Occup Environ Med, 53, 569-584.

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 –	<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal (see below)	<input type="checkbox"/> Not performed
Chest X-Ray –	<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal (see below)	<input type="checkbox"/> Not performed
Breathing Test (Spirometry) –	<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal (see below)	<input type="checkbox"/> Not performed
Test for Tuberculosis –	<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal (see below)	<input type="checkbox"/> Not performed
Other: _____	<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal (see below)	<input type="checkbox"/> 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: _____
(signature)

Date: _____

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)

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