OSHA® FactSheet

OSHA's Crystalline Silica Rule: General Industry and Maritime

OSHA is issuing two standards to protect workers from exposure to respirable crystalline silica — one for general industry and maritime, and the other for construction — in order to allow employers to tailor solutions to the specific conditions in their workplaces.

Who is affected by the general industry and maritime standard?

About 295,000 workers are exposed to respirable crystalline silica in over 75,000 general industry and maritime workplaces. Exposure to respirable crystalline silica can cause silicosis, lung cancer, other respiratory diseases, and kidney disease.

Some of the affected industries are shown below.

Number of Workers Exposed to Respirable Crystalline Silica in Selected General Industry/ Maritime Sectors

Industry sector	Workers currently exposed	Workers currently exposed above the new PEL
Asphalt Roofing Materials	3,158	1,410
Concrete Products	32,981	9,391
Cut Stone	9,429	5,243
Dental Laboratories	31,105	864
Foundries	34,591	12,173
Jewelry	6,772	2,434
Porcelain Enameling	4,113	1,654
Pottery	6,269	2,496
Railroads	16,895	5,340
Ready-Mix Concrete	27,123	19,941
Shipyards	3.038	2,228
Structural Clay Products	7,893	3,198
Support Activities for Oil and Gas Operations	16,960	11,207

OSHA estimates that over 100,000 workers in general industry and maritime are exposed to silica levels that exceed the new permissible exposure limit (PEL).

What does the standard require?

The standard for general industry and maritime requires employers to:

- Measure the amount of silica that workers are exposed to if it may be at or above an action level of 25 μg/m³ (micrograms of silica per cubic meter of air), averaged over an 8-hour day;
- Protect workers from respirable crystalline silica exposures above the permissible exposure limit of 50 µg/m³, averaged over an 8-hour day;
- Limit workers' access to areas where they could be exposed above the PEL;
- Use dust controls to protect workers from silica exposures above the PEL;
- Provide respirators to workers when dust controls cannot limit exposures to the PEL;
- Restrict housekeeping practices that expose workers to silica where feasible alternatives are available;
- Establish and implement a written exposure control plan that identifies tasks that involve exposure and methods used to protect workers;
- Offer medical exams including chest X-rays and lung function tests — every three years for workers exposed at or above the action level for 30 or more days per year;
- Train workers on work operations that result in silica exposure and ways to limit exposure; and
- **Keep records** of workers' silica exposure and medical exams.

Source: OSHA Directorate of Standards and Guidance

Examples — Dust control methods

In most cases, dust controls such as wet methods and ventilation can be used to limit workers' exposure to silica. These technologies are widely available, affordable and already commonly used by many employers.



A worker cutting granite using a saw that applies water to the blade. The water reduces the amount of silica-containing dust that gets into the air.



A worker grinding castings in a foundry. The work is performed in a ventilated booth to reduce the worker's exposure to silica.

When are employers required to comply with the standard?

General industry and maritime employers must comply with all requirements of the standard by **June 23, 2018**, except for the following:

- Medical surveillance must be offered to employees who will be exposed at or above the action level for 30 or more days a year starting on June 23, 2020. (Medical surveillance must be offered to employees who will be exposed above the PEL for 30 or more days a year starting June 23, 2018.)
- **Hydraulic fracturing** operations in the oil and gas industry must implement engineering controls to limit exposures to the new PEL by June 23, 2021.

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 highhazard 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 healthrelated 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.





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U.S. Department of Labor

OSHA® FactSheet

Workers' Exposure to Respirable Crystalline Silica: Final Rule Overview

More than 2 million workers gain protections from deadly dust

Background

Workplace illness takes the lives of thousands of workers each year. Those workers and their families rely on the U.S. Department of Labor's Occupational Safety and Health Administration to set and enforce standards that reduce the risk to those workers of contracting illnesses or suffering injuries on the job, so that no worker is forced to sacrifice their life or health for their livelihood. Respirable crystalline silica is particularly hazardous for the nation's workers.

Workers who inhale very small crystalline silica particles are at increased risk of developing serious — and often deadly — silica-related diseases. These tiny particles (known as "respirable" particles) can penetrate deep into workers' lungs and cause silicosis, an incurable and sometimes fatal lung disease. Crystalline silica exposure also puts workers at risk for developing lung cancer, other potentially debilitating respiratory diseases such as chronic obstructive pulmonary disease, and kidney disease. Approximately 2.3 million people in the U.S. are exposed to silica at work.

To better protect workers from dangerous crystalline silica, OSHA has finalized two new silica standards: one for general industry and maritime, and the other for construction. These rules are based on extensive review of peer-reviewed scientific evidence, current industry consensus standards, an extensive public outreach effort, and nearly a year of public comment, including several weeks of public hearings. They provide commonsense, affordable and flexible strategies for employers to protect workers in their workplaces from the serious risks posed by silica exposure.

OSHA estimates these standards will save the lives of more than 600 workers each year and prevent more than 900 cases of silicosis each year once the full effects of the rule are realized.

What is crystalline silica?

Crystalline silica is a common mineral that is found in materials that we see every day in roads, buildings, and sidewalks. It is a common component of sand, stone, rock, concrete, brick, block, and mortar.

• Exposures to crystalline silica dust occur in common workplace operations involving cutting, sawing, drilling, and crushing of concrete, brick, block, rock, and stone products (such as construction tasks), and operations using sand products (such as in glass manufacturing, foundries, sand blasting, and hydraulic fracturing).

Why do we need new silica standards?

- We have known about the dangers of silica for decades. More than 80 years ago, U.S. Secretary of Labor Frances Perkins first brought experts and stakeholders together to determine the best ways to protect workers from silica.
- OSHA's current permissible exposure limits for silica are more than 40 years old. They are based on research from the 1960s and earlier that do not reflect more recent scientific evidence.
- Strong evidence shows that the current exposure limits do not adequately protect worker health. For example, since the current exposure limits were adopted, respirable crystalline silica exposure has been found to cause lung cancer and kidney disease at the levels currently permitted.
- Many employers are already implementing the necessary measures to protect their workers from silica exposure. The technology for most employers to meet the new standards is widely available and affordable.

How will the rule protect workers?

 The rule significantly reduces the amount of silica dust that workers can be exposed to on the job. That means that employers will have to implement controls and work practices that reduce workers' exposure to silica dust. For most activities, that means that employers will have to ensure that silica dust is wetted down or vacuumed up before workers can breathe it in.

 Employers are required under the rule to limit access to high exposure areas, provide training, provide respiratory protection when controls are not enough to limit exposure, provide written exposure control plans, and measure exposures in some cases.
 Employers are also required to offer medical examinations to highly exposed workers.
 Workers who find out they have an illness, such as lung disease, can use that information to make employment or lifestyle decisions to protect their health.

How will OSHA help employers comply with the rule to protect their workers?

- The rule provides flexibility to help employers especially small businesses — protect workers from silica exposure, with staggered compliance dates to ensure sufficient time to meet the requirements. Employers have from one to five years to get the right protections in place.
- The rule includes special flexibility for the construction industry. For the most common tasks in construction, OSHA has spelled out exactly how to best protect workers. If employers follow those specifications, they can be sure that they are providing their workers with the required level of protection. If they have better ideas about how to provide protection, they can do that too as long as they make sure that their methods effectively reduce their workers' exposure to silica dust.

What industries are affected?

Affected industries include:

- Construction
- Glass manufacturing
- Pottery products
- Structural clay products

- Concrete products
- Foundries
- Dental laboratories
- Paintings and coatings
- Jewelry production
- Refractory products
- Ready-mix concrete
- · Cut stone and stone products
- Abrasive blasting in maritime, construction, and general industry
- Refractory furnace installation and repair
- Railroad transportation
- Oil and gas operations

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.

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Background and Health Impacts

What is crystalline silica?

Crystalline silica is a common mineral found in many naturally occurring materials and used in many industrial products and at construction sites. Materials like sand, concrete, stone and mortar contain crystalline silica. Crystalline silica is also used to make products such as glass, pottery, ceramics, bricks, concrete and artificial stone. Industrial sand used in certain operations, such as foundry work and hydraulic fracturing (fracking), is also a source of silica exposure.

How can exposure to crystalline silica affect workers' health?

Inhaling very small ("respirable") crystalline silica particles, causes multiple diseases, including silicosis, an incurable lung disease that can lead to disability and death. Respirable crystalline silica also causes lung cancer, chronic obstructive pulmonary disease (COPD), and kidney disease.

Who is at risk from exposure to crystalline silica?

Around 2.3 million workers are exposed to crystalline silica on the job. Simply being near sand or other silica-containing materials is not hazardous. The hazard exists when specific activities create respirable dust that is released into the air.

Respirable crystalline silica – very small particles typically at least 100 times smaller than ordinary sand found on beaches or playgrounds – is generated by high-energy operations like cutting, sawing, grinding, drilling and crushing stone, rock, concrete, brick, block and mortar; or when using industrial sand. Activities such as abrasive blasting with sand; sawing brick or concrete; sanding or drilling into concrete walls; grinding mortar; manufacturing brick, concrete blocks, or ceramic products; and cutting or crushing stone generates respirable dust.

What is the relationship between silica exposure and lung cancer?

There is strong scientific evidence showing that exposure to respirable crystalline silica can increase a person's risk of developing lung cancer. The World Health Organization's International Agency for Research on Cancer – the leading international voice on cancer causation – and the National Institutes of Health's National Toxicology Program have conducted extensive reviews of the scientific literature and have designated crystalline silica as a **known human carcinogen**. The American Cancer Society has adopted the WHO and NIH's determinations.

More than 50 peer-reviewed epidemiological studies that OSHA evaluated for this rulemaking have examined the link between silica exposure and lung cancer in at least 10 industries. In particular, several studies of workers in specific industrial sectors support the link between exposure to respirable crystalline silica and lung cancer among workers.

How will the crystalline silica rule protect workers' health?

The new rule requires that employers use engineering controls – such as ventilation and wet methods for cutting and sawing crystalline silica-containing materials – to reduce workers' exposure to silica dust. Once the full effects of the rule are realized, OSHA expects it to prevent 600 deaths a year from silica-related diseases – such as silicosis, lung cancer, other respiratory diseases and kidney disease – and to prevent more than 900 new cases of silicosis each year.

Need for a Silica Rule

Why is OSHA issuing a new crystalline silica rule?

OSHA's previous permissible exposure limits (PELs) for silica were outdated, inconsistent and did not adequately protect worker health. The previous PELs were based on studies from the 1960s and earlier that did not reflect more recent scientific evidence showing that low-level exposures to silica cause serious health effects, including lung cancer. In the 45 years since the previous PELs were established, the U.S. National Toxicology Program, the International Agency for Research on Cancer, and the National Institute for Occupational Safety and Health have all identified respirable crystalline silica as a human carcinogen. Previous construction and shipyard PELs were based on an old method of measuring worker exposures to silica that is not used today. Those previous limits are inconsistent, allowing permissible levels for construction and shipyards to be more than twice as high as levels in general industry. The revised rule will reduce the risk of disease among workers who inhale respirable crystalline silica and provide the same protection for all workers covered.

There is evidence of a decline of silicosis cases in recent years. Why is the rule necessary if the silicosis problem in the U.S. seems to be going away?

Silicosis deaths have declined in recent years but the problem remains serious. From 2005 through 2014, silicosis was listed as the underlying or a contributing cause of death on over 1,100 death certificates in the United States,¹ but most deaths from silicosis go undiagnosed and unreported. Also, those numbers of silicosis deaths do not include additional deaths from other silica-related diseases such as COPD, lung cancer and kidney disease.

While the number of silicosis cases has declined over the past several decades, it is still a very serious workplace health problem. In fact, more workers died from silicosis in 2014 than in fires, or from being caught in or crushed by collapsing materials, such as in trench and structure collapses.²

¹ Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2014 on CDC WONDER Online Database, released 2015. Data are from the Multiple Cause of Death Files, 1999-2014, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at http://wonder.cdc.gov/mcd-icd10.html on Mar 7, 2016 2:33:51 PM

² Bureau of Labor Statistics (2014). Fatal occupational injuries by event or exposure for all fatal injuries and major private industrial sector, all United States, 2014. <u>http://www.bls.gov/iif/oshwc/cfoi/cftb0294.pdf</u>

Unless action is taken, new cases of silicosis could increase as workers are being exposed to respirable crystalline silica in some newer industries such as hydraulic fracturing and artificial stone countertop fabrication.

What is the new permissible exposure limit (PEL)?

The PEL limits worker exposures to 50 micrograms of respirable crystalline silica per cubic meter of air (μ g/m³), averaged over an eight-hour day. This level is the same for all workplaces covered by the standard (general industry/maritime and construction), and is roughly 50 percent of the previous PEL for general industry, and roughly 20 percent of the previous PEL for construction and shipyards.

The National Institute for Occupational Safety and Health (NIOSH) first recommended this exposure limit to OSHA over 40 years ago, and the American Public Health Association has also recommended that OSHA adopt this PEL. The American Conference of Governmental Industrial Hygienists recommends an even lower exposure limit of 25 μ g/m³ of air, averaged over an eighthour day.

OSHA established a PEL of 50 μ g/m³ because the agency determined that occupational exposure to respirable crystalline silica at the previous PELs resulted in a significant risk of developing or dying from silicosis and dying from lung cancer, other lung diseases, or kidney disease, and that compliance with a 50 μ g/m³ PEL would substantially reduce that risk. OSHA also finds significant risk remaining at the new PEL, but considers a PEL of 50 μ g/m³ to be the lowest level that can reasonably be achieved through use of engineering controls and work practices in most affected operations.

Impacts on Industry

What industries will be affected by the rule?

The main industries affected include:

- Construction
- Glass manufacturing
- Pottery products
- Structural clay products
- Concrete products
- Foundries
- Dental laboratories
- Paintings and coatings
- Jewelry production
- Refractory products
- Landscaping

- Ready-mix concrete
- Cut stone and stone products
 - Abrasive blasting in:
 - Maritime work
 - Construction
 - General industry
- Refractory furnace installation and repair
- Railroads
- Hydraulic fracturing for gas and oil
- Asphalt products manufacturing

How many workplaces will be affected by the rule?

Approximately 676,000 workplaces will be affected, including in construction and in general industry and maritime.

How many workers will be affected by the rule?

About 2.3 million workers are exposed to respirable crystalline silica in their workplaces. The majority of these workers, about 2 million, are in the construction industry.

What is the economic impact of the rule?

The rule is estimated to provide average annual net benefits over the next 60 years of \$3.8 to \$7.7 billion. The total annualized cost of the rule is just over \$1 billion dollars.

The rule is expected to result in annual costs of about \$1,524 for the average workplace covered by the rule. The annual cost to a firm with fewer than twenty employees will be less, averaging about \$560.

Based on OSHA's analysis, the economic impact of the silica rule on most affected firms, including small businesses, will be minor.

Why does the total compliance cost of the rule appear to be so high?

The standards for general industry and construction are among the broadest that OSHA has issued, in terms of the number of industry sectors and establishments potentially affected. It potentially affects 2.3 million workers and 676,000 establishments. The costs are thus spread over a large number of affected establishments and workers.

OSHA's economic analysis indicates that the silica rule will not have a significant economic impact on firms, nor a significant effect on jobs due to implementation of the rules. The aggregate costs are more than offset by the potential benefits to society in terms of reduced costs associated with preventing silica-related illnesses and deaths.

How will the rule impact jobs?

According to a study conducted by Inforum, a well-recognized macroeconomics modeling firm based at the University of Maryland, the rule will have a negligible (but positive) net effect on overall U.S. employment.

How were small businesses included in design and evaluation of the rule?

OSHA consulted with small businesses through the normal Small Business Regulatory Enforcement Fairness Act (SBREFA) process and as part of its extensive analysis of the impacts on small businesses.

Before issuing its proposed silica rule, OSHA convened a Small Business Advocacy Review Panel in accordance with SBREFA. After issuing the proposed rule, OSHA gave members of the public, including small businesses, the opportunity to express their concerns about the rulemaking through written comments, testimony at a public hearing, and submission of data and post-hearing briefs. OSHA considered all information it received from the SBREFA panel, in addition to comments and testimony on the proposed rule, to inform the final rule and evaluate its impacts on small businesses.

In Table VII-40 in the preamble to the rule, OSHA addresses nearly 50 recommendations from small business representatives. Many of these resulted in changes to the rule or underlying cost, benefit, and economic analysis.

Rule Requirements

How can silica exposures be controlled to keep exposure at or below the PEL?

Employers must use engineering controls and work practices as the primary way keep exposures at or below the PEL.

- Engineering controls include wetting down work operations or using local exhaust ventilation (such as vacuums) to keep silica-containing dust out of the air and out of workers' lungs. Another control method that may work well is enclosing an operation ("process isolation").
- Examples of work practices to control silica exposures include wetting down dust before sweeping it up or using the water flow rate recommended by the manufacturer for a tool with water controls.
- Respirators are only allowed when engineering and work practice controls cannot maintain exposures at or below the PEL.

For construction, the standard includes Table 1, a list of common construction tasks along with exposure control methods and work practices that work well for those tasks and can be used to comply with the requirements of the standard.

Why can't silica-exposed workers just wear respirators all the time?

Respirators are not as protective as engineering controls, and they aren't always as practical either. Unless respirators are selected for each worker, individually fitted and periodically refitted, and regularly maintained, and unless filters and other parts are replaced as necessary, workers will continue to be exposed to silica. In many cases, workers using only respirators would also have to wear more extensive and expensive protection. Even when respirators are selected, fitted, and maintained correctly, they must be worn consistently and correctly by workers to be effective. Respirators can also be uncomfortable, especially in hot weather, and cannot be used by some workers.

What is Table 1: "Specified Exposure Control Methods When Working with Materials Containing Crystalline Silica"?

Table 1 is a flexible compliance option that effectively protects workers from silica exposures. It identifies 18 common construction tasks that generate high exposures to respirable crystalline silica and for each task, specifies engineering controls, work practices, and respiratory protection that effectively protect workers. Employers who fully and properly implement the engineering controls, work practices, and respiratory protection specified for a task on Table 1 are not required to measure respirable crystalline silica exposures to verify that levels are at or below the PEL for workers engaged in the Table 1 task.

OSHA developed Table 1 in response to stakeholders in the construction industry, who indicated the need for guidance and a standard that is different than a standard for general industry. Among the concerns of construction industry stakeholders were the impracticality of exposure monitoring based on short duration of task and constantly changing conditions, such as weather, job sites and materials.

Are the air sampling methods used to detect and measure silica reliable?

Yes, worker exposures to silica at the new PEL and action level can be reliably measured using existing sampling and analytical methods. Moreover, to improve reliability of silica measurements, employers must ensure that their silica samples are analyzed by laboratories that meet the qualifications and use methods specified in Appendix A of the standard.

- OSHA has carefully reviewed the available science and expert testimony contained in the rulemaking record on the ability of modern sampling and analytical methods to reliably measure respirable crystalline silica at the new PEL and action level.
- Published OSHA, NIOSH, and MSHA methods for analyzing respirable crystalline silica are able to measure concentrations at the new PEL and action level with acceptable precision, based on analyses of quality control samples and on studies conducted when those methods were developed in the 1970s.
- There are high-flow dust samplers now available that can collect more airborne dust, and more silica, than other samplers commonly used. Collecting more dust means that laboratories can measure the amount of silica in the dust with greater precision.

Why are construction employers required to implement engineering and work practice controls a year before laboratories are required to meet specifications for analyzing air samples?

There are approximately 40 laboratories in the U.S. that already meet the sample analysis requirements in the final rule. Demand for laboratory analysis of construction industry samples is likely to be modest because OSHA expects most construction employers to implement the specified exposure control measures in Table 1; therefore they will not be required to conduct exposure assessments. The small portion of construction employers that do not implement Table 1 will need to perform air monitoring, but they will be able to obtain reliable measurements of their employees' exposures from those laboratories. Employers in general industry and maritime, who are required to conduct exposure assessments, have an additional year to come into compliance.

What is the purpose of medical surveillance?

The purpose of medical surveillance is, when reasonably possible, to:

- Identify adverse health effects associated with respirable crystalline silica exposure so that appropriate actions can be taken.
- Determine if an employee has any condition, such as a lung disease, that might make him or her more sensitive to respirable crystalline silica exposure,
- Determine the employee's fitness to use respirators.

In response to the information gained through medical surveillance, employees can take actions to improve their health, such as making job choices to reduce exposures, wearing a respirator for extra protection, or making personal lifestyle or health decisions, such as quitting smoking or getting flu shots.

Why are the results of medical surveillance only given to the worker and not the employer?

The employer receives the physician or other licensed health care professional's recommended limitations on respirator use, which is vitally important information that the employer needs to protect the worker because those who are not fit to wear a respirator but wear one can be at risk of sudden incapacitation or death.

Other findings of the medical examination are only given to the employee because many employees and physicians testified that if employers received the results of the examination, many employees would not participate in medical surveillance because they feared discrimination or retaliation.

Employers do not need medical findings because they should base employee protections on exposure levels and how well controls are working. On the other hand, employees need the results of medical examinations to manage their health.

Compliance Dates

When must employers comply with the standard for general/industry and maritime?

For all operations in general industry and maritime, other than hydraulic fracturing operations in the oil and gas industry:

- Employers are required to comply with all obligations of the standard, with the exception of the action level trigger for medical surveillance, by June 23, 2018.
- Employers are required to offer medical examinations to employees exposed above the PEL for 30 or more days a year beginning on June 23, 2018.
- Employers are required to offer medical examinations to employees exposed at or above the action level for 30 or more days a year beginning on June 23, 2020.

For hydraulic fracturing operations in the oil and gas industry:

- Employers are required to comply with all obligations of the standard, except for engineering controls and the action level trigger for medical surveillance, by June 23, 2018.
- Employers are required to comply with requirements for engineering controls to limit exposures to the new PEL by June 23, 2021. From June 23, 2018 through June 23, 2021, employers can continue to have employees wear respirators if their exposures exceed the PEL.
- Employers are required to offer medical examinations to employees exposed above the PEL for 30 or more days beginning on June 23, 2018.
- Employers are required to offer medical examinations to employees exposed at or above the action level for 30 or more days a year beginning on June 23, 2020.

Why is there a different compliance date for the hydraulic fracturing industry?

Because controls for respirable crystalline silica in hydraulic fracturing are still in development, the rule allows hydraulic fracturing employers additional time to implement engineering controls to take advantage of emerging technologies. Those employers do not have to implement engineering controls to limit exposures to the new PEL until June 23, 2021, three years later than other general industry and maritime employers. From June 23, 2018 to June 23, 2021, hydraulic fracturing employers can continue to have employees use respirators when exposures exceed the PEL.

When must employers comply with the standard for construction?

Employers are required to comply with all obligations of the standard (except methods of sample analysis) by June 23, 2017.

Employers are required to comply with methods of sample analysis by June 23, 2018.

State Plans and Compliance Assistance

Will states with OSHA-approved programs adopt the standards?

Yes. States with OSHA-approved state plans have six months to adopt standards that are at least as effective as Federal OSHA standards. Many state plans adopt standards identical to OSHA, but some state plans may have different or more stringent requirements.

What resources are available to help small businesses and other employers comply with the standards?

OSHA recognizes that most employers want to keep their employees safe and protect them from workplace hazards. We therefore provide extensive compliance assistance through our <u>Compliance Assistance Specialists</u>, website, <u>publications</u>, webinars, and <u>training programs</u>, many of which are geared toward small and mid-sized employers. For silica, OSHA will develop a Small Entity Compliance Guide, fact sheets and other compliance assistance resources. For more information, see the <u>Crystalline Silica Rulemaking</u> page.

OSHA's <u>On-site Consultation Program</u> provides professional, high-quality, individualized assistance to small businesses at no cost. This service, which is provided by consultants from state agencies or universities, is separate and independent from enforcement programs in federal or state OSHA's programs, and provides free and confidential workplace safety and health evaluations and advice to small and medium-sized businesses. In FY 2015, the On-site Consultation Program conducted more than 27,800 free visits to small and medium-sized business worksites, helping to remove more than 3.5 million workers from hazards nationwide.

Additional information about the silica rule is available at <u>www.osha.gov/silica</u>. The website provides additional information on the hazards of occupational exposure to silica with links to fact sheets and an updated silica safety and health topics page, and further explains the provisions of the final rule.

§1910.1053 Respirable crystalline silica

(a) <u>Scope and application</u>. (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 μ g/m³) 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) <u>Definitions</u>. For the purposes of this section the following definitions apply:

<u>Action level</u> means a concentration of airborne respirable crystalline silica of 25 μ g/m³, calculated as an 8-hour TWA.

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

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

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

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

<u>Objective data</u> 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.

<u>Physician or other licensed health care professional [PLHCP]</u> means an individual whose legally permitted scope of practice (<u>i.e.</u>, 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.

<u>Regulated area</u> 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.

<u>Respirable crystalline silica</u> 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.

<u>This section</u> means this respirable crystalline silica standard, 29 CFR 1910.1053. (c) <u>Permissible exposure limit (PEL)</u>. The employer shall ensure that no employee is exposed to an airborne concentration of respirable crystalline silica in excess of 50 μ g/m³, calculated as an 8-hour TWA.

(d) <u>Exposure assessment</u>—(1) <u>General</u>. 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) <u>Performance option</u>. 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) <u>Scheduled monitoring option</u>. (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) <u>Reassessment of exposures</u>. 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) <u>Methods of sample analysis</u>. 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) <u>Employee notification of assessment results</u>. (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) <u>Observation of monitoring</u>. (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) <u>Regulated areas</u>—(1) <u>Establishment</u>. 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) <u>Demarcation</u>. (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) <u>Access</u>. 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) <u>Provision of respirators</u>. 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) <u>Methods of compliance</u>—(1) <u>Engineering and work practice controls</u>. 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) <u>Written exposure control plan</u>. (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) <u>Abrasive blasting</u>. 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) <u>Respiratory protection</u>—(1) <u>General</u>. 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) <u>Respiratory protection program</u>. Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.
(h) <u>Housekeeping</u>. (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) <u>Medical surveillance</u>—(1) <u>General</u>. (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) <u>Initial examination</u>. 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 (FEV₁) and FEV₁/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) <u>Periodic examinations</u>. 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) <u>Information provided to the PLHCP</u>. 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) <u>PLHCP's written medical report for the employee</u>. 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) <u>PLHCP's written medical opinion for the employer</u>. (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) <u>Additional examinations</u>. (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) <u>Communication of respirable crystalline silica hazards to employees</u>—(1) <u>Hazard</u>
<u>communication</u>. 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) <u>Signs</u>. 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) <u>Employee information and training</u>. (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) <u>Recordkeeping</u>—(1) <u>Air monitoring data</u>. (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) <u>Objective data</u>. (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) <u>Medical surveillance</u>. (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) <u>Dates</u>. (1) This section is effective June 23, 2016.

(2) Except as provided for in paragraphs (l)(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 (l)(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 thePEL 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:

 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;

<u>6.2</u> 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

<u>6.3</u> 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.

<u>1.1. Overview</u>. 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 <u>et al</u>. 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 <u>et al</u>. 2001; Steenland and Ward 2014). Symptoms for these diseases and other respirable crystalline silica-related diseases are discussed below.

<u>1.2. Chronic Silicosis</u>. 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.

<u>1.3. Accelerated Silicosis.</u> 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.

<u>1.4. Acute Silicosis.</u> 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.

<u>1.5. COPD</u>. 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 <u>et</u> <u>al</u>. 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.

<u>1.6. Renal and Immune System.</u> 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 <u>et al.</u> 2015).

<u>1.7. TB and Other Infections</u>. 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.

<u>1.8. Lung Cancer</u>. 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 <u>et al</u>. 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.

<u>2.1. History.</u>

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 <u>et al</u>. 2010; Slater <u>et al</u>.
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 <u>et</u> <u>al</u>. 2005; Townsend 2011; Redlich <u>et al</u>. 2014). OSHA's publication, <u>Spirometry Testing in</u> <u>Occupational Health Programs: Best Practices for Healthcare Professionals</u>, provides helpful guidance (<u>See</u> 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).

<u>2.6. Other Testing</u>. 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.

<u>3.1. PLHCP.</u> The PLHCP designation refers to "an individual whose legally permitted scope of practice (<u>i.e.</u>, 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.

<u>3.3. Public Health Professionals</u>. 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: <u>http://www.acoem.org/codeofconduct.aspx</u> 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. <u>J Occup Environ Med</u>, 48, 95-101.

5.2. Center for Disease Control and Prevention (CDC)
Tuberculosis webpage: <u>http://www.cdc.gov/tb/default.htm</u>
State TB Control Offices web page: <u>http://www.cdc.gov/tb/links/tboffices.htm</u>
Tuberculosis Laws and Policies webpage: <u>http://www.cdc.gov/tb/programs/laws/default.htm</u>
CDC. (2013). Latent Tuberculosis Infection: A Guide for Primary Health Care Providers.
Accessed at: <u>http://www.cdc.gov/tb/publications/ltbi/pdf/targetedltbi.pdf</u>

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: <u>http://www.ilo.org/safework/info/publications/WCMS_168260/lang--en/index.htm</u>

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: <u>http://www.cdc.gov/niosh/hhe/</u>

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: <u>http://www.osha.gov/html/Feed_Back.html</u>

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. <u>CA Cancer J Clin</u>, 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. <u>Am J Respir Crit Care Med</u>, 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.

<u>Morbidity and Mortality Weekly Report (MMWR)</u>, 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. <u>Occupational Medicine</u>, 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. <u>Acad Radiol</u>, 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). Artifical stone silicosis: disease resurgence among artificial stone workers. <u>Chest</u>, 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 pneumonconiotic opacities. <u>Chest</u>, 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. <u>Am J Epi</u>, 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. <u>Morbidity and Mortality Weekly Report (MMWR)</u>, 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. <u>Eur Respir J</u>, 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. <u>Am J Respir Crit Care Med</u>; 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. <u>Am</u> <u>J Respir Crit Care Med</u>, 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. <u>Cancer Causes</u>

<u>Control</u>,12(9):773-84.

Steenland, K. and Ward E. (2014). Silica: A lung carcinogen. <u>CA Cancer J Clin</u>, 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:			DAT	DATE OF EXAMINATION:		
TYPE OF EXAMINATION: [] Initial examination [] Other:				examination		
RESULTS OF MEDICAL EXAMIN	ATION:					
Physical Examination –	[] Normal	[] Abnorma	l (see below)	[] Not performe	ed	
	[] Normal		l (see below)			
Breathing Test (Spirometry) –			l (see below)			
Test for Tuberculosis – Other:			l (see below) l (see below)			
Results reported as abnormal:						
[] Your health may be at incr	eased risk from	exposure to re	espirable crystal	line silica due to the	e following:	
RECOMMENDATIONS: [] No limitations on respirator [] Recommended limitations o [] Recommended limitations o	on use of respira					
Dates for recommended limitations, if applicable:t t				D 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:	I/DD/YYYY	
Examining Provider:				Date:		
	(signature)					
Provider Name: Office Address:				Office Phone		
Office Address				Office Flione		
*These findings may not be rel	ated to respirab	le crystalline s	ilica exposure oi	r may not be work-re	elated, and therefore	
may not be covered by the em						

Respirable Crystalline Silica standard (§ 1910.1053 or 1926.1153)

physician.

WRITTEN MEDICAL OPINION FOR EMPLOYER

EMPLOYER:			
EMPLOYEE NAME:	DATE OF EXAMINATION:		
TYPE OF EXAMINATION: [] Initial examination [] Periodic examination [] Other:	[] Specialist examination		
USE OF RESPIRATOR: [] No limitations on respirator use [] Recommended limitations on use of respirator:			
Dates for recommended limitations, if applicable:MI	to M/DD/YYYY MM/DD/YYYY		
The employee has provided written authorization for disclosu [] This employee should be examined by an American Board Medicine [] Recommended limitations on exposure to respirable cryst	Certified Specialist in Pulmonary Disease or Occupational		
Dates for exposure limitations noted above:	to YY MM/DD/YYYY		
NEXT PERIODIC EVALUATION: [] 3 years	[] Other: MM/DD/YYYY		
Examining Provider:	Date:		
Provider Name:			
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