Attachment A - Summary of Major PRA-related Public Comments from Respirable Crystalline Silica Final Rule (Excerpts from Chapter XV. *Summary and Explanation of the Standards*)

A. Exposure Assessment

Commenters, such as the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO), the American Society of Safety Engineers (ASSE), the National Industrial Sand Association (NISA), and the International Diatomite Producers Association, supported the inclusion of an exposure assessment provision in the general industry standard (e.g., Document ID 4204, pp. 52-54; 2339, p. 4; 2195, pp. 5-6, 9-10, 33; 2196, Attachment 1, p. 4), while other commenters, including the American Public Health Association (APHA), the National Consumers League (NCL) and Dr. James Cone, more generally concurred with OSHA's proposed exposure assessment requirements (e.g., Document ID 2178, Attachment 1, p. 2; 2373, p. 2; 2157, p. 7). However, commenters from the construction industry, including the National Utility Contractors Association, the American Subcontractors Association (ASA), the Leading Builders of America (LBA), the Associated Builders and Contractors (ABC), the Associated General Contractors of America, Fann Contracting, Inc., the National Association of Home Builders (NAHB), and the Construction Industry Safety Coalition (CISC), as well as the American Fuel and Petrochemical Manufacturers (AFPM), whose members regularly perform construction tasks, contended that the proposed exposure assessment requirements were unworkable, impractical, or exceedingly expensive due to the dynamic construction environment where frequent changes in environmental conditions, materials, tasks and the amount of time tasks are performed, locations, and personnel would require constant assessment and monitoring (e.g., Document ID 2171, p. 2; 2187, p. 5; 2269, p. 6; 2289, p. 6; 2323, p. 1; 2116, Attachment 1, pp. 13-14; 2296, pp. 24-25; 2350, p. 10; 3521, p. 7; 4217, pp. 12-13). More specifically,

commenters, including the Distribution Contractors Association and the Sheet Metal and Air Conditioning Contractors National Association (SMACNA), expressed concerns about the initial or periodic assessment requirements (e.g., Document ID 2309, p. 3; 2226, p. 2). Fann Contracting, ASA, and the Edison Electric Institute (EEI) argued that initial and periodic exposure assessments do not make sense for construction projects where conditions, tasks, and potential exposures are constantly changing (Document ID 2116, Attachment 1, pp. 5, 16; 2187, p. 5; 2357, p. 13).

Other commenters from both construction and general industry, including Ameren Corporation (Ameren), the Concrete Company, the Glass Association of North America, the Washington Aggregates and Concrete Association, the North American Insulation Manufacturers Association (NAIMA), EEI, the National Stone, Sand, and Gravel Association (NSSGA), the National Association of Manufacturers (NAM), Lafarge North America (Lafarge), the Asphalt Roofing Manufacturers Association (ARMA), and NAHB, argued that employers should not be required to conduct air monitoring for employees on each shift, for each job classification, and in each work area unless differences exist between shifts (e.g., Document ID 2315, p. 3; 2317, p. 2; 2215, p. 9; 2312, p. 2; 2348, Attachment 1, p. 39; 2357, p. 23; 2327, Attachment 1, p. 18; 2380, Attachment 2, pp. 26-28; 2179, p. 3; 2291, pp. 20-21). The American Foundry Society (AFS) argued that repetitious full shift sampling is also "burdensome and unnecessarily dangerous to employees who must wear heavy and awkward equipment during the sampling session" (Document ID 2379, Attachment B, p. 28). Commenters from the construction industry, including ABC, LBA, the Hunt Construction Group, and CISC argued that conducting air

monitoring for employees on each shift, for each job classification, and in each work area or representative sampling of employees was not possible in constantly changing construction environments (e.g., Document ID 2289, p. 6; 2269, p. 6; 3442, pp. 2-3; 2319, pp. 83-84).

In response to these comments, OSHA restructured the exposure assessment requirements in order to provide employers with greater flexibility to meet their exposure assessment obligations using either the performance option or the scheduled monitoring option. This restructuring emphasizes the performance option in order to provide additional flexibility for employers who are able to characterize employee exposures through alternative methods. Commenters, including Arch Masonry, Inc., the Building and Construction Trades Department, AFL-CIO (BCTD), and the Precast/Prestressed Concrete Institute (PCI), strongly supported this approach (e.g., Document ID 2292, p. 3; 3587, Tr. 3655; 2371, Attachment 1, p. 10; 4223, p. 68; 2276, p. 10). However, some commenters from the construction industry, including CISC, Holes Incorporated, and ABC, considered a performance option to be unworkable in the construction industry due to variability in exposures (e.g., Document ID 2319, p. 85; 3580, Tr. 1448-1450; 4216, pp. 2-3; 2226, p. 2). SMACNA also suggested that using historical air monitoring data or objective data is not a legitimate option for small employers who do not have this type of information (Document ID 2226, p. 2).

While some small businesses and construction employers, like Holes Incorporated, noted the difficulties with utilizing this option, there were other similarly situated commenters, like Arch Masonry, that felt the performance option was necessary to fulfill their exposure assessment obligations (e.g., Document ID 3580, Tr. 1448-1450; 2292, p. 3). OSHA understands

that the performance option may not be the preferred choice of every employer, but it expects it will provide many employers with substantial flexibility to meet their exposure assessment obligations. Thus, the Agency has included the performance option in the rule to complement the scheduled monitoring option.

In addition, the restructured standard for construction provides added flexibility to construction employers in another significant way. As described in the summary and explanation of Specified Exposure Control Methods, where the employer fully and properly implements the engineering controls, work practices, and respiratory protection specified on Table 1 for a task, the employer is not required to assess the exposure of employees engaged in that task or take additional measures to ensure that the exposures of those employees do not exceed the revised PEL (see paragraph (c)(1) of the standard for construction). These revisions will relieve construction employers of the burden of performing exposure assessment in many situations and will provide them with greater flexibility to meet the requirements of the standard, while still providing construction workers with the same level of protection as that provided to other workers.

1. The Schedule Monitoring Option

The rule also includes the scheduled monitoring option in order to provide employers with a clearly defined, structured approach to assessing employee exposures. Some commenters, such as CISC and ASSE, urged OSHA to reconsider the inclusion of the scheduled monitoring option, finding it to be impractical, infeasible, and burdensome (e.g., Document ID 2319, p. 86; 3578, Tr. 1052). On the other hand, NISA and the Shipbuilders Council of America (SCA)

supported the inclusion of both a performance option and a scheduled monitoring option for exposure assessment (Document ID 2195, p. 36; 2255, p. 3). AFL-CIO supported periodic exposure assessments when exposures are above the action level, with more frequent assessments required if exposures exceed the PEL, as required under the scheduled monitoring option. It also noted that similar requirements for periodic exposure assessments are included in all other health standards that include exposure monitoring and argued that they should also be included in the rule (Document ID 4204, pp. 53-54). As discussed below, the Agency finds that this option may be useful for certain employers and has retained it in order to maximize flexibility in the rule.

2. The Performance Option

Several commenters requested that OSHA provide more guidance as to how employers should implement the performance option. Commenters, including AFL-CIO, the International Union of Bricklayers and Allied Craftworkers (BAC), the United Steelworkers, BCTD, and the International Union of Operating Engineers (IUOE), felt that clarification and guidance on the kind of data that may or may not be relied upon was needed in order to ensure that the data adequately reflected employee exposures (Document ID 2256, Attachment 2, p. 10; 2329, p. 4; 2336, p. 6; 2371, Attachment 1, pp. 11-13; 3581, Tr. 1693-1694; 3583, Tr. 2341; 4204, p. 54; 4223, p. 70). The American College of Occupational and Environmental Medicine recommended that OSHA more precisely specify the type and periodicity of collection of industrial hygiene data that would be required to assure representative exposure measurements (Document ID 2080, p. 4). The American Industrial Hygiene Association (AIHA) argued that a sufficient number of

samples and a sampling strategy that is representative of the employees and tasks being sampled is needed to ensure that exposure assessments using the performance option accurately characterize employee exposure (Document ID 3578, Tr. 1049-1050). To do this, AIHA suggested that OSHA,

> . . . point to American Industrial Hygiene Association language on what an acceptable judgment of exposure can be based upon: number of samples for statistical validity, an acceptable tolerance for an error in that statistical judgment, and the connection of the sample set to a set of conditions occurring during the worker exposure measurement (Document ID 2169, p. 3).

CISC also indicated that the construction industry needed additional guidance, such as how often and when monitoring should be conducted under the performance option in order to determine whether it would be effective and viable (Document ID 2319, p. 86). Charles Gordon, a retired occupational safety and health attorney, suggested the performance option was too flexible and needed to be omitted until real-time monitoring could be incorporated into it (Document ID 2163, Attachment 1, p. 17).

OSHA has not included specific criteria for implementing the performance option in the rule. Since the goal of the performance option is to give employers flexibility to accurately characterize employee exposures using whatever combination of air monitoring data or objective data is most appropriate for their circumstances, OSHA concludes it would be inconsistent to specify in the standard exactly how and when data should be collected. Where employers want a more structured approach for meeting their exposure assessment obligations, OSHA also provides the scheduled monitoring option.

OSHA does, however, offer two clarifying points. First, the Agency clarifies that when using the term "air monitoring data" in this paragraph, OSHA refers to any monitoring conducted by the employer to comply with the requirements of this standard, including the prescribed accuracy and confidence requirements. Second, the term does not include historic air monitoring data, which are "objective data." Additional discussion of the types of data and exposure assessment strategies that may be used by employers as "objective data" to accurately characterize employee exposures to respirable crystalline silica can be found in the summary and explanation of Definitions.

For example, trade associations and other organizations could develop objective data based on industry-wide surveys that members could use to characterize employee exposures to respirable crystalline silica. For example, the National Automobile Dealers Association (NADA) conducted air monitoring for employees performing a variety of tasks in automobile body shops (Document ID 4197; 4198). NADA worked to ensure that the results of the study were representative of typical operations. The sampling procedures and techniques for controlling dust were documented. These data may allow body shops that perform tasks in a manner consistent with that described in the NADA survey to rely on this objective data to characterize employee exposures to respirable crystalline silica.

Employers could also use portable, direct-reading instruments to accurately characterize employee exposures to respirable crystalline silica. These devices measure all respirable dusts, not only crystalline silica. But where the employer is aware of the proportion of crystalline silica in the dust, direct-reading instruments have the advantage of providing real-time monitoring

results. For example, in a facility using pure crystalline silica, the employer could assume that the respirable crystalline silica concentration in the air is equivalent to the respirable dust measurement provided by the direct reading instrument. Where exposures involve dusts that are not pure crystalline silica, the employer could determine the concentration of crystalline silica by analysis of bulk samples (e.g., geotechnical profiling) or information on safety data sheets, and calculate the air concentration accordingly. In such situations, the analysis of bulk samples or safety data sheets would be part of the objective data relied on by the employer. In addition, employers could use a wide variety of other types of objective data to assess exposures, including data developed using area sampling or area exposure profile mapping approaches. Where new methods become available in the future that accurately characterize employee exposure to respirable crystalline silica, data generated using those methods could also be considered objective data and could be used by employers to assess employee exposures.

Where employers rely on objective data generated by others as an alternative to developing their own air monitoring data, they will be responsible for ensuring that the data relied upon from other sources are accurate measures of their employees' exposures. Thus, the burden is on the employer to show that the exposure assessment is sufficient to accurately characterize employee exposures to respirable crystalline silica.

The Laborers' Health and Safety Fund of North America urged OSHA to collect and post all objective data that meet the definition on its website, so that it could be used by anyone performing the same task under the same conditions (Document ID 2253, p. 4). Other commenters, including BAC, BCTD, and IUOE, agreed that developing a means for collecting

and sharing objective data was important (Document ID 2329, p. 4; 2371, Attachment 1, p. 13; 3583, Tr. 2394-2395). OSHA recognizes that the collection and sharing of objective data can be a useful tool for employers characterizing exposures using the performance option. OSHA anticipates that there could be a substantial volume of objective data that would require significant resources to collect, organize, present, and maintain in a way that is accessible, understandable, and valuable to employers. The Agency does not have the resources to do this; however, employers, professional and trade associations, unions, and others that generate objective data are encouraged to aggregate and disseminate this type of information.

As with the standard for chromium (VI), 29 CFR 1910.1026, OSHA does not limit when objective data can be used to characterize exposure. OSHA permits employers to rely on objective data for meeting their exposure assessment obligations, even where exposures may exceed the action level or PEL. OSHA's intent is to allow employers flexibility to assess employee exposures to respirable crystalline silica, but to ensure that the data used are accurate in characterizing employee exposures. For example, where an employer has a substantial body of data (from previous monitoring, industry-wide surveys, or other sources) indicating that employee exposures in a given task exceed the PEL, the employer may choose to rely on those data to determine his or her compliance obligations (e.g., implementation of feasible engineering and work practice controls, respiratory protection, medical surveillance).

OSHA has also not established time limitations for air monitoring results used to characterize employee exposures under the performance option. Although the proposed standard would have limited employers using air monitoring data for initial exposure assessment purposes

to data collected no more than twelve months prior to the rule's effective date, there were no such time restrictions on monitoring data used to conduct periodic exposure assessments under the performance option. Nevertheless, many commenters, including Ameren, TCNA, NAM, NAIMA, Associated General Contractors of New York State, ARMA, EEI, the National Rural Electric Cooperative Association, the Glass Packaging Institute, Verallia North America, and Holes Incorporated, found the 12-month limit on the use of monitoring results for initial exposure assessments using existing data to be too restrictive (e.g., Document ID 2315, p. 3; 2363, p. 6; 2380, Attachment 2, pp. 28-29; 3544, pp. 12-13; 2145, p. 3; 2291, pp. 2, 21-23; 2348, pp. 37-39; 2357, pp. 22-23; 2365, pp. 10-11, 23; 2290, p. 4; 3493, p. 6; 3584, Tr. 2848; 3580, Tr. 1492). For example, Southern Company noted that:

> We have been collecting data on silica for several years as well as sharing within our industry group. This provision seems to be arbitrary and provides only a short window of time for data collection while eliminating the value and importance of past [efforts] we have placed on this issue (Document ID 2185, p. 7).

OSHA has been persuaded by these commenters not to establish time limitations for monitoring results used to assess exposures under the performance option, as long as the employer can demonstrate the data accurately characterize current employee exposures to respirable crystalline silica. The general principle that the burden is on the employer to show that the data accurately characterize employee exposure to respirable crystalline silica applies to the age of the data as well as to the source of the data. For example, monitoring results obtained 18 months prior to the effective date of the standard could be used to determine employee exposures, but only if the employer could show that the data were obtained during work operations conducted under workplace conditions closely resembling the processes, types of

material, control methods, work practices, and environmental conditions in the employer's current operations. Regardless of when they were collected, the data must accurately reflect current conditions.

Any air monitoring data relied upon by employers must be maintained and made available in accordance with the recordkeeping requirements in paragraph (k)(1) of the standard for general industry and maritime (paragraph (j)(1) of the standard for construction). Any objective data relied upon must be maintained and made available in accordance with the recordkeeping requirements in paragraph (k)(2) of the standard for general industry and maritime (paragraph (j)(2) of the standard for construction).

NISA commented that a performance option needs to be consistently interpreted by compliance officers in order for such an approach to be truly useful to employers (Document ID 2195, p. 36). OSHA agrees. OSHA regularly establishes policies and directives to guide compliance officers in a uniform, consistent manner when enforcing standards. These policies ensure that all the provisions of OSHA standards, including performance options, are consistently applied in the field.

NAIMA suggested that OSHA should make adjustments to exposure monitoring requirements for extended work shifts (e.g., 12-hour shifts). They proposed that

> . . .exposure assessment should follow the standard practice of measuring any continuous 8-hour period in the shift that is representative, or allow using multiple samples to sample the entire extended shift and selecting the 8 hours which represent the highest potential exposure (Document ID 3544, p. 14).

OSHA agrees that this is an appropriate way to conduct sampling for extended work shifts. This practice is already reflected in the OSHA Technical Manual, which describes the two

approaches advanced by NAIMA, including sampling the worst (highest exposure) eight hours of a shift or collecting multiple samples over the entire work shift and using the highest samples to calculate an 8-hour TWA (OSHA Technical Manual, Section II, Chapter 1, 2014, https://www.osha.gov/dts/osta/otm/otm_ii/otm_ii_1.html#extended_workshifts).

CISC argued that the ASTM Standard E 2625-09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities, takes what CISC considered to be a more reasonable approach to representative air monitoring in the construction industry. The ASTM standard states that measurements "need to be representative of the worker's customary activity and be representative of work shift exposure" (Document ID 1504). CISC argued that this approach is,

> . . . more reasonable because it inherently recognizes that an employee's exposure would vary on any given day due to a multitude of factors and that an employer should attempt to understand the exposure levels when performing his/her customary activity (Document ID 2319, pp. 83-84).

OSHA acknowledges that variability in exposures is a concern in the construction industry. The construction standard does not require exposure assessment for employees engaged in a task identified on Table 1 where the employer fully and properly implements the specified exposure control methods presented on Table 1 (see paragraph (c) of the standard for construction). As noted above, the performance option, in paragraph (d)(2) of the standard for general industry and maritime (paragraph (d)(2)(ii) of the standard for construction), also provides flexibility to characterize employee exposures in a manner that accounts for variability, in that it allows exposures to be assessed using any combination of air monitoring data and objective data. But OSHA does not consider that it is appropriate to allow exposure assessment

to include only an employee's "customary activity," because such an approach would ignore activities that may involve higher exposures to respirable crystalline silica, and the higher levels of risk associated with those exposures.

Under the scheduled monitoring option, requirements for periodic monitoring depend on the results of initial monitoring and, thereafter, any required subsequent monitoring. Paragraphs (d)(3)(ii)-(iv) of the standard for general industry and maritime (paragraphs (d)(2)(iii)(B)-(D) of the standard for construction) describe the employers' duties depending on the initial (and, after that, the most recent) monitoring results. If the initial monitoring indicates that employee exposures are below the action level, no further monitoring is required. If the most recent exposure monitoring reveals employee exposures to be at or above the action level but at or below the PEL, the employer must repeat monitoring within six months of the most recent monitoring. If the most recent exposure monitoring reveals employee exposures to be above the PEL, the employer must repeat monitoring within three months of the most recent monitoring.

Paragraph (d)(3)(v) of the standard for general industry and maritime (paragraph (d)(2)(iii)(E) of the standard for construction) provides that if the most recent (non-initial) exposure monitoring indicates that employee exposures are below the action level, and those results are confirmed within six months of the most recent monitoring by a second measurement taken consecutively at least seven days afterwards, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring. As discussed below, reassessment is always required whenever a change in the workplace may be reasonably expected to result in new or additional exposures at or above the action level or the employer has

any reason to believe that new or additional exposures at or above the action level have occurred, regardless of whether the employer has ceased monitoring because exposures are below the action level under paragraph (d)(3)(ii) or (d)(3)(v) of the standard for general industry and maritime (paragraph (d)(2)(iii)(B) or (d)(2)(iii)(E) of the standard for construction) (see paragraph (d)(4) of the standard for general industry and maritime (paragraph (d)(2)(iv) of the standard for construction)).

OSHA made a number of minor changes to the requirements for periodic monitoring under the scheduled monitoring option from the proposal based on stakeholder comments. For example, paragraph (d)(3)(i)(B) of the proposed regulatory text provided that "[w]here initial or subsequent exposure monitoring reveals that employee exposures are above the PEL, the employer shall repeat such monitoring at least every three months." Subparagraph (C) then stated: "the employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are below the action level, at which time the employer may discontinue monitoring . . ."

ARMA argued that these provisions were confusing and "might be interpreted to require employers to continue monitoring quarterly, even if two consecutive measurements are at or above the action level but at or below the PEL"—a reading that ARMA believed conflicted with the language of paragraph (d)(3)(i)(A), which provided that "[w]here initial or subsequent exposure monitoring reveals that employee exposures are at or above the action level but at or below the PEL, the employer shall repeat such monitoring at least every six months" (Document ID 2291, p. 23). ARMA added that it anticipated that OSHA intended these provisions to impose

the same periodic monitoring requirements that appear routinely in other OSHA health standards. It explained: "[u]nder that approach, even if periodic monitoring must be conducted quarterly because the initial (or subsequent) assessment shows exposures in excess of the PEL, the frequency can be reduced to quarterly once two consecutive measurements more than seven days apart fall below the PEL but above the action level" (Document ID 2291, p. 23).

OSHA agrees with ARMA's comment and has revised the periodic monitoring provisions under the scheduled monitoring option to better reflect OSHA's intent—as a general rule, the most recent exposure monitoring sample determines how often an employer must monitor. OSHA has also revised proposed paragraph (d)(3)(i)(C) to clarify the circumstances under which employers who choose the scheduled monitoring option may discontinue periodic monitoring.

Stakeholders also commented on how often employers should be required to conduct exposure monitoring. Several commenters, including the National Tile Contractors Association (NTCA), Dal-Tile, Grede Holdings, ORCHSE Strategies (ORCHSE), Benton Foundry, PCI, TCNA, and NISA, disagreed with the proposed frequency of monitoring and suggested other frequencies (every 6 months, 12 months, 18 months, or as determined by a competent person) (e.g., Document ID 2267, p. 7; 2147, p. 3; 2298, p. 4; 2277, p. 3; 1972, p. 2; 2276, p. 6; 3584, Tr. 2744; 2363, p. 7; 2195, p. 36). IUOE and EEI, among others, suggested that the three or six-month intervals for follow-up exposure assessment will do nothing to protect employees on jobs of short duration (e.g., Document ID 2262, p. 11; 2357, p. 31). AFS suggested that a scheduled monitoring option "that includes quarterly and semi-annual monitoring does not gather useful

information and is punitive in intent" (Document ID 2379, Appendix 1, p. 55). EEI urged OSHA to revise the scheduled monitoring option to either:

> . . . (a) permit employers to conduct subsequent exposure assessments without an arbitrary timetable of three or six months; (b) permit employers to conduct subsequent exposure assessments in longer, more reasonable intervals, such as annually or biennially; or (c) create an exception to periodic exposure assessment requirement when no changes in the workplace, control equipment, or work practices have occurred (Document ID 2357, p. 21).

Francisco Trujillo, representing Miller and Long, proposed that where exposures were between the action level and the PEL, exposure assessment be required at least every six months unless employers implement the same controls used to control exposures above the PEL (Document ID 2345, p. 3). OSHA recognizes that exposures in the workplace may fluctuate. Periodic monitoring, however, is intended to provide the employer with reasonable assurance the employees are not experiencing exposures that are higher than the PEL and require the use of additional control measures. If the employer installs or upgrades controls, periodic monitoring will demonstrate whether or not controls are working properly or if additional controls are needed. In addition, periodic monitoring reminds employees and employers of the continued need to protect against the hazards associated with exposure to respirable crystalline silica. Because of the fluctuation in exposures, OSHA finds that when initial monitoring results equal or exceed the action level, but are at or below the PEL, employers must continue to monitor employees to ensure that exposures remain at or below the PEL. Likewise, when initial monitoring results exceed the PEL, periodic monitoring allows the employer to maintain an

accurate profile of employee exposures. Selection of appropriate respiratory protection also depends on adequate knowledge of employee exposures.

In general, the more frequently periodic monitoring is performed, the more accurate the employee exposure profile. Selecting an appropriate interval between measurements is a matter of judgment. OSHA concludes that the frequencies of six months for subsequent periodic monitoring for exposures in between the action level and the PEL, and three months for exposures above the PEL, provide intervals that are both practical for employers and protective for employees. This finding is supported by OSHA's experience with comparable monitoring intervals in other standards, including those for chromium (VI) (1910.1026), cadmium (29 CFR 1910.1027), methylenedianiline (29 CFR 1910.1050), methylene chloride (29 CFR 1910.1052), and formaldehyde (29 CFR 1910.1048). Where employers find that a different frequency of monitoring is sufficient to accurately characterize employee exposure to respirable crystalline silica, they can use that air monitoring data to meet their exposure assessment obligations under the performance option.

3. Reassessment of Exposures

Some commenters, including Southern Company, EEI, API, and AFPM, raised concerns about the requirement to conduct additional exposure assessments (e.g., Document ID 2185, p. 7; 2357, pp. 21-22; 2301, Attachment 1, p. 80; 2350, p. 10). Southern Company commented that employers should not have to reassess exposures for every personnel change, but rather only those changes that result in significant changes in employee exposure (Document ID 2185, p. 7). EEI urged OSHA to clarify what kind of change could trigger additional assessments (Document

ID 2357, pp. 21-22). API presented concerns that this requirement could be interpreted to require additional assessments at unworkably frequent intervals (Document ID 2301, Attachment 1, p. 80). AFPM argued that the provision would require its members to conduct continuous monitoring given the requirement to reassess every time there is an environmental shift that would result in a new respirable crystalline silica level (Document ID 2350, p. 10).

As described above, the requirement to reassess exposures only applies where there are changes in the workplace that 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. OSHA does not intend for employers to conduct additional monitoring simply because a change has occurred, so long as the change is not reasonably expected to result in new or additional exposures to respirable crystalline silica at or above the action level. Thus, in some of the situations highlighted by the commenters, employers may not need to reassess exposures. For example, where a personnel change does not have an expected impact on the magnitude of employee exposure to respirable crystalline silica, the employer would not have to reassess exposures. When the environmental conditions on a construction site change in ways that would not result in new or additional exposures at or above the action level, such as a change from dry, dusty conditions to wet, rainy conditions, the employer would not have to reassess exposures. Other changes that would be reasonably expected to lower exposures to respirable crystalline silica, rather than result in new or additional exposures at or above the action level, such as moving from an indoor to an outdoor

location or using a product with a lower silica content than that previously used in the same process, would not require the employer to reassess exposures.

4. Notification of Assessment Results

A number of commenters offered opinions on these provisions. For example, some commenters, including Southern Company and EEI, objected to the differences between the general industry and construction notification requirements. These stakeholders argued that establishing different reporting requirements for general industry and construction (i.e., requiring notification within 5 working days in construction and 15 working days in general industry), would create confusion and make compliance difficult to achieve, especially for employers with blended general industry/construction operations, such as electric utilities (Document ID 2185, p. 4; 2357, p. 23). EEI urged OSHA to harmonize the requirements or clarify which section applies to the situation with blended general industry/construction operations (Document ID 2357, p. 23).

This issue is not unique to this rulemaking. In October 2002, OSHA published the second phase of its Standard Improvement Project (SIPS), which proposed to revise a number of health provisions in its standards for general industry, shipyard employment, and construction. The proposal was part of OSHA's effort to continue to remove and revise provisions of its standards that are outdated, duplicative, unnecessary, or inconsistent. One of the issues OSHA examined in Phase II of SIPS was the “variety of different time limits between receipt of employees' exposure monitoring results and notification of employees” in OSHA's substance specific standards. After a thorough review of the record, OSHA adopted a 15-day notification period for general industry

and a 5-day period in construction. The Agency explained that its decision to set two different time frames was due, in part, to the general differences in the industries, i.e., general industry on average has "a more stable workforce," while "[e]mployment at a particular location is often brief in construction. . . " (70 FR 1112, 1126 (1/5/05)).

Some stakeholders from the construction industry, including CISC and ASA, were concerned that they could not comply with the proposed five-day notification requirement due to the often short duration of tasks and employment in this sector. They argued that employers and employees will frequently have moved to a different job before the results are available, making it difficult or impossible to reach affected employees and rendering the data irrelevant to the new project with varying conditions and circumstances (e.g., Document ID 2319, p. 87; 2187, p. 5). These comments suggest that a 5-working-day notification period would be too long for many employers in the construction industry. Thus, OSHA concludes that it would make little sense to lengthen the notification period in the construction standard to correspond to the time period proposed in general industry and maritime.

OSHA also concludes that shortening the proposed provision in general industry to mirror that in construction would likewise make little sense, especially insofar as most of OSHA's health standards for general industry already utilize a 15-working-day period. As OSHA explained in Phase II of SIPS, "a uniform time limit for notifying employees in general industry has substantial benefits[,]" including reduced employer paperwork burdens because of simpler, uniform compliance programs and probable improvement in employee protection due to improved compliance. Therefore, OSHA finds that the reasons discussed in the SIPS rulemaking

apply equally here. Consequently, OSHA has chosen to adopt the proposed 5 and 15-working-day assessment results notification periods in the rule.

OSHA has also considered commenters' concerns that the nature of construction work will make it logistically difficult to notify employees of assessment results because they may have moved on to different jobsites or employers. Employers have options available for notifying employees in such circumstances; for example, notifications could be made individually in writing by including the assessment results in the employees' final paycheck.

OSHA considers notification of assessment results to be important, even if the work conditions and circumstances have changed by the time the assessment results are available. Notification is not simply for purposes of identifying appropriate controls at the time the work is performed. The assessment results are still relevant after the exposure has occurred, to inform employees of their exposure, to provide context for future work that may be performed under similar conditions and circumstances, and to inform PLHCPs who provide medical surveillance for the employee.

NAM urged OSHA to provide flexibility as to when an assessment is deemed complete rather than obligating the employer to notify employees within five days of receiving a laboratory result (Document ID 2380, Attachment 2, p. 32). NAM argued that employers need time to perform and get the results of comprehensive surveys, perform appropriate quality assurance of those results, and meet with employees as appropriate to discuss the results. OSHA recognizes the value of these measures, but also considers the necessity of assessing exposures and notifying employees in a timely manner so that appropriate protective measures are taken.

The Agency is convinced that the required notification can be made within the required 15 or 5 day time period, which are standard in OSHA health standards. Additional information that is developed from the collection of data in comprehensive surveys, any revisions to initial results as a result of quality assurance activities, or meetings to discuss the assessment results can take place at a later date.

Where the employer follows the performance option provided in paragraph (d)(2) of the standard for general industry and maritime (paragraph (d)(2)(ii) of the standard for construction), the 15 (or 5) day period commences when the employer completes an assessment of employee exposure levels (i.e., normally prior to the time the work operation commences, and whenever exposures are re-evaluated). OSHA expects that many construction employers will follow the performance option, where they are not using the specified exposure control methods approach. Therefore, OSHA expects that it will not be difficult to reach affected employees as the assessment would take place prior to the time the work operation begins and the assessment results could then be posted in a location accessible to employees at the beginning of the job. Where the employer follows the scheduled monitoring option provided in paragraph (d)(3) of the standard for general industry and maritime (paragraph (d)(2)(iii) of the standard for construction), the 15 (or 5) day period for notification commences when monitoring results are received by the employer.

In addition, as discussed in the summary and explanation of Scope, where tasks performed in a general industry setting may be essentially indistinguishable from construction tasks listed on Table 1, OSHA permits employers to comply with either all of the provisions of

the standard for general industry and maritime or all of the provisions of the standard for construction. When choosing to follow the construction standard, the employer must notify employees within five working days after completing an exposure assessment.

The notification provisions in the rule, like those in the proposal, require employers to notify "affected" employees. As noted above, the term "affected" as used here means all employees for which an exposure assessment has been conducted, either individually or as part of a representative monitoring strategy. It includes employees whose exposure was assessed based on other employees who were sampled, and employees whose exposures have been assessed on the basis of objective data. Several commenters, including Ameren and EEI, suggested that notification should only be required where air monitoring has been performed, should not be applicable to employers who choose the performance option for meeting the exposure assessment requirement, and should already be captured by training or a written safety program (e.g., Document ID 2315, p. 3; 2357, p. 23). Newmont Mining Corporation commented that notification for every exposure assessment would be excessive and should only be required when the results change (e.g., exposures above the PEL drop below PEL) (Document ID 1963, p. 4).

OSHA disagrees. Notifying employees of their exposures provides them with knowledge that can permit and encourage them to be more proactive in working to control their own exposures through better and safer work practices and more active participation in safety programs. As OSHA noted with respect to its Hazard Communication Standard: "Employees provided with information and training on chemical hazards are able to fully participate in the

protective measures instituted in their workplaces" (77 FR 17574, 17579 (3/26/12)). Exposures to respirable crystalline silica below the PEL may still be hazardous, and making employees aware of such exposures may encourage them to take whatever steps they can, as individuals, to reduce their exposures as much as possible. The results of exposure assessment are not specifically required to be communicated to employees under the hazard communication and employee information and training requirements in paragraph (j) of the standard for general industry and maritime (paragraph (i) of the standard for construction) nor as a part of the written exposure control plan required in paragraph (f)(2) of the standard for general industry and maritime (paragraph (g) of the standard for construction). Exposure assessments are likely to be conducted more frequently than training and, given the differences in timing, OSHA concludes that it would not make sense to incorporate them into a written exposure control plan. Thus, it is important to separate the notification of exposure assessment results from other information and training employees are required to receive under the rule.

NAM offered its opinion on what information the notification should provide to employees and urged OSHA to provide flexibility in this area:

> Many employers require that air sampling results be accompanied by statements concerning the relationship of the results to existing standards, practices and procedures required as a result of the exposure levels, and a discussion of any steps the employer is taking in addition to further control exposures. OSHA acknowledges that employees benefit from having information about the exposures and potential control measures, including the use of PPE, to reduce their risk. OSHA should recognize that an assessment may include more than simple analytical results from a laboratory. Therefore, OSHA should propose language to make clear that the employers have this flexibility in communicating the results to employees (Document ID 2380, Attachment 2, p. 32).

The notification requirement specifies what information must be included; however, this does not limit employers from including the types of information described by NAM in the written notification to employees.

The standard also requires employers to either notify each affected employee in writing or post the assessment results in an appropriate location accessible to all affected employees. CPR urged OSHA to strengthen the notification requirements by requiring: personal notification to workers in writing; notification in a language the employee can understand; and inclusion of information about the silica standard, silica-related disease from an individual or community perspective, and available health care benefits (Document ID 2351, p. 12). The Agency has determined that the notification requirements and the training requirements in the rule adequately address these suggestions. As discussed, the rule requires employers to notify employees, either in writing or by posting in an appropriate location. The training requirements in paragraph (j)(3) of the standard for general industry and maritime (paragraph (i)(2) of the standard for construction) require the employer to ensure that each covered employee can demonstrate knowledge and understanding of the silica standard, tasks that could result in exposure to respirable crystalline silica, the health hazards associated with exposure, specific procedures the employer has implemented to protect employees from exposure, and the medical surveillance provided under the rule. OSHA intends that these requirements will ensure that employees comprehend their exposure to respirable crystalline silica, the potential adverse effects of that exposure, and protective measures that are available. This would include employee understanding of any corrective action the employer is taking to reduce exposures below the PEL

that is described in the written notification. The notification requirement, however, does not require that employers provide notification in a language that the employee can understand; as with other information provided to employees (e.g., labels and safety data sheets), training ensures that the information is understood.

In addition, paragraph (d)(6)(ii) of the standard for general industry and maritime (paragraph (d)(2)(vi)(B) of the standard for construction) requires that whenever the PEL has been exceeded, the written notification must contain a description of the corrective action(s) being taken by the employer to reduce employee exposures to or below the PEL. Several commenters raised issues with the requirement to notify employees about corrective actions being taken where exposures are above the PEL. ASA and CISC suggested that in the construction environment, five days is not sufficient time to determine what caused the exposure, to research alternative solutions to limit future exposure, and to decide on the appropriate corrective action (Document ID 2187, p. 5; 2319, p. 87; 3442, pp. 3-4).

Similarly, in the general industry context, Newmont Mining Corporation argued that "[d]etermination of controls to reduce exposures when exposure assessments exceed the PEL may take more than 15 days" and suggested that OSHA revise the proposed language to allow employers 60 to 90 days to develop a corrective action plan and explain it to employees (Document ID 1963, p. 4). NAM also noted that the requirement to notify employees of the corrective actions being taken to reduce employee exposures below the PEL does not make sense for situations where it is infeasible to bring the exposure level down to the PEL (Document ID 2380, Attachment 2, p. 32).

OSHA disagrees. In OSHA's view, the requirement to inform employees of the corrective actions the employer is taking to reduce the exposure level to or below the PEL is necessary to assure employees that the employer is making efforts to furnish them with a safe and healthful work environment, and is required under section 8(c)(3) of the OSH Act (29 U.S.C. 657(c)(3)). OSHA understands that it may take more than 15 days to determine what engineering controls may be appropriate in a particular situation. However, the corrective action described in the written notification is not limited to engineering controls; when the exposure assessment indicates that exposures exceed the PEL, and the employer needs more than 15 days (or, in the case of the standard for construction, 5 days) to identify the engineering controls that will be necessary to limit exposures to the PEL, the employer is required to provide exposed employees with appropriate respiratory protection. In such a situation, respiratory protection is the corrective action that would be described in the written notification. Similarly, respiratory protection is the corrective action that would be described in the written notification in situations where it is infeasible to limit exposures to the PEL.

CEG and Upstate Medical University suggested that exposure assessment results should not only be reported to employees, but also should be reported to OSHA (Document ID 3586, Tr. 3321; 2244, p. 4). OSHA has not included such a requirement in the rule as such information would not be of practical use to the Agency. OSHA does not possess the resources to review and consider all of the material that will be generated by employers assessing employee exposures under the rule. OSHA would not have sufficient context to consider that material even if sufficient resources were available, given that only limited information is included in such

assessments. Where such information would be of practical value to OSHA, such as when compliance staff conduct workplace inspections, the Agency is able to review exposure records in accordance with the standard addressing access to exposure and medical records (29 CFR 1910.1020).

B. Respiratory Protection

OSHA proposed to require the use of respiratory protection when specified by the written access control plan—an option given to employers in the proposed rule as an alternative to establishing regulated areas. The Agency is not including an access control plan option in the rule (see discussion in the summary and explanation of Regulated Areas). Thus, without an option for an employer to develop a written access control plan, there is no reason to require respirators pursuant to a written access control plan.

Commenters, including Charles Gordon, a retired occupational safety and health attorney, and the American Industrial Hygiene Association recommended that OSHA require employers to provide employees with respirators upon request in certain situations where they are not required under the rule (e.g., exposures below the PEL, Table 1 tasks for which respirators are not required) (Document ID 2163, Attachment 1, p. 16; 2169, p. 5). Dr. George Gruetzmacher, an industrial hygiene engineer, suggested that OSHA require respiratory protection and a respiratory protection program at the action level (Document ID 2278, p. 4).

While the Agency considers the level of risk remaining at the PEL to be significant, OSHA is not including a provision in this rule permitting employees to request and receive a respirator in situations where they are not required under the rule, nor is OSHA requiring

respiratory protection and a respiratory protection program at the action level. There has been significant residual risk below the PEL in many previous health standards, but OSHA has only rarely included provisions permitting employees to request and receive a respirator to mitigate this risk (cotton dust (29 CFR 1910.1043(f)(1)(v)), lead (29 CFR 1910.1025(f)(1)(iii)), cadmium (29 CFR 1910.1027(g)(1)(v))) and the Agency has never established a requirement for respiratory protection and a respiratory protection program at a standard's action level.

If respirators were mandated at the action level or available upon employee request in situations where they are not required under the rule, employers would need to have respirators available at all times. Moreover, they would need to establish and implement a full respiratory protection program for all employees exposed to silica—a considerable undertaking for many employers that involves not only the purchase and retention of suitable respirators but an ongoing program of training, fit-testing, and maintenance. OSHA concludes that "on request" respirator use or requiring respiratory protection at the action level is not a practical or responsible approach to occupational safety and health regulation, and requiring such an investment in respirators would divert resources from the development and implementation of engineering controls that could more effectively reduce exposure levels to or below the PEL. Thus, OSHA's approach for reducing employee exposure to respirable crystalline silica in this and all other standards for air contaminants is to focus on engineering controls, rather than additional requirements for respiratory protection. For these reasons, OSHA has determined that a requirement for employers to provide respirators to employees upon request in situations where they are not required under the rule, or a requirement to provide respirators to employees

exposed at or above the action level, is not reasonably necessary and appropriate for this respirable crystalline silica rule.

Many employers commented that they already have respiratory protection programs in place to protect employees from exposures to respirable crystalline silica (Document ID 1964; 2183, p. 1; 2276, p. 5; 2292, p. 2; 2301, Attachment 1, p. 5, 37; 2338, p. 2; 2366, p. 3; 3577, Tr. 711; 3583, Tr. 2386-2387). The International Union of Bricklayers and Allied Craftworkers and the International Union of Operating Engineers also indicated that their members' employers have established respiratory protection programs (Document ID 2329, p. 7; 3583, Tr. 2342, 2367).

The American Association of Occupational Health Nurses, Ameren Corporation, 3M Company, and Dr. George Gruetzmacher supported the reference to the respiratory protection standard (Document ID 2134; 2278, p. 3; 2313, p. 6; 2315, p. 4). For example, the 3M Company, which manufactures respirators, stated:

> 3M believes that by not requiring separate, individual respiratory protection provisions for respirable crystalline silica, the . . . rule should enhance consolidation and uniformity of the 1910.134 respirator requirements and could result in better compliance concerning the use of respiratory protection. Many of our customers use respirators to help protect workers from exposures to multiple contaminants and the reference in the respirable crystalline silica standard to the requirements of 1910.134 brings uniformity that could likely result in better compliance and protection for workers with exposures to silica and other materials (Document ID 2313, p. 6).

Expressing an opposing view, the National Stone, Sand, and Gravel Association commented that the respiratory protection paragraph was duplicative of existing requirements in 29 CFR 1910.134 (Document ID 2327, Attachment 1, p. 11).

OSHA concludes that referencing the requirements in the respiratory protection standard is important for ensuring that respirators are properly used in the workplace and are effective in protecting employees. Simply cross-referencing these requirements merely brings the applicable requirements to the attention of the employer; the cross-reference does not add to the employer's existing legal obligations, but it makes it more likely that the employer covered by this standard will meet all its obligations with regard to providing respirators when required to do so. Thus, the Agency has incorporated in the rule the reference to the respiratory protection standard that was proposed.

C. Written Exposure Control Plan

A number of commenters questioned the practicality of a written access control plan in workplaces with continually changing tasks, conditions, or materials, which they argued can lead to the need for multiple plans and subsequent costs. The National Stone, Sand, and Gravel Association (NSSGA) commented that written access control plans and establishing boundaries are not feasible in many workplaces, such as aggregate facilities or large construction sites, because of varying silica amounts in materials (Document ID 2327, Attachment 1, p. 20). The Construction Industry Safety Coalition (CISC) stated that a written access control plan is impractical in construction and especially difficult and costly for small businesses because a different plan would need to be developed for each project, as a result of changing materials, tasks, and environmental conditions (Document ID 2319, pp. 5-6, 91-92). Associated Builders and Contractors, Inc. (ABC), Associated General Contractors of America, and American Society of Safety Engineers (ASSE) expressed similar concerns about constantly changing conditions on

construction sites (Document ID 2289, p. 6-7; 2323, p. 1; 4201, p. 2). The National Federation of Independent Business and Leading Builders of America also expressed concerns about time and resource burdens that a requirement for a written access control plan would impose on construction companies or small businesses (Document ID 2210, Attachment 1, p. 7; 2269, p. 22). ABC and CISC further stated that a written access control plan is not needed if employees are trained (Document ID 2289, pp. 6-7; 4217, p. 25).

CISC noted that section 4.2.5 of the ASTM standard E 2625 – 09 limits the need for a written exposure control plan to areas where overexposures are persistent, and contemplated that it is not needed when the PEL may be exceeded on a particular day because of conditions such as weather or silica content in a material. CISC stated that OSHA's requirement for a regulated area or written access control plan when exposures can reasonably be expected to exceed the PEL deviated from section 4.2.5 of the ASTM standard (Document ID 2319, p. 89; 1504, p. 2). OSHA clarifies that a written access control plan, which describes specified methods for limiting access to high-exposure areas, is different from a written exposure control plan, which can address specified protections for controlling exposure other than limiting access to high-exposure areas.

Commenters representing industry, labor, and employee health advocate groups addressed the issue of what, if any, type of written plan should be required and what level of respirable crystalline silica exposure should trigger that requirement. Some industry representatives favored a written access control plan over a regulated area, while others opposed a written exposure control plan. For example, in comparing regulated areas and the written

access control plan, Edison Electric Institute favored the flexibility of the written access control plan and stated that it might use that option in larger areas or for activities that can change over time. It opposed a written exposure control plan, asserting that the training required by OSHA's hazard communication standard (HCS) was sufficient to keep employees informed (Document ID 2357, pp. 33, 37). The Non-Ferrous Founders' Society expressed concerns about costs if a consulting industrial hygienist would need to be hired to develop a written access control plan (Document ID 2248, p. 13). The National Association of Home Builders (NAHB) stated that some of its members would prefer a written access control plan over regulated areas, while other members expressed concern that developing a written access control plan might be difficult for many small companies. NAHB also commented that many small companies would not have the knowledge to develop a written exposure control plan and would have to hire a professional to develop it. NAHB opposed a written exposure control plan, stating that a standard checklist was adequate for protecting employees from exposure (Document ID 2296, pp. 40 and 41). On the other hand, National Electrical Carbon Products (NECP) commented that if OSHA required a written plan, NECP would prefer an exposure control plan rather than an access control plan. It stated that OSHA's proposed access restrictions do not relate to the goal of ensuring compliance with the PEL (Document ID 1785, pp. 6-7).

Commenters from labor organizations and employee health advocate groups supported the inclusion of a written exposure control plan. For example, BCTD stated that the proposed written access control plan could be used as a starting point for the development of a written exposure control plan, which it said should be required for every employer that has employees

who may be exposed to respirable crystalline silica (Document ID 2371, Attachment 1, pp. 14-16). International Union of Operating Engineers (IUOE), Public Citizen, American Federation of Labor and Congress of Industrial Organizations (AFL-CIO), and International Union of Bricklayers and Allied Craftworkers (BAC) also supported a requirement for a written plan for all covered employers and not just those with regulated areas or exposures exceeding the PEL (Document ID 2262, p. 42; 2249, p. 3; 4204, p. 62; 4219, p. 25-26; 4223, p. 119).

Other commenters, such as ASSE, favored a written exposure control plan for suspected or documented overexposure scenarios (Document ID 2339, p. 8). The National Industrial Sand Association (NISA) originally opposed a written exposure control program in its prehearing comments (Document ID 2195, p. 38). However, in its post-hearing comments, it supported one, stating that formulating and writing down an exposure control program would ensure that an employer thinks through the engineering and administrative controls required to achieve compliance in situations with persistent overexposures. NISA also stated that the plan would help employers defend against potential liability by documenting due care (Document ID 4208, pp. 20-21).

The American Foundry Society (AFS) disagreed with the need for a separate written exposure control plan and instead called for planning as part of other business initiatives. It supported written exposure control plans in enforcement situations. AFS favored an approach similar to that in the ASTM standard. AFS stated that the ASTM's approach, which involves identifying and analyzing dust sources in scenarios with overexposures to determine effective

controls, was more effective in reducing exposures than requiring controls to be installed by a certain date (Document ID 2379, Appendix 1, pp. 61-62; 4229, p. 26).

Advocates of written exposure control plans explained why they supported those plans. The National Institute for Occupational Safety and Health (NIOSH) stated that written exposure control plans could be a simple mechanism for ensuring performance of maintenance checks and, for construction employers, maintaining Table 1 conditions (Document ID 2177, Attachment B, pp. 16-17). Dr. Paul Schulte, Director of the Education and Information Division at NIOSH, testified that ". . . a written plan would greatly improve reliability of the protection provided." (Document ID 3403, p. 5). AFL-CIO, NISA, and BCTD agreed (Document ID 4204, p. 61; 4208, pp. 20-21; 4223, p. 74). Eileen Betit, representing BCTD, testified:

> Written exposure control plans are important for identifying operations that will result in exposures, the specific control measures, and how they will be implemented and the procedures for determining if controls are being properly used and maintained. Such plans also facilitate the communication of this information to other employers on multi-employer worksites so that they, in turn, can take steps to protect their employees. Without such plans, there's no assurance that employers and employees will take a systematic and comprehensive approach to identifying, controlling, and sharing information about silica exposures on job sites (Document ID 3581, Tr. 1569-1570).

The United Steelworkers (USW), Public Citizen, the United Automobile, Aerospace and Agricultural Implement Workers of America (UAW), and AFL-CIO also supported a requirement for a written exposure control plan as a method to continually, systematically, or comprehensively identify or control exposures (Document ID 2336, p. 9; 2249, p. 2; 2282, Attachment 3, p. 17; 4204, p. 60). NIOSH, Public Citizen, and BAC also stated that written

exposure control plans are a useful way to communicate protections to employees (Document ID 2177, Attachment B, pp. 16-17; 2249, p. 3; 2329, p. 5).

BlueGreen Alliance, UAW, USW, and AFL-CIO also supported a written plan because requiring the written plan would be consistent with the many other OSHA substance-specific standards that include written plans or programs (Document ID 2176, p. 3; 2282, Attachment 3, p. 17; 3584, Tr. 2540; 4204, p. 62). In addition, commenters observed that other U.S. and Canadian regulatory agencies require written plans. Frank Hearl, Chief of Staff at NIOSH, stated that the Mine Safety and Health Administration requires a dust control plan to be filed at coal mines (Document ID 3579, Tr. 235-236). In addition, AFL-CIO and BCTD noted that written dust or silica control plans are included in a proposed standard for the Canadian Province of British Columbia and a standard promulgated in the Canadian Province of Newfoundland (Document ID 4204, p. 61; 4223, p. 73 Fn. 14; 4072, Attachment 38, pp. 6-7, Attachment 41, p. 7).

BCTD stated that a requirement for a written exposure control plan would not be unduly burdensome to employers because creating such plans is an extension of planning functions in construction (Document ID 4223, pp. 74-80). In fact, several hearing participants testified that written safety or hazard control plans are already being developed and used in the construction industry (Document ID 4223, pp. 74-80; 3580, Tr. 1383-1385; 3583, Tr. 2267-2268, 2385; 3585, Tr. 3093-3094; 3587, Tr. 3560). For example, Kevin Turner, Director of Safety at Hunt Construction Group and representing CISC testified: ". . . we require a site-specific safety plan

which addresses the hazards dealt with in that [particular] contractor's scope of work." (Document ID 3580, Tr. 1383).

In addition, written plans are consistent with general industry practices. For example, the National Service, Transmission, Exploration, and Production Safety Network (STEPS Network), whose members are involved in the oil and gas industry, recommends a written plan that describes how exposures to respirable crystalline silica will be reduced or prevented (Document ID 4024, Attachment 2, p. 1). Member companies of the National Ready Mix Concrete Association, who hire third-party contractors to chip out their drum mixers, follow strict written practices and procedures to ensure that exposures do not exceed the PEL. Specifically, they require the contractors to submit to them a company-approved safety and health policy and procedures and plans (Document ID 2305, pp. 8-9). AFL-CIO submitted to the record a silica dust control plan developed by Sonic Drilling (Document ID 4072, Attachment 11).

BCTD stressed that preparing a written exposure control plan does not have to be burdensome and, along with BAC and AFL-CIO, pointed to online tools that are available to help users create written exposure control plans, such as the CPWR-Center for Construction Research and Training (CPWR) tool, available free of charge, on the silica-safe.org website (Document ID 2329, p. 5; 4204, p. 61; 4223, pp. 80-81; 4073, Attachment 5a and 5b). AFL-CIO and BCTD also pointed to guidance products and model exposure control plans from the Canadian Province of British Columbia as additional resources for assisting users in developing written exposure control plans (Document ID 4204, p. 61; 4223, p. 81; 4072, Attachment 14, 19, 20). Industry associations are another resource to help employers prepare written plans. For

example, Anthony Zimbelman, general contractor, representing NAHB, testified that his industry association teaches courses and helps businesses develop safety plans (Document ID 3587, Tr. 3559-3560).

OSHA finds the evidence on the benefits of a written exposure control plan – as distinct from the proposed written access control plan – convincing and has concluded that a requirement for a written exposure control plan is needed for both the standard for general industry/maritime and the standard for construction because the plan will improve employee protections. OSHA agrees with commenters who stated that a written plan should not be limited to scenarios where the PEL is exceeded. Therefore, OSHA concludes that it is appropriate for the rule to require a written exposure control plan, instead of a written access control plan that would only apply to restricting access to areas where exposures to respirable crystalline silica exceed the PEL. Requiring a written exposure control plan for all employers covered by the rule is more protective than the ASTM approach of only requiring written exposure control plans for persistent overexposures. Even if exposures are below the PEL due to the use of engineering controls or work practices, a systematic approach for ensuring proper function of engineering controls and effective work practices is crucial for ensuring that those controls and practices remain effective. Thus, OSHA finds that a written exposure control plan is integral to preventing overexposures from occurring.

OSHA agrees with NISA that requiring employers to articulate conditions resulting in exposure and how those exposures will be controlled will help to ensure that they have a complete understanding of the controls needed to comply with the rule. OSHA expects a written

exposure control plan will be instrumental in ensuring that employers comprehensively and consistently protect their employees. Even in cases where employees are well trained, the written plan can help to ensure that controls are consistently used and become part of employees' routine skill sets. Employers could opt to use the plans to ensure that maintenance checks are routinely performed and optimal conditions are maintained. In addition, OSHA concludes the written plans are a useful method for communicating protections to employees.

Requiring a written plan maintains consistency with the majority of OSHA substance-specific standards for general industry and construction, such as lead (29 CFR 1910.1025 and 1926.62) and cadmium (29 CFR 1910.1027 and 1926.1127), which require written compliance plans. A requirement for a written exposure control plan is also consistent with Canadian standards. In addition, it is generally consistent with industry practices, as evidence in the record indicates that some employers in general industry and construction are already developing and using written plans. OSHA concludes that even for small businesses, preparing a written exposure control plan based on identifying and controlling respirable crystalline silica hazards will not be unduly burdensome, because of the widespread availability of tools and guidance from groups such as CPWR and the Canadian government. In addition, OSHA anticipates that industry associations will provide guidance on developing written exposure control plans for respirable crystalline silica.

Contrary to the concerns indicated by comments from representatives from the construction industry, OSHA does not intend or expect that employers will need to develop a new written plan for each job or worksite. Many of the same tasks will be conducted using the

same equipment and materials at various worksites. For example, a stationary masonry saw used outdoors to cut concrete will perform similarly in any outdoor setting. Most construction employers are expected to use the specified exposure control methods in Table 1 of paragraph (c), which will help them identify tasks and controls to be included in the written exposure control plan. Table 1 does not usually specify different controls for different types of crystalline silica-containing materials, thus supporting the conclusion that a new plan does not need to be continually developed. Table 1 does list some conditions, such as time performing tasks or use of equipment in enclosed areas, that would require respirator use in addition to the specified controls; those different scenarios can be indicated in the written exposure control plan, as applicable. Therefore, the written exposure control plan does not have to be limited by materials, tasks, and conditions for a particular job site and can include all materials, tasks, and conditions typically encountered. In many cases there will be no need to modify the written plan just because the location has changed. However, the plan must address all materials, tasks, and conditions that are relevant to the work performed by a particular company. OSHA is including in the docket a sample written exposure control plan for a bricklaying company for reference.

OSHA concludes that it is appropriate to include a requirement for a written exposure control plan in the respirable crystalline silica standards for general industry/maritime and construction. Therefore paragraph (f)(2)(i) of the standard for general industry and maritime (paragraph (g)(1) of the standard for construction) requires the employer to establish and implement a written exposure control plan that contains at least the elements specified in paragraphs (f)(2)(i)(A)-(C) of the standard for general industry and maritime (paragraph (g)(1)

(i)-(iv) of the standard for construction). This provision not only requires that a written exposure control plan be established but also implemented. OSHA does not consider it sufficient to develop a plan and have a copy of it on a shelf. It must be followed in the day-to-day performance of tasks identified.

OSHA considered existing written exposure control plans, such as the ASTM plans, and commenter suggestions to determine what should be included in a written exposure control plan. Section 4.2.5 of ASTM standard E 2625 – 09 concerning construction and demolition provides:

> In areas where overexposures are persistent, a written exposure control plan shall be established to implement engineering, work practice, and administrative controls to reduce silica exposures to below the PEL, or other elected limit, whichever is lower, to the extent feasible. Conduct a root cause analysis for all exposures in excess of the PEL that cannot be accounted for. Root cause analysis involves investigating cause(s) for the excessive exposure, providing remedies, and conducting follow-up sampling to document that exposures are below the PEL (Document ID 1504, p. 2).

The exposure control plan described in section 4.2.6 of ASTM standard E 1132 – 06 is substantively consistent with the approach described by section 4.2.5 of ASTM standard E 2625 – 09 (Document ID 1466, p. 2; 1504, p. 2).

Several stakeholders commented on what should be included in provisions for a written exposure control plan. ASSE described an approach similar to that in the ASTM standards, and AFS preferred the ASTM approach during enforcement actions (Document ID 2339, p. 8; 2379, Appendix 1, pp. 61-62).

NIOSH stated that the exposure control plan could be based on OSHA's Job Hazard Analysis approach (Document ID 2177, Attachment B, p. 16; OSHA document 3071, Revised

2002). The OSHA job hazard analysis form calls for descriptions of tasks, hazards, hazard controls, and rationale and comments (OSHA document 3071, Revised 2002, Appendix 3). Similarly, NISA recommended that written exposure control programs convey an understanding of work processes and their appropriate controls for managing exposures (Document ID 4208, p. 21).

Some labor unions, such as AFL-CIO and BCTD, recommended more extensive requirements for a written exposure control or compliance program that included identification of exposures and controls, in addition to exposure assessment methods or results, and descriptions of the respiratory protection, medical surveillance, and training programs (Document ID 2371, Attachment 1, pp. 16-17; 4204, p. 62; 4223, p. 82).

Commenters such as Public Citizen, USW, UAW, and BCTD all agreed that the value of a written exposure control plan is that it allows for consistent identification and control of respirable crystalline silica hazards (Document ID 2249, p. 2; 2336, pp. 8-9; 2282, Attachment 3, p. 17; 3581, Tr. 1569-1571; 4204, p. 60). OSHA affirms that the purpose of the written exposure control plan is the consistent identification and control of respirable crystalline silica hazards, and it is basing the requirements for a written exposure control plan on that purpose.

As discussed more fully below, the written exposure control plan required under this rule for respirable crystalline silica is similar to the ASTM standards in most, but not all, respects. The major difference between the written plans in the ASTM standards and in this rule is that written exposure control plans in this rule are not limited to overexposure scenarios.

OSHA thus considered the ASTM standards and commenter suggestions to develop requirements for a written exposure control plan. The Agency also considered which aspects of the proposed written access control plan should be retained or modified. Therefore, the requirement for a written exposure control plan evolved from comments on OSHA's proposed written access control plan and in response to OSHA raising the possible inclusion of a written exposure control plan as an issue.

Requirements for the written exposure control plan. Paragraphs (f)(2)(i)(A)-(C) of the standard for general industry and maritime (paragraphs (g)(1)(i)-(iv)) of the standard for construction) identify the elements to be addressed in a written exposure control plan. Requirements for the written exposure control plan are performance-based to allow employers to tailor written exposure control plans to their particular worksites. The following discussion describes the minimum requirements for the written exposure control plan and the evidence that supports those requirements. It also recommends general information to include for each section of the plan.

Paragraph (f)(2)(i)(A) of the standard for general industry and maritime (paragraph (g)(1)(i)) of the standard for construction) requires a description of tasks involving exposures to respirable crystalline silica. The proposed written access control plan called for identification of areas where respirable crystalline silica exposure may exceed the PEL. Communication Workers of America (CWA), Public Citizen, USW, AFL-CIO, NISA, and BCTD recommended that the written exposure control plan describe tasks, operations, or work processes that result in exposures to respirable crystalline silica (Document ID 2240, p. 2; 2249, p. 3; 2336, p. 9; 4204,

p. 62; 4208, p. 21; 4223, p. 82). A description of tasks involving exposures to respirable crystalline silica is consistent with the first step of the root cause analysis in the ASTM exposure control plans, which involves investigating sources of overexposures (Document ID 1466, p. 2; 1504, p. 2). It is also consistent with the identification of tasks and hazards in the OSHA Job Hazard Analysis approach that is recommended by NIOSH as a model for a respirable crystalline silica written exposure control plan (Document ID 2177, Attachment B, p. 16; OSHA Document 3071, Revised 2002, Appendix 3).

Paragraph (f)(2)(i)(A) of the standard for general industry and maritime (paragraph (g)(1)(i) of the standard for construction) reflects OSHA's agreement with commenters that it is important for employers to consistently identify tasks resulting in exposure to ensure that appropriate employee protections are applied when needed. The identification of tasks with potential respirable crystalline silica exposure is no longer limited to exposures above the PEL, as it was in the proposed written access control plan. This is more protective because it identifies all tasks that could contribute to employee exposures, thereby furthering the purpose of the rule.

In preparing this section of the written plan, employers must list all tasks that employees perform that could expose them to respirable crystalline silica dust. This section of the written plan could include a description of factors that affect exposures, such as types of silica-containing materials handled in those tasks (e.g., concrete, tile). It could also describe factors such as weather (e.g., wind, humidity) and soil compositions (e.g., clay versus rock) (Document ID 3583, Tr. 2350-2352, 2356-2360; 4234, Part 2, pp. 37-38). Another factor that could affect exposure and protective requirements and thus could be described in the written plan is the

location of the task, for instance, whether the task is performed in an enclosed space (Document ID 2177, Attachment B, pp. 16-17). For example, the Table 1 entry for walk-behind saws with integrated water delivery systems indicates that a respirator is only required when the equipment is used indoors or in an enclosed area.

Paragraph (f)(2)(i)(B) of the standard for general industry and maritime (paragraph (g)(1)(ii) of the standard for construction) requires a description of engineering controls, work practices, and respiratory protection used to limit employee exposure to respirable crystalline silica for each task. CWA, Public Citizen, USW, AFL-CIO, NISA, and BCTD requested that the written plan describe controls for managing exposures. Engineering and work practice controls were specifically mentioned by Public Citizen, USW, AFL-CIO, and BCTD (Document ID 2240, p. 2; 2249, pp. 3-4; 2336, p. 9; 4204, p. 62; 4208, p. 21; 4223, p. 82). AFL-CIO further recommended that the written plan describe jobs where respiratory protection is required (Document ID 4204, p. 62). BCTD also requested that the written plan describe procedures for implementing the controls and for determining if the controls are being used and maintained correctly (Document ID 4223, p. 82). NIOSH stated that a written exposure control plan can be a simple mechanism for ensuring that maintenance checks are conducted and Table 1 conditions are maintained (Document ID 2177, Attachment B, pp. 16-17).

Paragraph (f)(2)(i)(B) of the standard for general industry and maritime (paragraph (g)(1)(ii) of the standard for construction) reflects OSHA's agreement that the written exposure control plan must address controls, work practices, and respiratory protection used to manage exposures for each task identified in paragraph (f)(2)(i)(A) of the standard for general industry and

maritime (paragraph (g)(1)(i) of the standard for construction). The purpose of this requirement is to ensure that exposures to respirable crystalline silica hazards are consistently controlled. Therefore, written exposure control plans must include information such as types of controls used (e.g., dust collector with manufacturer's recommended air flow and a filter with 99 percent efficiency), effective work practices (e.g., positioning local exhaust over the exposure source), and if required, appropriate respiratory protection (e.g., a respirator with an assigned protection factor (APF) of 10) for each task. The requirement is consistent with the exposure control plans in the ASTM standards that address implementation of engineering controls and work practices to reduce respirable crystalline silica exposures (Document ID 1466, p. 2; 1504, p. 2). It is also consistent with OSHA's Job Hazard Analysis approach, which is recommended by NIOSH as a model for the exposure control plan and calls for a description of controls (Document ID 2177, Attachment B, p. 16; OSHA document 3071, Revised 2002, Appendix 1 and 3).

OSHA also agrees with NIOSH and BCTD about the necessity of addressing the proper implementation and maintenance of controls for each task. This is reflected in paragraph (c) of the standard for construction, in the Table 1 requirements to operate or maintain tools according to manufacturers' instructions. Proper implementation and maintenance of controls is also necessary to meet the PEL under paragraph (c) of the standard for general industry and maritime and paragraph (d)(1) of the standard for construction for construction employers who choose or are required to follow the alternative exposure control methods. Therefore, to help ensure compliance with the rule, the employer, in this section of the written exposure control plan, could indicate signs that controls may not be working effectively (e.g., dust is visible, no water is

delivered to the blade). The plan could also include a description of procedures the employer uses for verifying that controls are functioning effectively (e.g., pressure checks on local exhaust ventilation) and schedules for conducting maintenance checks.

OSHA finds the written exposure control plan especially important for construction employers who use the specified exposure control methods in Table 1 of paragraph (c). For them, the description of engineering controls, work practices, and respiratory protection is especially necessary to ensure adequate protection of employees and the use of controls according to the manufacturer's instructions, since employers are not required to conduct exposure assessments to verify that controls are working properly. In cases where the employer owns a particular type of equipment and it is repeatedly used at different job sites, describing the manufacturer's instructions for operating the dust controls in a written exposure control plan will demonstrate that the employer has a complete understanding of and is applying those specifications needed to control dust emissions. Describing those specifications in the written exposure control plans will also serve as a convenient reference for employees.

As an example, in completing this section of the written plan, an employer whose employees use a Stihl® Model TS 410 saw to cut concrete could consult the user's manual to list or summarize those instructions in his or her written exposure control plan. Based on the user's manual, this section of the plan could indicate that (1) before using a Stihl® Model TS 410 saw for cutting concrete, the employee must examine the diamond cutting wheel for signs of excessive wear, damage, or "built-up edges" (i.e., a pale, grey deposit on the top of the diamond segments that clogs and blunts them) and (2) while cutting, the employee must use a water flow

rate no less than 0.6 liters (20 fluid ounces) per minute, stop and rinse the screen on the water connection if no or too little water is delivered while cutting, and not cut into the ballast layer of road surfaces to avoid excessive wear on the cutting wheel (Document ID 3998, Attachment 12a, pp. 9, 21-23). The specified exposure control methods in Table 1 indicate that the employee must wear a respirator with an APF of 10 when using this saw outdoors for more than 4 hours a day, and this type of information must be included in this section, if applicable.

Paragraph (f)(2)(i)(C) of the standard for general industry and maritime (paragraph (g)(1)(iii) of the standard for construction) requires a description of the housekeeping measures used to limit employee exposure to respirable crystalline silica. BCTD requested that the exposure control plan describe housekeeping methods (Document ID 2371, Attachment 1, pp. 16-17). Similarly, CWA and USW recommended that the written plan describe procedures for preventing the migration of silica, and USW further noted that the plan should address keeping surfaces visibly clean (Document ID 2240, p. 2; 2336, p. 9). USW also requested that the written exposure control plan describe procedures for removing, laundering, storing, cleaning, repairing, or disposing of protective clothing and equipment (Document ID 2336, p. 9).

Paragraph (f)(2)(i)(C) of the standard for general industry and maritime (paragraph (g)(1)(iii)) of the standard for construction) reflects OSHA's agreement that housekeeping needs to be addressed in the written exposure control plan because some cleaning methods can contribute to employee exposure to respirable crystalline silica. OSHA intends this requirement to help ensure that employers identify and implement appropriate cleaning methods so that employees are protected from respirable crystalline silica dust that can become airborne while performing

housekeeping activities. Ensuring safe housekeeping methods helps to consistently control exposures and hazards related to respirable crystalline silica. Housekeeping is another type of work practice to be used to limit employee exposures, and thus, it is consistent with the written exposure control plans in the ASTM standards, which call for implementing work practices to decrease exposures (Document ID 1466, p. 2; 1504, p. 2). It is also consistent with OSHA's Job Hazard Analysis approach, which is recommended by NIOSH as a model for the exposure control plan and calls for a description of controls (Document ID 2177, Attachment B, pp. 16-17; OSHA document 3071, Revised 2002, Appendix 1 and 3).

OSHA concludes that requiring the written exposure control plan to include a description of housekeeping methods is important because acceptable housekeeping methods can vary among different companies. As described more fully in the summary and explanation of Housekeeping, certain housekeeping practices, such as wet sweeping, are infeasible in some work scenarios. Therefore, OSHA modified proposed prohibitions on cleaning activities, such as dry sweeping or compressed air, to indicate that those housekeeping methods can be used if there are no other feasible methods. However, to comply with the rule, employers must ensure that wet sweeping, HEPA-filtered vacuuming, or other appropriate cleaning methods are used wherever feasible, if dry sweeping or dry brushing could contribute to employee exposure to respirable crystalline silica. It is therefore important for the employer to specify in the written exposure control plan the housekeeping practices the employer uses to limit employee exposures and any special protections that are needed when a particular housekeeping method is used.

AFL-CIO and BCTD recommended that written plans describe procedures that employers will use to limit exposure to employees who are not performing respirable crystalline silica-related tasks (Document ID 4204, p. 63; 4223, p. 82). Similarly, BAC stated that the written plan should contain provisions for a regulated area (Document ID 2329, p. 5). USW requested the written plan address labeling of areas with potential respirable crystalline silica exposure (Document ID 2336, p. 14).

Paragraph (g)(1)(iv) of the standard for construction reflects OSHA's agreement that written exposure control plans must address limiting exposure to construction employees who are not engaged in respirable crystalline-silica-related tasks. However, as explained in the summary and explanation of Regulated Areas, regulated areas are not required in the standard for construction because most employers are expected to rely on the specified exposure control methods in Table 1 of paragraph (c) and, therefore, will not have air monitoring data to estimate boundaries of the regulated area. In the summary and explanation of Regulated Areas, OSHA also acknowledges the impracticality of demarcating regulated areas in many construction scenarios. Nonetheless, it remains crucial that access to high-exposure areas and employee exposure levels be limited at construction worksites. A written description of the employer's plan for limiting access is another tool the employer has that helps to consistently control hazards.

The exposure control plans in the ASTM standards do not specifically call for procedures used to restrict access. However, they do call for a description of administrative controls used to reduce exposures (Document ID 1466, p. 2; 1504, p. 2). An example of an administrative control that can be used to minimize the number of employees exposed to respirable crystalline silica is

scheduling high-exposure tasks when others will not be in the area (Document ID 3583, Tr. 2385-2386). For example, Anthony Zimbelman stated that when granite countertops are being installed, silica dust may be generated when drilling holes for plumbing fixtures or grinding to make adjustments, but the installers are usually the only employees at the job site at that time (Document ID 3521, pp. 6-7). CISC stated that in lieu of developing a written access control plan, employers could instruct employees to stay out of areas where dust is generated or, if employees have to be in those areas, to avoid dust clouds (Document ID 2319, pp. 91-92). OSHA considers the CISC recommendation to be an additional example of administrative controls for limiting access or exposures that could be addressed in the written exposure control plan. Similarly, a written exposure control plan could include guidance requiring employees to maintain a safe distance from dust created by the use of explosives in demolition and to stay out of the affected area until the dust sufficiently dissipates; this would also serve as an acceptable administrative control. Therefore, a requirement for the written plan in the construction standard to address minimizing the number of employees exposed and their exposure levels is consistent with the exposure control plans in the ASTM standards.

OSHA concludes that the written exposure control plan for the construction standard must address restricting access of those employees who are not engaged in tasks that generate respirable crystalline silica (i.e., bystanders). Therefore, as noted above, paragraph (g)(1)(iv) of the standard for construction requires a description of the procedures used to restrict access to work areas, when necessary, to limit the number of employees exposed and their exposure levels, including exposures generated by other employers or sole proprietors (i.e., self-employed

individuals). Restricting access is necessary where respirator use is required under Table 1 or an exposure assessment reveals that exposures are in excess of the PEL. The competent person, who is designated by the employer to implement the written exposure control plan under paragraph (g)(4) of the standard for construction, could further identify situations where limiting access is necessary. For example, limiting access may be necessary when an employer or sole proprietor exposes another company's employees to respirable crystalline silica levels that could reasonably be considered excessive (e.g., above the PEL).

Such a situation might occur when an employee engaged in a Table 1 task with fully and properly implemented controls is exposed to clearly visible dust emissions by an employee or sole proprietor who is performing a task not listed on Table 1, is not fully and properly implementing Table 1 controls, or is performing a Table 1 task requiring a higher level of respiratory protection. In that case, the competent person would assess the situation to determine if it presents a reasonably anticipated hazard, and if it does, take immediate and effective steps to protect employees by implementing the procedures described in the written exposure control plan. Actions by the competent person could include reminding employees to stay out of the areas where respirable crystalline silica is being generated or repositioning employees so that they will not be exposed to respirable crystalline silica.

This approach is consistent with current industry practices. For example, Anthony Zimbelman testified that in his experience, implementing a safety plan was sufficient to protect employees in situations where subcontractors that are not required to comply with the Occupational Safety and Health (OSH) Act are working alongside employees. Mr. Zimbelman

further testified that in the home building industry, this situation does not happen often and contractors would stop working with a subcontractor who does not comply with OSHA standards (Document ID 3587, Tr. 3547-3549). OSHA expects that excessive exposures created by sole proprietors not covered by the respirable crystalline silica rule will be an infrequent occurrence because, as CISC indicated in its post-hearing brief, employers and general contractors will likely demand that everyone on the site follow regulatory requirements (Document ID 4217, Appendix B, p. 16). OSHA thus expects that the employers or their competent persons will work with general contractors of construction sites to avoid high exposures of employees working alongside others generating respirable crystalline silica. For example, the competent person could ask the general contractor to schedule high-exposure tasks when employees will not be in the area.

OSHA is not retaining the proposed requirement in the written access control plan that the employer describe how employees will be notified about respirable crystalline silica exposures and how areas will be demarcated. The requirements of the written exposure control plan are more performance-oriented to permit each employer to address unique scenarios of worksites. Demarcation (i.e., direct access control), notifying or briefing employees, and scheduling high-exposure tasks when others are not around, are likely to be the most common methods of restricting access. Demarcating areas is not required because, as noted above, it is not applicable to many construction scenarios. However, if it is possible to demarcate areas, such as by posting a warning sign, and that is the employer's chosen method for limiting access or exposures, it must be described in this section of the written exposure control plan. If notifying

or briefing employees is the method chosen to limit access or exposures, the procedures for doing that must be described under this section of the written exposure control plan.

As noted above, the standard for general industry and maritime does not require the written exposure control plan to address how access to high-exposure areas or employee exposures will be limited. As described in more detail in the summary and explanation of Regulated Areas, OSHA concludes that establishing regulated areas is reasonable and generally feasible in general industry and maritime workplaces. Therefore, the standard for general industry and maritime clearly specifies establishment of regulated areas that are demarcated and have warning signs posted at the entrances to those areas (paragraph (e)(1) and (2)(i) and (ii)). With the procedure clearly laid out in the standard, there is no reason to address it in the written exposure control plan. However, employers can address more than the minimum requirements for a written exposure control plan, and general industry and maritime employers always have the option of describing methods for limiting access in their written exposure control plan.

The proposed written access control plan called for a description of the methods that employers at multi-employer sites would use to notify other employers about the presence and location of areas where respirable crystalline silica may exceed the PEL and any precautionary methods needed to protect employees. AFL-CIO, BAC, and BCTD commented that written plans should provide for a method of communication at multi-employer sites (Document ID 4204, pp. 62-63; 4219, pp. 25-27; 4223, pp. 83-84). BCTD stated that a requirement for a written plan to describe methods of communication at multi-employer sites was not sufficient and requested that employers also be required to give their written plan to a general contractor or

other "controlling employer" at a multi-employer construction site. The controlling employer would be required to share that information with other employers or use the plan to coordinate activities to reduce exposures to employees (Document ID 4223, pp. 118-123). AFL-CIO and BAC endorsed BCTD's approach and/or recommended a similar method for using the written exposure control plan to communicate at multi-employer worksites (Document ID 4204, p. 63; 4219, pp. 25-27). Similarly, ASSE stated that employers who generate respirable crystalline silica exposures at multi-employer sites should inform the general contractor or host employer about the need for access control and work cooperatively with the general contractor or host employer to ensure compliance and notify other employers at the site (Document ID 2339, p. 8).

In contrast, NSSGA commented that the HCS already requires employers to establish methods for communicating hazards to employees of other employers (Document ID 2327, Attachment 1, p. 11). NAHB commented that ". . . the imposition of multi-employer burdens in the proposed rule is inconsistent with the clear wording of §1910.12(a) requiring a construction employer to protect 'each of his employees engaged in construction work' (Emphasis added)" (Document ID 2296, pp. 27-28). OSHA disagrees that a requirement to communicate the presence of crystalline silica to other employers contradicts the 29 CFR 1910.12(a) requirement that employers protect their employees. Communication among employers about areas where respirable crystalline silica exposures may exceed the PEL will provide each employer with the information needed to protect its own employees.

OSHA nonetheless concludes that the written exposure control plan need not specify communication methods at multi-employer sites, or require that employers share their written

exposure control plans at multi-employer sites. Communication at multi-employer worksites is already addressed in the HCS. As part of the written hazard communication program required under the HCS, employers who use hazardous chemicals in such a way that employees of other employers may be exposed must include specific information in the written hazard communication program. This includes methods the employer will use to inform the other employers of any precautionary measures that need to be taken to protect employees (29 CFR 1910.1200(e)(2)(ii)). Because the provisions for a written hazard communication program under the HCS already require employers to share relevant information on hazards and protective measures with other employers in multi-employer workplaces, OSHA does not find it necessary to restate a requirement for sharing of information between employers in the respirable crystalline silica rule. However, as discussed above, written exposure control plans are useful for communicating information, and employers may decide that they are a convenient way for sharing information with other employers at multi-employer workplaces.

Some commenters requested that written plans address additional topics and requirements. For example, Public Citizen, BCTD, and AFL-CIO, requested that the written exposure control plan describe exposure assessment methods or programs (e.g., air monitoring or objective data) and results (Document ID 2249, pp. 3-4; 2371, Attachment 1, p. 16; 4204, p. 62; 4223, p. 82). Public Citizen indicated that this should include detailed descriptions of analytical methods and air sampling protocols or objective exposure assessment methods, and BCTD stated that employers using Table 1 could indicate the portion of Table 1 upon which they are relying (Document ID 2249, pp. 3-4; 4223, p. 82). BCTD and AFL-CIO recommended that the written

plan address respiratory protection, medical surveillance, and training programs, including documentation that employees have received respiratory fit testing, medical evaluations or examinations, and training (Document ID 4204, p. 62; 4223, p. 82). Public Citizen requested that the plan be prepared by a technically qualified person if the employer lacks the expertise to prepare and implement the plan (Document ID 2249, p. 4). ASSE preferred that the plans be developed by a certified safety professional or certified industrial hygienist (CIH) (Document ID 2339, p. 8). NAHB expressed concern about costs if small companies had to hire safety consultants or industrial hygienists to develop the plan (Document ID 2296, p. 41).

OSHA disagrees with commenters that the written exposure control plan needs to address these topics. The major purpose of a written exposure control plan is to ensure that respirable crystalline silica hazards are consistently identified and controlled. OSHA concludes that this purpose is best served if the written plan is limited to information useful for the employer or the employer's designated representative who will conduct inspections on job sites to ensure that employees are adequately and consistently protected. Requiring a written exposure control plan to contain information that is not directly relevant to identifying and controlling hazards at job sites would needlessly increase the burdens to employers preparing the written plans and could make the plans cumbersome for them to use on job sites. In addition, OSHA does not see the need for including a description of the respiratory protection program because employers are already required to develop a written respiratory protection program under the respiratory protection standard (29 CFR 1910.134(c)). Recordkeeping requirements are clearly specified for fit testing and medical evaluations in the respiratory protection standard (29 CFR 1910.134) and

for medical examinations and exposure assessments in this rule. The respirable crystalline silica rule does not require employers to keep training records. As explained in more detail in the summary and explanation of Recordkeeping, the rule does not require training records because employers must instead ensure that employees demonstrate knowledge and understanding of training subjects and in addition, such a requirement would increase paperwork burdens for employers and would not be consistent with the HCS and most OSHA standards.

Therefore, OSHA is neither requiring nor precluding employers to include in written exposure control plans descriptions of exposure assessment methods and results or information on respiratory protection, medical surveillance, and training programs. Requiring information, such as highly technical details on analytical methods, would increase the likelihood that small employers would need to hire a safety and health professional to develop the plans, thus increasing the costs and burdens to those employers. Although OSHA encourages companies to seek professional assistance when needed to develop the plans, requiring a plan that is so complex that many employers would not develop it themselves defeats the advantage of employers gaining an increased understanding of the rule by articulating its requirements. The additional information may be useful as part of a compliance plan, and employers have the option to develop such a plan if they find it helpful.

Paragraph (f)(2)(ii) of the standard for general industry and maritime (paragraph (g)(2) of the standard for construction) requires the employer to review and evaluate the effectiveness of the written exposure control plan at least annually and update it as necessary. A similar requirement was included in the proposed written access control plan. Public Citizen requested

revisions of written exposure control plans as needed, including after annual review of exposure assessment methods (Document ID 2249, p. 4). OSHA agrees with Public Citizen that the written exposure control plan needs to be periodically reviewed and updated as needed because work conditions can change (e.g., the employer purchases a new type of equipment). As discussed above, a written exposure control plan will not likely need to be updated often because employees tend to use the same equipment to perform the same tasks at many locations. However, a yearly review is needed to ensure that all current scenarios are captured in the plan.

Paragraph (f)(2)(iii) of the standard for general industry and maritime (paragraph (g)(3) of the standard for construction) requires that the employer make the written exposure control plan readily available for examination and copying, upon request, to each employee covered by this section, his or her designated representative, the Assistant Secretary (i.e., OSHA), or the Director (i.e., NIOSH). A similar requirement was included in the proposed written access control plan. Public Citizen, USW, BCTD, and AFL-CIO requested a requirement to make written exposure control plans available upon request by employees or their representatives (Document ID 2249, p. 4; 2336, p. 9; 2371, Attachment 1, p. 17; 4204, p. 63). NIOSH, Public Citizen, and BAC also stated that written exposure control plans are a useful way to communicate protections to employees (Document ID 2177, Attachment B, pp. 16-17; 2249, p. 3; 2329, p. 5). OSHA agrees with commenters that a written exposure control plan is an effective method for communicating protections to employees and their designated representatives. Making the written plan readily available to employees and their designated representatives upon request empowers and protects employees by giving them and their representatives the

information to question employers if controls are not fully and properly implemented or maintained. Similarly, making written exposure control plans readily available to OSHA or NIOSH allows them to verify effectiveness of employee protections.

BCTD also requested that the rule require employers to address in their written plans how temporary workers will be protected and that the rule require staffing agencies and employers who use temporary staff to share their written exposure control plans (Document ID 4223, pp. 83-84). OSHA disagrees with BCTD that the rule needs to include a requirement for host employers and temporary staffing agencies to share their written exposure control plans with each other. However, OSHA agrees with the importance of ensuring that temporary workers receive the protections they are entitled to under the OSH Act. As BCTD noted in its comments, OSHA addresses the issue of temporary employee protections in its July 15, 2014, memorandum titled Policy Background on the Temporary Worker Initiative (Document ID 4223, p. 84). The policy memorandum indicates that both the host and staffing agency are responsible for the health and safety of temporary employees and encourages compliance officers to review written contracts between the staffing agency and host employer to determine if they have fully addressed employee health and safety. For example, the policy memorandum indicates that host employers are well suited for assuming responsibility for compliance related to workplace hazards, while staffing agencies may be best positioned to provide medical surveillance. The memorandum also states that although the host employer has the primary responsibility for assessing hazards and complying with occupational safety and health rules in his or her workplace, staffing agencies must also ensure that they are not sending employees to workplaces

where the employees would be inadequately protected from or trained about hazards. A temporary staffing agency could review a host employer's written exposure control plan to verify that the employer has identified hazards and is implementing the appropriate controls. Staffing agencies and host employers would have the option to supplement their written contract with a written exposure control plan if that is useful for them. OSHA is not requiring that host employers and staffing agencies share written exposure control plans for respirable crystalline silica because sharing information is an issue that affects all OSHA safety and health regulations and is therefore most efficiently addressed through general policy statements.

Competent Person (Construction).

Specific duties for a competent person were recommended by a diverse group of commenters, including AIHA, NIOSH, National Asphalt Pavement Association (NAPA), IUOE, National Rural Electric Cooperative Association (NRECA), retired occupational safety and health attorney Charles Gordon, LHSFNA, and BCTD (Document ID 2169, p. 5; 2177, Attachment B, pp. 9-10, 14; 2181, pp. 10-11; 2262, pp. 38-39, 42-43; 2365, pp. 19-20; 3588, Tr. 3800-3801; 3589, Tr. 4197-4201; 4223, pp. 106-114). BCTD, which had among the most extensive recommendations, noted that OSHA standards for lead, asbestos, and cadmium specify duties for a competent person (Document ID 4223, p. 112). For the respirable crystalline silica standard, BCTD requested that the employer designate a competent person to be on site whenever work covered by the standard is being conducted to ensure that the employer's written exposure control plan is implemented, and to:

> . . . use the written exposure control plan to identify locations where silica is present or is reasonably expected to be present in the workplace prior to the performance of work. In addition the competent person's duties shall include ensuring: 1) the employer has assessed the exposures as required by this section; 2) where necessary, regulated areas are established and access to and from those areas is limited to authorized persons; 3) the engineering controls and work practices required by this standard, including all elements of Table 1 (if it is being used), are fully and properly implemented, maintained in proper operating condition, and functioning properly; 4) employees have been provided with appropriate PPE, including respiratory protection, if required; and 5) that all employees exposed to silica have received the appropriate silica training . . . (Document ID 4223, p. 113).

NIOSH recommended similar duties in addition to indicating that the competent person should assure proper hygiene to prevent employees from taking home silica dust on clothing and to conduct daily checks of engineering controls and respirators in abrasive blasting operations involving sand (Document ID 2177, Attachment B, pp. 9-10, 14). IUOE stated that the competent person could assist with employee training, ensure good housekeeping in heavy equipment cabs, and assume responsibility for exposure assessments (Document ID 2262, p. 41; 3583, Tr. 2369-2370; 3583, Tr. 2345). NISA stated that a competent person could conduct qualitative objective exposure assessments or determine frequency of exposure estimates under the performance option (Document ID 2195, pp. 35-36).

CISC opposed a requirement for a competent person and stated that thorough training eliminated the need for a competent person and access control plan (Document ID 4217, pp. 25-26). In disputing the value of expanding the competent person role in the standard, CISC claimed that the ubiquitous presence of silica in construction precluded the need for a designated person who is capable of identifying existing and predictable respirable crystalline silica hazards and has authorization to take prompt corrective actions (Document ID 2319, p. 127).

OSHA concludes that the ubiquitous presence of respirable crystalline silica and the many variables that can affect employee exposure when performing construction tasks justify a requirement for a competent person in construction, who is not only trained to identify and correct respirable crystalline silica hazards, but also is authorized to take immediate corrective actions to eliminate or minimize them.

Exposures and hazards can vary according to environmental conditions such as wind and humidity, geological profile of soil, if work is performed indoors or outdoors, or how well exposure controls are maintained. Consequently, there is an obvious need for a competent person to frequently inspect the construction job site, identify respirable crystalline silica hazards, and verify that effective control measures are being used. Site assessment is a continuous process because of changing environmental and work conditions as a construction job is being completed. In cases where the competent person is the only person from his or her company on a job site, frequent inspections of the job site would equate to continuous assessment of variables associated with the job that the competent person is conducting (e.g., signs that the controls are not functioning effectively, a change in weather condition that might require an adjustment of controls, or moving from an outdoor area to an enclosed area). Therefore, paragraph (g)(4) of the standard for construction requires an employer to designate a competent person to make frequent and regular inspections of job sites, materials, and equipment to implement the written exposure control plan. OSHA concludes that the uniqueness and complexity of scenarios on construction sites justify the designation of a competent person.

OSHA agrees with commenters that a competent person is needed in construction because employers who use the specified exposure control methods in Table 1 are not required to conduct exposure assessments and because large numbers of small construction companies do not typically employ health and safety professionals. Another reason for including a competent person provision in the construction standard is because at multi-employer worksites, the actions of one employer may expose employees of other employers to hazards. For these reasons, OSHA agrees with ACCSH and commenters from NIOSH, labor unions, and employee health advocate groups that a requirement for a designated competent person is needed and will improve employee protections in construction.

In addition, as noted above, a requirement for a competent person is consistent with OSHA substance-specific standards for construction, such as lead (29 CFR 1926.62), asbestos (29 CFR 1926.1101), and cadmium (29 CFR 1926.1127). OSHA's general safety and health provisions for construction require the employer to initiate and maintain programs for accident prevention, as may be necessary, and such programs require frequent and regular inspections of job sites, materials, and equipment by a designated competent person (29 CFR 1926.20(b)(1) and (2)). Designating a competent person is consistent with current construction industry practices because, as the record indicates, employers in the construction industry are already using competent persons.

In its prehearing comments, BCTD also requested that the exposure control plan list the identity of the competent person (Document ID 2371, Attachment 1, pp. 16-17). OSHA is not requiring that the written exposure control plan include the identity of the competent person

because it is both impractical and unnecessary. Construction companies could have more than one designated competent person because they need a backup competent person or they have jobs being conducted at various construction sites. Therefore the identity of the competent person could change from day to day if employees work at different job sites, or if a backup person is sent to a particular job site. However, it is important for employees to be able to identify the competent person. Therefore, OSHA is requiring that employers covered by the standard for construction notify employees about the identity of the competent person as part of the training provision under paragraph (i)(2)(i)(E). OSHA expects this could simply involve announcing the identity of the competent person at the start of each work shift.

Competent Person (General Industry). As part of the proposed written access control plan, OSHA proposed that a competent person identify and maintain regulated areas in workplaces covered by the general industry and maritime standard. AFL-CIO and USW requested expanded competent person duties and training requirements for general industry and maritime because a competent person could recognize and take action to protect employees from high exposures (Document ID 4204, pp. 58-60; 4214, pp. 14-16). AFL-CIO urged OSHA to reinstate the competent person duties from the 2003 SBREFA draft standard (Document ID 4204, pp. 58-60). USW commented that a competent person could ensure that hazards are recognized, employees receive proper training, adequate controls and PPE are implemented, and an effective exposure control plan is developed (Document ID 4214, pp. 14-15). In describing how a competent person is relevant to general industry, AFL-CIO pointed to testimony by employees who were trained to evaluate the function of ventilation systems (Document ID 4204,

p. 60). AFL-CIO also asserted that NIOSH and AIHA urged OSHA to include a competent person requirement for both general industry and construction (Document ID 4204, pp. 59-60). OSHA examined the AIHA and NIOSH comments referenced by AFL-CIO and identified only recommendations for a competent person regarding construction-related topics, such as Table 1 (Document ID 2169, pp. 4-5; 2177, Attachment B, pp. 8-10, 25-26).

OSHA is not requiring a competent person for the general industry and maritime standard. OSHA has determined that in most cases, general industry scenarios are not as variable as those in construction. For example, most work is performed indoors and therefore, not subject to variables such as wind shifts and moving exposure sources that could significantly affect exposures or complicate establishment of regulated areas. In general industry and maritime, controls are not usually built into tools that require action by the individual employees who use them to function effectively. The exposure assessments that employers in general industry and maritime are required to conduct will verify that controls are functioning effectively. Employers covered under the general industry and maritime standard are more likely to have health and safety professionals on staff who could assist with implementation of the standard. Finally, competent persons have not been included in other OSHA substance-specific standards for general industry. For example, a competent person requirement was included in the construction standard for cadmium because of environmental variability and the presence of multiple employers on the job site, but a competent person requirement was not included in the general industry standard for cadmium (29 CFR 1910.1027; 29 CFR 1926.1127; 57 FR 42101, 42382 (9/14/1992)). Moreover, as explained in the summary and explanation of Regulated Areas,

establishing regulated areas is reasonable in most general industry scenarios because employers are required to conduct exposure assessment and are thus able to determine the boundaries of a regulated area. Therefore, the general industry and maritime standard requires regulated areas that are demarcated and posted with warning signs. This negates the need for a competent person to identify and maintain regulated areas. These factors explain and support OSHA's conclusion that there is no regulatory need for including a competent person requirement in the respirable crystalline silica standard for general industry and maritime.

D. Medical Surveillance

Some commenters representing the construction industry questioned the practicality of medical surveillance for construction employees due to a number of particular difficulties, such as the short-term nature and high turnover rate of construction jobs (e.g., Document ID 2116, Attachment 1, p. 20; 2187, p. 7; 2247, p. 1; 2276, p. 10; 2289, p. 8; 2295, p. 2; 2296, pp. 42-43; 3230, p. 1; 3442, pp. 5-6; 4029, p. 3; 4217, p. 21). For example, American Subcontractors Association and Hunt Construction Group stated that the difficulty in tracking medical surveillance in a mobile work force could result in repeated, unnecessary testing for construction employees (Document ID 2187, p. 7; 3442; pp. 5-6). Kenny Jordan, Executive Director of the Association for Energy Services Companies (AESC), which represents another industry with high turnover rates, expressed similar concerns about repeated testing, although he did not oppose medical surveillance and asked for a medical record that would follow the employee (Document ID 3589, Tr. 4063). The Laborers' Health and Safety Fund of North America (LHSFNA) supported medical surveillance, but expressed concerns about repeated testing and

urged OSHA to include provisions for contractor associations and union management funds to coordinate medical examinations for employees who work for several contractors in a year to avoid unnecessary medical examinations (Document ID 4207, p. 5).

After considering these comments, OSHA concludes that the necessity for medical surveillance is not negated by the practical challenges of tracking medical surveillance in a mobile work force. OSHA has included medical surveillance in other health standards where construction has been a primary industry impacted by those rules (e.g., lead, asbestos, and chromium (VI)) and finds no reason why the respirable crystalline silica standard for construction should be an exception. Moreover, there are practical solutions for tracking medical surveillance to avoid duplicative, unneeded testing. One simple solution, which OSHA has included in this rule, is to have employers ensure that each employee receives a dated copy of the PLHCP's written medical opinion for the employer. The employee can then provide the opinion to his or her next employer as proof of up-to-date medical surveillance (Document ID 4207, p. 5; 4223, p. 125). Employers could also work with a third party, such as an industry association, union, or local medical facility, to coordinate, provide, or keep records of medical examinations (Document ID 4207, p. 5; 4236, pp. 3-4, Appendix 1, pp. 1-2). Such an approach has been used by LHSFNA to avoid unnecessary testing of employees who work for several contractors in a year (Document ID 3759, Appendix 3). The respirable crystalline silica rule does not preclude such pooled employer-funded approaches, and OSHA expects such coordination to occur in response to this rule. OSHA concludes that there are practical solutions for addressing the challenge posed by employee mobility and turnover in the construction industry, and those

factors should not prevent construction employees who are eligible for medical surveillance under the standard (i.e., those who will be engaged in tasks requiring respirator use for 30 or more days in the upcoming year) from being offered such surveillance as part of the employer's compliance obligations.

Some commenters expressed concerns about the practicality of requiring employers to offer medical surveillance for exposures exceeding a trigger level for 30 days or more in the construction industry. George Kennedy, Vice President of Safety for the National Utility Contractors Association, testified that they do not know what employees are doing in the field each day and so will have to assume that they are exposed and, therefore, offer medical surveillance to every employee (Document ID 3583, Tr. 2245). BCTD questioned the feasibility of the 30-day exposure-duration trigger because the transient nature of construction work makes it difficult to predict if an employee will be exposed for 30 days; the American Industrial Hygiene Association (AIHA), AFL-CIO, and LHSFNA expressed similar views (Document ID 2169, p. 6; 4204, p. 81; 4207, p. 4; 4223, p. 125). CISC and some of its member companies questioned how an employer would know if employees were exposed above the PEL for 30 or more days a year unless they were following Table 1 or conducting near continuous monitoring (Document ID 2269, pp. 6-7; 2289, p. 8; 2319, p. 116). CISC and AIHA questioned how OSHA could verify the number of days an employee was exposed (Document ID 2169, p. 6; 2319, p. 116). Larger employers, such as Fann Contracting, expressed the challenges of tracking employee exposures due to large numbers of employees and various ongoing projects (e.g., Document ID 2116, Attachment 1, p. 11).

OSHA acknowledges that tracking exposures in construction can be challenging but observes that some employers are currently able to track employee exposures to determine which employees should be offered medical surveillance. For example, Kevin Turner, Director of Safety at Hunt Construction Group and representing CISC, testified that safety representatives on job sites keep track of exposures based on employees' schedules, and the company provides medical surveillance for employees exposed above the preceding construction PEL for 30 or more days a year (Document ID 3580, Tr. 1535-1536). Francisco Trujillo, Safety Director at Miller and Long, Inc., testified that at his company, they conduct hazard assessments based mainly on the tasks the employees will be performing, to determine which employees are likely to be exposed above the preceding PEL, and they offer those employees medical evaluations as part of the company's respiratory protection program. The company has a system that monitors participating employees' training, medical evaluations, and fit tests. The system sends email reminders to company representatives when the participating employees are due to be re-examined or re-evaluated. However, Mr. Trujillo expressed concern that if the number of employees participating in the program greatly increases, then maintaining the company's tracking program would become a more daunting task (Document ID 3585, Tr. 3008-3010).

After reviewing the comments and testimony submitted on the proposed construction trigger, OSHA concludes that the special circumstances in construction, such as lack of exposure data for employees using Table 1 or difficulties in tracking exposures for numerous short-term assignments conducted at various sites, warrant a simpler approach for triggering medical surveillance. Therefore, OSHA revised paragraph (h)(1)(i) of the standard for construction to

require that employers offer medical surveillance to employees who will be required to wear a respirator under this standard for 30 or more days a year to limit exposure to respirable crystalline silica. Under the standard for construction, employees must wear a respirator when required to do so under Table 1 (paragraph (c)) or when, pursuant to the performance option or the scheduled monitoring option set forth in paragraph (d)(2), their exposures exceed the PEL (paragraph (e)(1)(ii)). Respirator use under Table 1 is equivalent to the PEL because the tasks that require respirator use are those that, in its technological feasibility analysis of the construction industry, OSHA has determined result in exposures exceeding 50 µg/m^3 a majority of the time (see Chapter IV of the FEA and the summary and explanation of Specified Exposure Control Methods). Based on the number of commenters who indicated that exposure assessment is not practical in construction because of changing tasks and conditions (see summary and explanation of Exposure Assessment), OSHA expects most employers to use Table 1 for tasks listed on the Table (i.e., most of the tasks that generate silica exposure in construction). Under any available exposure control method, however, the most convenient way for construction employers to determine eligibility for medical surveillance is by counting the number of days the employee will be required to wear a respirator. Because respirator use is tied with certain tasks in Table 1, medical surveillance based on respirator use in Table 1 is consistent with the task-based approach described by Francisco Trujillo above. It is also consistent with the task-based triggers in the cadmium construction standard (29 CFR 1926.1127) and operation-based triggers (e.g., Class I work) in the asbestos construction standard (29 CFR 1926.1101).

OSHA concludes that a trigger based on respirator use will greatly simplify determining which employees covered by the construction standard must be offered medical surveillance. Consistent with the approach described by Kevin Turner above, company personnel on site, such as supervisors, could easily record or estimate when employees perform, or will perform, tasks requiring respirator use. Such information could be conveyed to a company employee who tracks it. Despite testifying that he would have a hard time tracking a greater number of employees who may require medical surveillance if the PEL or action level in effect at that time were lowered, Francisco Trujillo, from Miller and Long, a company with approximately 1,500 field employees, indicated that his company has a system that monitors and sends emails when employees are due for another medical examination (Document ID 3585, Tr. 3008-3010). OSHA sees no reason why this system could not be applied to larger numbers of employees, and this shows that it is possible for large companies to track exposures for numerous employees. Tracking exposures or days of respirator use will likely be easier for smaller companies who have fewer employees to track; OSHA estimates from existing data that approximately 93 percent of construction companies covered by the respirable crystalline silica standard have fewer than 20 employees (see Chapter III of the FEA). In addition, compliance officers would be able to determine if employees were exposed for 30 or more days a year but not offered medical surveillance by questioning employees about how often they engage in tasks that require respirator use for that employer.

Fann Contracting asked how a trigger for medical surveillance would apply to employees, such as heavy machine operators, who may briefly use respirators, such as when

outside a cab for 30 minutes (Document ID 2116, Attachment 1, p. 3). OSHA clarifies that if an employee is required to wear a respirator at any time during a given day, whether to comply with the specified exposure control methods in paragraph (c) or to limit exposure to the PEL under the construction standard for respirable crystalline silica, that day counts toward the 30-day threshold.

Commenters also questioned the appropriateness of a 30-day exposure-duration trigger for construction. For example, American Society of Safety Engineers (ASSE) voiced concerns about the standard not addressing temporary employees who are continually exposed from job to job but may never stay with an employer for a full 30 days (Document ID 2339, p. 5). Conversely, CISC questioned why OSHA diverged from the ASTM exposure-duration trigger of 120 days, which would reduce the need to make medical surveillance available for short-term employees, and stated that OSHA needed to explain how this would improve the health of employees (Document ID 2319, p. 118; 1504, pp. 4-5). Members of the ASTM committee that developed the ASTM E 2625 – 09 standard testified that a 120-day exposure-duration trigger was selected so that employers did not have to provide medical surveillance to transient employees and that even a trigger of less than 90 days was considered but would have resulted in too much pressure and cost for employers because of the transient nature of construction work (Document ID 3580, Tr. 1452-1453; 3585, Tr. 2919-2920).

OSHA understands that offering medical surveillance for a transient workforce may be challenging, especially for small companies. However, the requirement to offer periodic medical examinations every three years rather than annually will reduce the cost and burden of providing

such examinations considerably (see Chapter V of the FEA). OSHA finds both the 120-day exposure-duration trigger (in the ASTM standards) and the 90-day trigger (considered by the ASTM committee) overly exclusive and insufficiently protective. Under those longer triggers, many short-term employees (i.e., those doing tasks requiring respirator use or otherwise exposed above the PEL for 30 or more days a year but nonetheless exposed for less than 90 days with the same employer) would be deprived of the health benefits of medical surveillance, such as early detection of disease, despite being at risk due to repeated exposures with different employers. As noted above, the health effects of respirable crystalline silica are most likely to occur as a result of repeated exposures. OSHA concludes that a 30-day exposure-duration trigger strikes a reasonable balance between the administrative burden of offering medical surveillance to all employees, many of whom may not be further exposed or only occasionally exposed, and the need for medical surveillance for employees who are regularly exposed and more likely to experience adverse health effects. The 30-day trigger is also administratively convenient insofar as it is consistent with OSHA standards for construction, including asbestos (29 CFR 1926.1101), cadmium (29 CFR 1926.1127), chromium (VI) (29 CFR 1926.1126), and lead (29 CFR 1926.62).

Charles Gordon suggested that employers give each departing employee a card indicating the number of days they were exposed above the trigger point so that future employers would have a better idea if the employee was eligible for another medical examination based on 30 days of exposure (Document ID 4236, pp. 3-4). Such a record of past exposure with any prior employer is not necessary because of OSHA's decision to not consider exposures with past

employers when triggering medical surveillance. Requiring employers to record exposures with past employers and to give employees a card indicating the number of days they were exposed above the trigger point increases recordkeeping and paperwork burdens for employers. It also imposes a burden on employees because it gives them an additional document that they need to maintain. To avoid these added burdens and for the reasons previously given for not counting exposures with other employers towards an employee's medical surveillance requirement, OSHA rejects Mr. Gordon's suggestion.

Initial examination.

In the preamble of the Notice of Proposed Rulemaking (NPRM), OSHA indicated that where an examination that complies with the requirements of the standard has been provided in the past three years, an additional initial examination would not be needed (78 FR at 56468). Ameren agreed with OSHA's preliminary determination on this issue and asked the Agency to verify that examinations conducted in the last three years could be supplemented with any additional requirements of the rule, such as tuberculosis testing (Document ID 2315, p. 4). OSHA agrees that this is a reasonable approach. For example, if an employee received an examination that met all the requirements of the initial medical examination, with the exception of a tuberculosis test, within the last three years, the employer could supplement that examination by offering only the tuberculosis test. That same employer or a future employer could then offer a periodic medical examination, which does not require a tuberculosis test, three years from the last medical examination. New hires, who received medical surveillance that met the requirements of the respirable crystalline silica rule from a past employer, should have a copy

of the PLHCP's written medical opinion for the employer, which the employer must ensure that the employee receives within 30 days of the examination (paragraph (i)(6)(iii) of the standard for general industry and maritime, paragraph (h)(6)(iii) of the standard for construction), as proof of a current initial or periodic medical examination that met the requirements of this section (see example of the PLHCP's written medical opinion for the employer in non-mandatory Appendix B). If a newly hired employee eligible for medical surveillance presents proof of an examination that met the requirements of the rule, the employer's obligation is to offer the periodic examination required by paragraph (i)(3) of the standard for general industry and maritime (paragraph (h)(3) of the standard for construction) within three years of the previous examination.

Commenting on the three year period in which the result of a prior examination can substitute for a new initial (baseline) examination, APHA, Collegium Ramazzini, and the American Federation of State, County and Municipal Employees (AFSCME) opined that three years between examinations is an excessive time period because it does not provide for an adequate baseline; Collegium Ramazzini further commented that medical findings and medical or work histories can change in three years and that spirometry performed at other locations does not provide an adequate baseline (Document ID 2178, Attachment 1, p. 4; 3541, pp. 4-5; 4203, p. 6). Dr. Celeste Monforton, from George Washington University School of Public Health, agreed with APHA (Document ID 3577, Tr. 846). OSHA disagrees. The three-year interval is consistent with the frequency of periodic examinations, and the reasons for this interval, such as the typical slow progression of respirable crystalline silica-related diseases, are discussed below.

The American Foundry Society (AFS) supported the 30-day period for offering medical surveillance, stating that it addressed the turnover rates in its industry because employees who work 30 days are likely to continue their employment (Document ID 2379, Appendix 1, p. 71). AESC requested that OSHA allow medical examinations to be provided within 90 days of assignment to address the turnover rate in its industry (Document ID 2344, p. 2). The National Stone, Sand and Gravel Association (NSSGA) noted difficulties in scheduling medical examinations within 30 days in remote locations because testing vans that offer medical examinations might not be available within that time period (Document ID 3583, Tr. 2316-2317). Because a 30-day period for offering medical examinations is reasonable for AFS, which represents an industry with high turnover rates, OSHA concludes that a 30-day period should be reasonable in most general industry settings. OSHA does not agree with AESC that the period to offer medical surveillance should be extended to 90 days in the standard for general industry and maritime. That longer time period to offer medical surveillance would exclude and leave unprotected many employees who may be exposed to significant amounts of silica while working short-term assignments, for periods up to 90 days, for numerous companies within the same industry.

Representatives from the construction industry also commented on the 30-day period to offer medical surveillance. BAC and BCTD recommended that medical examinations be made available as soon as practicable, instead of within 30 days after assignment, in the construction industry because it would be difficult for employers to predict if an employee would be exposed for 30 days or more during the upcoming year, and it could encourage employers to terminate

employees before the 30-day period ends (Document ID 4219, p. 29; 4223, p. 125). Fann Contracting suggested that a better trigger would be after the employee has been exposed for 30 days instead of within the first 30 days of assignment (Document ID 2116, Attachment 1, p. 43).

OSHA rejects this reasoning, and is maintaining the requirement to offer medical surveillance within 30 days of assignment for the construction standard. The requirement better assures that medical examinations will be offered within a reasonable time period than allowing the employer to offer them "as soon as practicable." As noted above, employers can determine who will be eligible for medical surveillance based on required respirator use under Table 1 or similar task-based approaches. Even at the time of initial assignment, OSHA expects that employers will know the tasks that the employee will be performing, and in the case of short-term employees, the approximate duration the employee will be with the company. In addition, terminating employees to avoid offering medical surveillance would not be cost effective because the employer would incur more costs from constantly having to train new employees.

Contents of initial medical examination.

OSHA received a range of comments related to the contents of the initial examination. Some stakeholders, including NIOSH and commenters representing the medical community, labor unions, and industry, supported the contents of medical surveillance that OSHA proposed, though some wanted to expand the contents, as addressed below (e.g., Document ID 2175, p. 6; 2177, Attachment B, pp. 38-39; 2282, Attachment 3, p. 19; 2336, p. 12; 2371, Attachment 1, p. 43; 3589, Tr. 4205; 4204, p. 82). Further, the contents of medical surveillance in this standard are

fairly consistent with the recommendations in occupational health programs, such as those by NISA and NSSGA (Document ID 2195, pp. 40-41; 2327, Attachment 1, p. 23).

However, not all stakeholders agreed that the list of proposed initial examination contents was appropriate. For example, Fann Contracting favored limiting the contents of medical examinations to X-rays, while Dal-Tile Corporation, the 3M Company, and the Tile Council of North America indicated that requirements for medical examinations under the respiratory protection standard were sufficient (Document ID 2116, Attachment 1, p. 37; 2147, p. 3; 2313, p. 7; 2363, pp. 5-6). Similarly, Nevada Mining Association commented that the need to conduct physical examinations, X-rays, or pulmonary function testing should be left to the discretion of the PLHCP (Document ID 2107, pp. 3-4). Newmont Mining also said that one or more of these tests should be at the discretion of the PLHCP (Document ID 1963, pp. 2-3) .

OSHA finds that X-rays alone are not sufficient because, as explained in more detail below, some employees may have symptoms or abnormal lung function that are not detected by X-ray but may become evident by other tests, such as spirometry. The Agency also finds that the evaluations offered under the respiratory protection standard are insufficient because the information gathered under that standard is limited and may not involve examinations, while the respirable crystalline silica rule requires examinations that include objective measures, such as physical examinations, spirometry testing and X-rays, that may detect early disease in asymptomatic employees. In addition, OSHA does not agree that all required tests should be left to the discretion of the PLHCP because the Agency has determined that employees who must be offered medical surveillance are at risk of developing respirable crystalline silica-related

diseases, and the required tests are the minimum tests needed to screen for those diseases. Therefore, OSHA concludes that limiting medical surveillance to only X-rays, the evaluations performed under the respiratory protection standard, or only tests selected by the PLHCP is not sufficiently protective.

The first item required as part of the initial medical examination is 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 (paragraph (i)(2)(i) of the standard for general industry and maritime, paragraph (h)(2)(i) of the standard for construction). OSHA is requiring medical and work histories because they are an efficient and inexpensive means for collecting information that can aid in identifying individuals who are at risk due to hazardous exposures (Document ID 1505, p. 2; 1517, p. 25). Recording of symptoms is important because, in some cases, symptoms indicating onset of disease can occur in the absence of abnormal laboratory test findings (Document ID 1517, p. 25).

Because symptoms may be the earliest sign of disease and to allow for consistent and comprehensive data collection, Collegium Ramazzini recommended that an appendix with a standardized questionnaire be included; it also recommended that the questionnaire address non-respiratory effects, such as renal disease and connective tissue disorders (Document ID 3541, pp. 3, 6). While not going as far as this recommendation, OSHA includes in the rule a non-mandatory appendix for medical surveillance (Appendix B), which gives PLHCPs detailed

information on what is to be collected as part of the medical history. The appendix recommends collecting information on renal disease and connective tissue disorders. OSHA intends for this approach to allow PLHCPs to easily standardize their method for gathering information for work and medical histories related to respirable crystalline silica exposure.

Newmont Mining and Nevada Mining Association objected to a requirement for a medical and work history, asserting that a personal medical history is not related to silica exposure (Document ID 1963, p. 2; 2107, p. 3). Commenters, including DCA and International Brotherhood of Teamsters, objected to employees revealing medical and work history information not related to respirable crystalline silica exposure because of privacy concerns (e.g., Document ID 2309, p. 5; 2318, pp. 13-14). Retired foundry employee, Allen Schultz, representing WisCOSH, expressed concern that information, such as smoking history, could be used against employees (Document ID 3586, Tr. 3255). As noted above, a purpose of medical surveillance is to inform employees if they may be at increased risk of adverse effects from respirable crystalline silica exposure. Personal habits, such as smoking, could lead to compromised lung function or increased risk of lung cancer, and exposure to respirable crystalline silica could compound those effects (see Section V, Health Effects). Collecting information, such as smoking habits and related medical history, allows the PLHCP to warn employees about their increased risks from exposure to respirable crystalline silica so employees can make informed health decisions.

As discussed below, OSHA is addressing employee privacy issues by reducing the information to be included in the PLHCP's written medical opinion for the employer without the

employee's permission (paragraphs (i)(6)(i)(A)-(C) of the standard for general industry and maritime and paragraphs (h)(6)(i)(A)-(C) of the standard for construction); under those paragraphs, the only medically related information that is to be reported to the employer without authorization from the employee is limitations on respirator use. Personal habits, such as smoking, are not included in the medical opinion for the employer. Therefore, employees' privacy will not be compromised as a result of the information collected as part of the exposure and medical history.

The second item required as part of the initial medical examination is a physical examination that focuses on the respiratory system (paragraph (i)(2)(ii) of the standard for general industry and maritime, paragraph (h)(2)(ii) of the standard for construction), which is known to be susceptible to respirable crystalline silica toxicity. OSHA finds that aspects of the physical examination, such as visual inspection, palpation, tapping, and listening with a stethoscope, allow the PLHCP to detect abnormalities in chest shape or lung sounds that are associated with compromised lung function (Document ID 1514, p. 74; 1517, pp. 26-27). Dr. Michael Fischman, occupational and environmental physician/toxicologist and professor at the University of California, representing ACOEM, strongly endorsed a physical examination and noted that another valuable aspect is that it allows the employee to have a face-to-face interaction with the clinician to talk about symptoms or other concerns (Document ID 3577, Tr. 767). OSHA agrees and concludes that the physical examination is necessary.

The third item required as part of the initial medical examination is a chest X-ray, specifically 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 (paragraph (i)(2)(iii) of the standard for general industry and maritime, paragraph (h)(2)(iii) of the standard for construction). The proposed rule specified only film X-rays but would have allowed for an equivalent diagnostic study, such as digital X-rays; OSHA also sought comment on whether computed tomography (CT) or high resolution computed tomography (HRCT) scans should be considered equivalent diagnostic tests (78 FR at 56469-56470). As discussed in greater detail below, OSHA received many comments on the proposed provision, and in response to those comments, the current provision differs substantially from the proposed rule in two main ways. First, the rule now specifically allows for chest X-rays to be recorded on either film or digital radiography systems. Second, the rule does not allow for an "equivalent diagnostic study."

Medical experts including ACOEM, the American Thoracic Society (ATS), and NIOSH recommend X-rays as part of medical examinations for employees exposed to respirable crystalline silica (e.g., Document ID 1505, p. 2; 2175, p. 6; 2177, Attachment B, pp. 38-39). The initial X-ray provides baseline data against which to assess any subsequent changes. An initial chest X-ray can be useful for diagnosing silicosis and for detecting mycobacterial disease (e.g., active pulmonary tuberculosis, which employees with latent tuberculosis infections and exposed to respirable crystalline silica are at greater risk of developing (Document ID 1514, pp. 75, 100). X-rays are important because the findings can lead to the initiation of employment choices that

can reduce exposures to respirable crystalline silica and might decrease the risk of silicosis progression or allow for treatment of mycobacterial infections (Document ID 1505, p. 3).

As noted above, OSHA proposed that the required chest X-ray be interpreted and classified according to ILO International Classification of Radiographs of Pneumoconiosis by a NIOSH-certified B Reader. The ILO system was designed to assess X-ray and digital radiographic image quality and to describe radiographic findings of pneumoconiosis in a simple and reproducible way by comparing an employee's X-ray to a standard X-ray to score opacities according to shape, size, location, and profusion (Document ID 1475, p. 1; 1511, pp. 64-68; 1514, pp. 77-78). A NIOSH-certified B Reader is a physician who has demonstrated competency in the ILO classification system by passing proficiency and periodic recertification examinations (Document ID 1498, p. 1). The NIOSH certification procedures were designed to improve the proficiency of X-ray and digital radiographic image readers and minimize variability of readings.

Commenters, such as Collegium Ramazzini, NIOSH, and the Dow Chemical Company, agreed with OSHA that digital radiographic images are equivalent to conventional X-rays; NIOSH and Dow Chemical suggested OSHA clarify that the proposed requirement for chest X-rays may be satisfied either with conventional film-based technology or with digital technology; and NIOSH and Collegium Ramazzini referred OSHA to an interim final regulation for coal miners that allows for digital technology (Document ID 2177, Attachment B, pp. 40-41; 2270, p. 13; 3541, p. 7). After reviewing the record evidence on this issue, OSHA reaffirms its preliminary conclusion that X-rays recorded on digital radiography systems are equivalent to those recorded on film. Therefore, OSHA has revised paragraph (i)(2)(iii) of the standard for

general industry and maritime (paragraph (h)(2)(iii) of the standard for construction) to indicate that X-rays can be recorded on either film or digital systems, using language that is consistent with that in the interim final regulation for coal miners (42 CFR part 37.2 (10-1-13 Edition)).

NSSGA commented that good quality digital images reproduced on film should also be considered acceptable as equivalent to X-rays (Document ID 2327, Attachment 1, p. 23). OSHA disagrees. The Agency does not recommend classification using hard copies printed from digital images because a 2009 study by Franzblau et al. indicates that they give the appearance of more opacities compared to films or digital images (Document ID 1512). OSHA does not find hard copy printouts of digital images equivalent to conventional X-rays. Consequently, classification through the use of hard copies printed from digital images may not be used to satisfy the requirement for chest X-rays.

OSHA noted in the preamble for the NPRM that CT or HRCT scans could be considered "equivalent diagnostic studies." CT and HRCT scans are superior to chest X-ray in the early detection of silicosis and the identification of progressive massive fibrosis. However, CT and HRCT scans have risks and disadvantages that include higher radiation doses and current unavailability of standardized methods for interpreting and reporting the results (78 FR at 56470). Because of these concerns, OSHA specifically sought comment on whether CT and HRCT scans should be considered equivalent diagnostic studies under the rule, and a number of stakeholders provided comments on this issue.

In its prehearing comments, ATS stated that despite the lack of standardized interpretation and reporting methods, CT or HRCT are reasonable "equivalent diagnostic

studies" to standard chest X-rays because they are more sensitive than X-rays for early detection of diseases, such as silicosis and lung cancer; however, the group's representative, Dr. Robert Cohen, later testified that HRCT is not ready as a screening technique but is a useful diagnostic tool (Document ID 2175, p. 6; 3577, Tr. 825). USW noted that interpretation methods are being developed for the evaluation of pneumoconiosis by CT scan and suggested approaches for the use of low dose CT (LDCT) scans to evaluate silicosis and lung cancer in some employees (Document ID 4214, pp. 9-12).

Physicians, such as those representing ACOEM, Collegium Ramazzini, and NIOSH, did not consider CT or HRCT to be equivalent diagnostic studies because of the lack of a widely-accepted standardized system of interpretation, such as the ILO method (e.g., Document ID 2080, pp. 7-8; 2177, Attachment B, p. 40; 3541, p. 7). In addition, NIOSH, APHA, Edison Electric Institute (EEI), Collegium Ramazzini, and ACOEM indicated the higher radiation doses received from CT and HRCT scans make it inappropriate to consider these methods equivalent to X-rays (Document ID 2177, Attachment B, p. 40; 2178, Attachment 1, p. 6; 2357, pp. 34-35; 3541, p.7; 3577, Tr. 768).

NIOSH and Collegium Ramazzini also commented on the increased sensitivity of CT scans in detecting abnormalities that require follow-up, which they cited as another reason why CT scans should not be considered equivalent to X-rays (Document ID 2177, Attachment B, p. 40; 3541, p. 7). NIOSH said the abnormalities can suggest lung cancer, but most are found to be "false positives" (Document ID 2177, Attachment B, p. 40). Detection of abnormalities that might suggest cancer can lead to anxiety in patients; it can also lead to follow-up with more

imaging tests that increase radiation exposures or invasive biopsy procedures that have a risk of complications (Document ID 2177, Attachment B, p. 40; 3978, pp. 2423, 2427). Commenters also noted that CT scans cost more than X-rays (Document ID 2177, Attachment B, p. 40; 2178, Attachment 1, p. 6; 3541, p. 7). In addition, Collegium Ramazzini stated that chest X-rays are readily accessible in most cases, but availability of CT scanning is more limited, especially in rural areas (Document ID 3541, p. 7).

ACOEM, NIOSH, APHA, NSSGA, EEI, and AFL-CIO stated that CT scans are appropriate in some cases, such as a part of follow-up examinations or if recommended by the PLHCP (Document ID 2080, p. 8; 2177, Attachment B, pp. 40-41; 2178, Attachment 1, p. 6; 2327, Attachment 1, p. 26; 2357, pp. 34-35; 4204, p. 82). Dr. David Weissman and Dr. Rosemary Sokas, occupational physician from Georgetown University, representing APHA, indicated that if an employee happens to have had a CT scan that was conducted as part of a clinical workup or diagnosis, it should be accepted in place of X-rays (Document ID 3577, Tr. 792; 3579, Tr. 256).

After reviewing the record on this issue, OSHA has determined that CT or HRCT scans should not be considered "equivalent diagnostic studies" to conventional film or digital chest X-rays for screening of silicosis because of higher radiation exposures, lack of a standardized classification system for pneumoconiosis, increased false positive findings, higher costs, and limited availability in some areas. OSHA also agrees with commenters that CT scans may be useful for follow-up purposes, as determined on a case-by-case basis by the PLHCP. For example, the PLHCP could request a CT scan to diagnose possible abnormalities detected by X-

ray or other testing done as part of surveillance, and the rule gives the PLHCP this option (paragraph (i)(2)(vi) of the standard for general industry and maritime, paragraph (h)(2)(vi) of the standard for construction). However OSHA does not agree that a CT scan conducted within the past three years can meet the requirement for an X-ray because the CT scan cannot be evaluated according to ILO methods.

OSHA also received comments on the use of CT scans to screen for lung cancer, and those comments are discussed below, as part of the Agency's discussion of additional tests that commenters proposed for inclusion in medical examinations.

In sum, unlike the proposed rule, paragraph (i)(2)(iii) of the standard for general industry and maritime (paragraph (h)(2)(iii) of the standard for construction) specifically allows for digital X-rays, but does not allow for an equivalent diagnostic study. The rule was revised to allow for digital radiography because OSHA determined that digital X-rays are equivalent to film X-rays. The rule was also revised to remove the allowance for equivalent diagnostic studies because OSHA determined that CT scans are not equivalent to X-rays for screening purposes and no other imaging tests are equivalent to film or digital X-rays interpreted by ILO methods at this time. The provision for X-rays does not contain any other substantive changes compared to the proposed provision.

The fourth item required as part of the initial medical examination is a pulmonary function test, including forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), and FEV_1/FVC ratio, administered by a spirometry technician with a current certificate from a NIOSH-approved spirometry course (paragraph (i)(2)(iv) of the standard for general

industry and maritime, paragraph (h)(2)(iv) of the standard for construction). FVC is the total volume of air exhaled after a full inspiration, FEV_1 is the volume of air exhaled in the first second, and the FEV_1/FVC ratio is the speed of expired air (Document ID 3630, p. 2). OSHA proposed the inclusion of pulmonary function testing (i.e., spirometry, as required by this rule) because it is useful for obtaining information about the employee's lung capacity and expiratory flow rate and for determining baseline lung function status against which to assess any subsequent lung function changes.

Some industry representatives, such as Fann Contracting and CISC, opposed the requirement for spirometry testing because reduced pulmonary function can be related to smoking or exposures other than respirable crystalline silica (Document ID 2116, Attachment 1, Page 39; 2319, pp. 118-119). CISC further commented that OSHA did not address statements in the ASTM standard about the non-specificity of lung function changes to respirable crystalline silica exposure, and a lack of evidence that routine spirometry is useful for detecting respirable crystalline silica-related diseases in early stages.

In contrast, commenters, such as Collegium Ramazzini and NIOSH, noted that spirometry is useful for detecting lung function changes associated with COPD, a disease outcome related to respirable crystalline silica exposure (Document ID 3541, p. 8; 3579, Tr. 255). ACOEM and Collegium Ramazzini explained that respirable crystalline silica exposures can result in lung function changes in the absence of radiological abnormalities, and spirometry is important for detecting those changes in the early stages of disease; ACOEM further commented that early detection of abnormal lung function is important to fully assess

employees' health and apply protective intervention methods (Document ID 2080, p. 8; 3541, p. 8).

ASSE and some industry representatives, including Newmont Mining, NISA and AFS, also supported spirometry testing (e.g., Document ID 1963, pp. 2-3; 2339, p. 9; 2379, Appendix 1, p. 70; 4208, p. 22). NISA includes spirometry testing as part of its occupational health program for respirable crystalline silica-exposed employees; it emphasized that spirometry testing: (1) allows for early detection and measurement of severity of lung function loss, the most direct symptom of silicosis or other nonmalignant respiratory disease, and (2) is useful for determining an employee's ability to safely wear a negative pressure respirator (Document ID 4208, p. 22).

The fifth item required as part of the initial medical examination is a test for latent tuberculosis infection (paragraph (i)(2)(v) of the standard for general industry and maritime, paragraph (h)(2)(v) of the standard for construction). This provision is unchanged from the proposed rule. "Latent" refers to a stage of infection that does not result in symptoms or possible transmission of the disease to others. OSHA proposed the inclusion of a test for latent tuberculosis infection because exposure to respirable crystalline silica increases the risk of a latent tuberculosis infection becoming active (i.e., the infected person shows signs and symptoms and is contagious), even in employees who do not have silicosis (see Section VI, Final Quantitative Risk Assessment and Significance of Risk) (Document ID 0360; 0465; 0992, p.1461-1462). This places not only the employee, but also his or her coworkers, at increased risk of acquiring this potentially fatal disease.

OSHA sought comment on its preliminary determination that all employees receiving an initial medical examination should be tested for latent tuberculosis infection. A number of stakeholders, including Dr. James Cone, ATS, NIOSH, APHA, NISA, NSSGA, ASSE, BCTD, and ACOEM agreed with OSHA's preliminary conclusion that testing for latent tuberculosis infection should be part of the initial examination (e.g., Document ID 2157, p. 6; 2175, p. 6; 2177, Attachment B, pp. 38-39; 2178, Attachment 1, p. 5; 2195, p. 41; 2327, Attachment 1, p. 23; 2339, p. 9; 2371, Attachment 1, p. 43). However, other stakeholders, such as Newmont Mining, Nevada Mining Association, and EEI, recommended that testing for latent tuberculosis infection be limited to employees who have silicosis (e.g., Document ID 1963, p. 2; 2107, p. 3; 2357, p. 34). EEI specifically opposed testing for latent tuberculosis infection in the absence of radiological evidence of silicosis, arguing that there are no good methods for quantifying the benefits of that testing.

After reviewing the comments on this issue, OSHA affirms its conclusion that testing for latent tuberculosis infections is a necessary and important part of the initial examination. As noted above, evidence demonstrates that exposure to respirable crystalline silica increases the risk for developing active pulmonary tuberculosis infection in individuals with latent tuberculosis infection, independent of the presence of silicosis (Document ID 0360; 0465; 0992, pp. 1461-1462). Active tuberculosis cases are prevented by identifying and treating those with latent tuberculosis infections. Therefore, OSHA concludes it is appropriate to test for latent tuberculosis infection in all employees who will be exposed to respirable crystalline silica and are eligible for medical surveillance, for their protection and to prevent transmission of an active,

potentially fatal infection to their coworkers. Any concerns about a lack of good methods for calculating benefits associated with latent tuberculosis infection testing do not negate the scientific evidence demonstrating that exposure to respirable crystalline silica increases the risk of a latent infection becoming active.

Newmont Mining, Nevada Mining Association, and Fann Contracting did not support testing for latent tuberculosis infection because employees with the infection may not have contracted it in an occupational setting (Document ID 1963, p. 2; 2107, p. 3; 2116, Attachment 1, p. 38). While that may be true, testing for latent tuberculosis infection provides another example and support for two of the main objectives of medical surveillance: (1) to identify conditions that might make employees more sensitive to respirable crystalline silica exposure; and (2) to allow for intervention methods to prevent development of serious disease. Employees with latent tuberculosis infections are at greater risk of developing active disease with exposure to respirable crystalline silica, and informing them that they have a latent infection allows for intervention in the form of treatment to eliminate the infection. Treating latent tuberculosis disease before it becomes active and can be transmitted to coworkers (and others) is in the best interest of both the employer and the affected employee.

Dr. James Cone and APHA have stated that a positive boosted or initial test for tuberculosis infection warrants medical referral for further evaluation (Document ID 2157, p. 6; 2178, Attachment 1, p. 5). Ameren commented that a positive tuberculosis test warrants medical removal (Document ID 2315, p. 9). OSHA agrees that employees who test positive for active tuberculosis should be referred to their local public health departments as required by state public

health law (Document ID 2177, Attachment B, p. 50). Those employees will need treatment and, if necessary, to be quarantined until they are no longer contagious. That is the appropriate action for employees with active tuberculosis to prevent infection of coworkers and others, according to procedures established by state public health laws. In the case of latent tuberculosis, the PLHCP may refer the employee to the local public health department, where the employee may get recommendations or prescriptions for treatment. Removal is not necessary for latent tuberculosis infections because employees with latent tuberculosis infections are not contagious. More information about testing for latent tuberculosis infections is included in non-mandatory Appendix B.

The sixth and final item required as part of the initial medical examination is any other test deemed appropriate by the PLHCP (paragraph (i)(2)(vi) of the standard for general industry and maritime, paragraph (h)(2)(vi) of the standard for construction). This provision, which is unchanged from the proposed rule, gives the examining PLHCP the flexibility to determine additional tests deemed to be appropriate. While the tests conducted under this section are for screening purposes, diagnostic tests may be necessary to address a specific medical complaint or finding related to respirable crystalline silica exposure (Document ID 1511, p. 61). For example, the PLHCP may decide that additional tests are needed to address abnormal findings in a pulmonary function test. OSHA considers the PLHCP to be in the best position to decide if any additional medical tests are necessary for each individual examined. Under this provision, if a PLHCP decides another test related to respirable crystalline silica exposure is medically indicated, the employer must make it available. EEI commented that OSHA should clarify that

additional tests must be related to occupational exposure to respirable crystalline silica (Document ID 2357, p. 35). OSHA agrees and intends the phrase "deemed appropriate" to mean that additional tests requested by the PLHCP must be both related to respirable crystalline silica exposure and medically necessary, based on the findings of the medical examination.

Finally, some stakeholders suggested additional tests to be included as part of medical examinations. OSHA did not propose a requirement for the initial examination to include a CT scan to screen for lung cancer, but a number of commenters thought the rule should contain such a requirement. UAW requested that OSHA consider LDCT scanning for lung cancer, with guidance from NIOSH and other medical experts (Document ID 2282, Attachment 3, pp. 19-20). Charles Gordon asked Dr. David Weissman if OSHA should consider CT scans for lung cancer screening of silica-exposed employees, as has been recently recommended by the U.S. Preventive Service Task Force (USPSTF) for persons at high risk of lung cancer. Dr. Weissman responded:

> Well, the recommendation that you're referring to related to very heavy cigarette smokers, people who are age 55 to 80, had a history of smoking I believe at least 30 pack-years and had smoked as recently as 15 years ago. That group has a very, very high risk of lung cancer, and as of this time, there are no recommendations that parallel that for occupational carcinogens (Document ID 3579, Tr. 159-160, Attachment 2, p. 2).

Collegium Ramazzini and USW asked OSHA to consider various scenarios for LDCT lung cancer screening of employees exposed to respirable crystalline silica; the different scenarios considered age (as a proxy for latency), smoking history, and other risk factors, such as non-malignant respiratory disease (Document ID 4196, pp. 5-6; 4214, pp. 10-12). Both groups

recommended screening in non-smokers, and Collegium Ramazzini also recommended screening in employees less than 50 years of age; both groups cited National Comprehensive Cancer Network (NCCN) guidelines as a basis for one or more recommendations, and Collegium Ramazzini also cited the American Association for Thoracic Surgery (AATS) guidelines. The Communication Workers of America (CWA) requested LDCT scans every three years for silica-exposed employees over 50 years of age (Document ID 2240, p. 3). Consistent with one scenario presented by USW, AFL-CIO requested that OSHA require LDCT scans if recommended by the PLHCP or specialist, and AFL-CIO also requested that OSHA include a provision (for employees exposed to respirable crystalline silica) to allow for regular LDCT scans if recommended by an authoritative group (Document ID 4204, p. 82). Dr. Rosemary Sokas and Dr. James Melius, occupational physician/epidemiologist for LHSFNA, requested that OSHA reserve the right to allow for adoption of LDCT scans (Document ID 3577, Tr. 793; 3589, Tr. 4205-4206). Dr. Sokas went on to say that OSHA should start convening agencies and organizations to look at levels of risk that warrant LDCT (Document ID 3577, Tr. 793).

In addition to the issues that Dr. Weissman testified about regarding the USPSTF recommendations, OSHA notes that the USPSTF recommendations are based on modeling studies to determine optimum ages and frequency for screening and the scenarios in which benefits of LDCT screening (e.g., increased survival) would outweigh harms (e.g., cancer risk from radiation exposure). The screening scenario recommended by USPSTF (55-to 80-year-olds with a 30-pack-year smoking history who have not quit more than 15 years ago) is estimated to result in a 14 percent decrease in lung cancer deaths, with a less than 1 percent risk for radiation-

related lung cancer (Document ID 3965, p. 337). USPSTF stresses that LDCT screening should be limited to high-risk persons because persons at lower risk are expected to experience fewer benefits and more harm; they cautioned that starting LDCT screening before age 50 might result in increased rates of radiation-related lung cancer deaths (Document ID 3965, p. 336). USPSTF also warns about the high rate of false positive findings with LDCT, which often lead to more radiation exposure through additional imaging tests and can result in invasive procedures, which have their own risks, to rule out cancer. It cautions that lower rates of lung cancer mortality from LDCT screening are most likely to be found at institutions demonstrating accurate diagnoses, appropriate follow-up procedures for abnormal findings, and clear standards for performing invasive procedures (Document ID 3965, pp. 333, 336).

Both NCCN and AATS guidelines recommend screening scenarios that are similar to the USPSTF guideline (e.g., 55 or more years of age and at least a 30-pack-year history) (Document ID as cited in 3965, p. 338; 3976, p. 33). NCCN and AATS guidelines also recommend screening for 50-year-olds or older, who have a 20-pack-year or more smoking history and an additional risk factor. AATS specifies that the additional risk factor should result in a cumulative lung cancer risk of at least 5 percent in the next 5 years, and they identify additional risk factors, such as COPD, with an FEV_1 of 70 percent or less of predicted value, and environmental or occupational exposures, including silica (Document ID 3976, pp. 33, 35-37). Neither the NCCN nor AATS guideline recommend screening for individuals younger than 50 years of age or nonsmokers, and neither NCCN nor AATS indicates that its guidelines are based on risk-benefit analyses.

OSHA agrees that employees exposed to respirable crystalline silica are at increased risk of developing lung cancer, as addressed in Section V, Health Effects. However, OSHA has two major concerns that preclude the Agency from requiring LDCT screening for lung cancer under the respirable crystalline silica rule. The first concern is that availability of LDCT is likely to be limited. Few institutions that offer LDCT have the specialization to effectively conduct screening for lung cancer. The second major concern is the lack of a risk-benefit analysis. There is no evidence in the rulemaking record showing that the benefits of lung cancer screening using LDCT in respirable crystalline silica-exposed employees outweigh the risks of lung cancer from radiation exposure. OSHA has also not identified authoritative recommendations based on risk-benefit analyses for LDCT scanning for lung cancer in persons who do not smoke or are less than 50 years of age. OSHA concludes that without authoritative risk-benefit analyses, the record does not support mandating LDCT screening for respirable crystalline silica-exposed employees.

Periodic examinations.

Some commenters disagreed with the proposed three-year interval for periodic medical examinations. WisCOSH and Charles Gordon thought that medical examinations should be offered more often than every three years (Document ID 3586, Tr. 3200-3201; 2163, Attachment 1, p. 14). Other commenters, including AFSCME and some employee health advocates and labor unions, requested that one or more components of medical examinations be offered annually (Document ID 1960; 2208; 2240, p. 3; 2351, p. 15; 4203, p. 6). Collegium Ramazzini recommended annual medical surveillance consisting of medical and work history and spirometry testing to better characterize symptoms, changes in health and work history that could

be forgotten, and lung function changes (Document ID 3541, p. 12). CISC stated that OSHA did not explain why it found an examination every three years necessary and appropriate (Document ID 2319, p. 119).

ATS, NIOSH, USW, and AFS supported the three-year frequency requirement for medical surveillance (Document ID 2175, p. 6; 2177, Attachment B, pp. 38-39; 2336, p. 11; 2379, Appendix 1, p. 70). NSSGA, however, recommended examinations every three to five years (Document ID 2327, Attachment 1, p. 24). Although WHO guidelines recommend an annual history and spirometry test, the guidelines state that if that is not possible, those examinations can be conducted at the same frequency they recommend for X-rays (every 2-to-5 years) (Document ID 1517, p. 32). In support of triennial medical examinations, ATS commented that an examination provided every three years is appropriate to address a lung disease that typically has a long latency period (Document ID 2175, p. 6).

ACOEM agreed with a frequency of every three years for a medical examination, provided that a second baseline examination (excluding X-rays) is conducted at 18 months following the initial baseline examination; this approach was recommended to detect possible symptoms of acute silicosis and to more effectively establish a spirometry baseline since rapid declines in lung function can occur in dusty work environments (Document ID 2080, pp. 5-6). Dr. Celeste Monforton agreed with a follow-up examination at 18 months (Document ID 3577, Tr. 846).

APHA, AFL-CIO, BAC, and BCTD also agreed with ACOEM's suggestion for a follow-up examination within 18-months, adding that a three-year interval between examinations is

acceptable if medical examinations are offered to employees experiencing signs and symptoms related to respirable crystalline silica exposure (Document ID 2178, Attachment 1, pp. 4-5; 4204, pp. 81-82; 4219, pp. 30-31; 4223, pp. 127-128). BlueGreen Alliance, UAW, Center for Effective Government (CEG), CPR, WisCOSH, and AFSCME also requested that medical surveillance be offered for employees experiencing symptoms (Document ID 2176, p. 2; 2282, Attachment 3, pp. 22-23; 2341, pp. 2-3; 2351, p. 15, Fn 29; 3586, Tr. 3200-3201; 4203, p. 6). The AFL-CIO and UAW stated that a symptom trigger is appropriate based on the high level of risk remaining at OSHA's proposed action level and PEL (Document ID 2282, Attachment 3, p. 22; 4204, p. 81). APHA, CEG, and BCTD also argued that employees should be allowed to see a PLHCP if they are concerned about excessive exposure levels or their ability to use a respirator (Document ID 2178, p. 5: 2341, pp. 2-3; 4223, pp. 127-128).

After considering all comments on this issue, OSHA concludes that the record supports requiring periodic examinations to be offered to employees at least every three years after the initial (baseline) or most recent periodic medical examination for employees who are eligible for initial and continued medical surveillance under the rule. Accordingly, paragraph (i)(3) of the standard for general industry and maritime (paragraph (h)(3) of the standard for construction) requires periodic examinations at least every three years, or more frequently if recommended by the PLHCP. One of the main goals of periodic medical surveillance for employees exposed to respirable crystalline silica is to detect adverse health effects, such as silicosis and other non-malignant lung diseases, at an early stage so that medical and other appropriate interventions can be taken to improve health. Consistent with the NIOSH and ATS comments, OSHA finds that

medical examinations offered at a frequency of at least every three years is appropriate for most employees exposed to respirable crystalline silica in light of the slow progression of most silica-related diseases. This decision is also consistent with ASTM standards E 1132 – 06 and E 2625 – 09 (Section 4.6.5), which recommend that medical surveillance be conducted no less than every three years (Document ID 1466, p. 5; 1504, p. 5).

OSHA declines to adopt ACOEM's recommendation for a second baseline examination at 18 months. As noted above, this request was based upon detection of possible acute silicosis symptoms. Considering that acute silicosis and the rapid declines in lung function associated with it, as a result of extremely high exposures, are rare, OSHA determines that this extra examination would not benefit the vast majority of employees exposed to respirable crystalline silica. However, as noted above, paragraph (i)(3) of the standard for general industry and maritime (paragraph (h)(3) of the standard for construction) authorizes the PLHCP to recommend, and requires the employer to make available, increased frequency of medical surveillance. OSHA agrees with Dr. James Melius that more frequent medical examinations are appropriate if requested by the PLHCP based on abnormal findings or signs of possible illness, and the Agency agrees with ACOEM that the PLHCP may recommend more frequent medical surveillance based on an exposure history indicating unknown or high exposure to respirable crystalline silica (Document ID 2080, p. 6; 3589, Tr. 4203). OSHA concludes that allowing the PLHCP to determine when increased frequency of medical examinations is needed is a better approach than requiring all employees to receive annual medical examinations or a second baseline examination at 18 months.

OSHA did not include a symptom trigger because symptoms of silica-related lung diseases (e.g., cough, shortness of breath, and wheeze) are very common and non-specific, unlike symptoms resulting from exposures to some other chemicals OSHA has regulated. In addition, based on the employee health privacy concerns expressed in this rulemaking (discussed below), OSHA does not expect many employees to ask their employer for a medical examination when they experience symptoms. Furthermore, employees who are the most likely to develop symptoms are those exposed above the PEL. Those employees, who would be required to wear respirators, and also construction employees required to wear respirators under Table 1, are entitled to an additional medical evaluation under the respiratory protection standard if they report signs or symptoms that are related to ability to use a respirator (29 CFR 1910.134(e)(7)(i)). Therefore, employees at the highest risk of developing symptoms will be able to take advantage of that provision in the respiratory protection standard.

AIHA recommended that OSHA consider decreased frequency of testing in employees with less than 10 to 15 years of experience because of the small chance of finding disease, and it noted that this was done in the asbestos standard (29 CFR 1910.1001, 1926.1101) (Document ID 2169, p. 6). Medical surveillance guidelines from ACOEM, Industrial Minerals Association (IMA)/Mine Safety and Health Administration (MSHA) and NISA recommend periodic medical examinations at intervals from two to four years (with the exception of a follow-up examination in some cases), depending on age, years since first exposure, exposure levels, or symptoms (Document ID 1505, pp. 3-4; 1511, pp. 78-79; 1514, pp. 109-110). As noted by the IMA/MSHA guidelines, a compromise schedule that is easier to administer is acceptable if it is difficult to

offer surveillance based on multiple considerations (Document ID 1511, pp. 78-79). OSHA agrees with the IMA/MSHA approach of choosing a schedule that is easy to administer. The Agency concludes that surveillance every three years is an administratively convenient frequency that strikes a reasonable balance between the resources required to provide surveillance and the need to diagnose health effects at an early stage to allow for interventions.

In addition to the above general comments as to the appropriate frequency of periodic examinations, some stakeholders offered comments on particular components of periodic examinations, in particular chest X-rays and pulmonary function tests. As noted above, chest X-rays are included in the periodic, as well as initial (baseline), medical examinations. Periodic chest X-rays are appropriate tools for detecting and monitoring the progression of silicosis and possible complications, such as mycobacterial disease, including tuberculosis infection (Document ID 1505, p. 3; 1511, pp. 63, 79). Safety professional Albert Condello III stated that X-rays should be offered annually (Document ID 1960). OSHA concludes that every three years is an appropriate interval for X-ray examinations. The frequency is within ranges recommended by ACOEM, IMA/MSHA, NISA, and WHO (Document ID 1505, pp. 3-4; 1511 pp. 78-79; 1514, pp. 109-110; 1517, p. 32). Commenters representing NIOSH, the medical community, and industry agreed that a frequency of every three years is appropriate for X-rays (Document ID 2157, p. 6; 2177, Attachment B, pp. 38-39; 2315, p. 9; 2327, Attachment 1, p. 25; 2379, Appendix 1, p. 70; 3541, p. 5).

OSHA also received comments on the inclusion of pulmonary function (i.e., spirometry) tests in periodic examinations and the appropriate frequency for such tests. As noted under the

discussion of tests included as part of the initial medical evaluation, some commenters questioned whether spirometry in general should be required for employees exposed to respirable crystalline silica. For the same reason that OSHA decided to include spirometry as a required element in the initial medical examination, it concludes that requiring spirometry as part of the periodic examination is appropriate; that reason is that a spirometry test is a valuable tool for detecting possible lung function abnormalities associated with respirable crystalline silica-related disease and for monitoring the health of exposed employees. Spirometry tests that adhere to strict quality standards and that are administered by a technician who has a current certificate showing successful completion of a NIOSH-approved spirometry course, are useful for monitoring progressive lung function changes in individual employees and in groups of employees.

The proposed interval of three years for spirometry testing was an issue in the rulemaking. OSHA proposed this interval because exposure to respirable crystalline silica does not usually cause severe declines in lung function over short time periods. Spirometry testing conducted every three years is within ranges of recommended frequencies, based on factors such as age and exposure duration or intensity, in guidelines by ACOEM and BCTD, although ACOEM and BCTD recommend an evaluation at 18 months following the baseline test (Document ID 1505, p. 3; 1509, p. 15; 2080, pp. 5-6; 4223, p. 128). Guidelines from WHO recommend yearly spirometry tests, but indicate that if that is not possible, spirometry can be conducted at the same frequency as X-rays (every 2-to-5 years) (Document ID 1517, p. 32).

OSHA specifically requested comment on the appropriate frequency of lung function testing, which it proposed at intervals of every three years. ASSE agreed that spirometry testing

every three years is consistent with most credible occupational health programs for respirable crystalline silica exposure (Document ID 2339, p. 9). Industry stakeholders, such as Ameren, NSSGA, and AFS, also supported conducting spirometry testing every three years (Document ID 2315, p. 9; 2327, Attachment 1, pp. 24-25; 2379, Appendix 1, p. 70).

Collegium Ramazzini stated that spirometry testing should be conducted annually rather than triennially (Document ID 3541, pp. 12-13). In support of its statement, Collegium Ramazzini interpreted data from a Wang and Petsonk (2004) study to mean that an FEV_1 loss of 990 milliliters (mL) or higher could occur before detection of lung function loss with testing every three years (Document ID 3541, pp. 12-13; 3636).

The Wang and Petsonk 2004 study was designed to measure lung function changes in coal miners over 6- to 12-month intervals. The study authors reported that in the group of coal miners studied, a year-to-year decline in lung function (i.e., FEV_1) of 8 percent or 330 mL or more, based on the 5th percentile, should not be considered normal (i.e., the results did not likely occur by chance in healthy males). To understand the implications of this finding, OSHA consulted 2014 ATS guidelines. Those guidelines urge caution in interpreting early lung function changes in miners because early, rapid declines in lung function are often temporary and might occur because of inflammation. They further indicate that estimates of lung function decline are more precise as the length of follow-up increases and that real declines in lung function become easier to distinguish from background variability. In addition, ATS cautions that short-term losses in lung function can be difficult to evaluate because of variability (Document ID 3632, pp. 988-989).

OSHA notes that, in fact, Figure 1 of the Wang and Petsonk study shows that lung function loss measured over a 5-year period in that cohort of miners is much less variable than changes measured over 6- to 12-month intervals. OSHA therefore finds that this study indicates that long-term measurements in lung function are more reliable for assessing the level of lung function decline over time. Based on Table 1 of the Wang and Petsonk study, mean annual FEV_1 loss, when evaluated over a 5-year period, was 36 and 56 mL/year in stable and healthy miners, respectively. Even among rapid decliners evaluated over five years, mean decline in FEV_1 was 122 mL/year. Unlike Collegium Ramazzini, OSHA does not interpret the Wang and Petsonk study to mean that an FEV_1 loss of 990 mL or higher could occur before detection of lung function loss with testing every three years The study authors themselves conclude:

> However, even among workers in our study who met this >8% or >330 mL criterion, many did not show accelerated declines over the entire 5 years of follow up (data not shown), emphasizing that a finding of an increased year-to-year decline in an individual requires further assessment and confirmation (Document ID 3636, p. 595).

In sum, OSHA finds that the Wang and Petsonk study is not a basis for concluding that triennial spirometry testing is inadequate for assessing lung function loss in most employees exposed to respirable crystalline silica.

Collegium Ramazzini also cited a 2012 Hnizdo study that demonstrated greater stability and predictability for excessive loss of lung function with more frequent testing. In that study, spirometry data were useful for predicting decline only after the fourth or fifth year of follow-up; Collegium Ramazzini stated that only two spirometry tests would be available in six years if employees are tested every three years (Document ID 3541, p.

13; 3627, p. 1506). OSHA notes that three spirometry reports would be available following six years of triennial testing (the initial examination, the three-year examination, and the six-year examination). In addition, Hnizdo concluded that annual spirometry was best, but even in employees tested every three years, useful clinical data were generated with five to six years of follow-up (Document ID 3627, p. 1511).

The ATS committee also reviewed the Hnizdo study and concluded that precision in determining rate of FEV_1 decline improves with greater frequency of measurement and duration of follow-up. Because chronic diseases, such as COPD and pneumoconiosis, typically develop over a span of years, the ATS committee concluded that spirometry performed every two-to-three years should be sufficient to monitor the development of such diseases (Document ID 3632, p. 988). NIOSH Division of Respiratory Disease Studies Director, Dr. David Weissman, who was on the ATS committee, also agreed that spirometry testing every three years is appropriate for respirable crystalline silica-exposed employees (Document ID 3632, p. 1; 3579, Tr. 255).

After consideration of the rulemaking evidence on this issue, OSHA concludes that spirometry testing every three years is appropriate to monitor employees' lung function and that the frequency is well supported in the record. Therefore, consistent with its proposed rule, OSHA is including a frequency of at least every three years for spirometry testing.

As discussed above in connection with the initial testing requirement, spirometry usually involves cross-sectional testing for assessing lung function at a single time point. Longitudinal spirometry testing that compares employees' lung function to their baseline levels is also useful

for detecting excessive declines in lung function that could lead to severe impairment over time. OSHA did not propose a requirement to assess longitudinal changes in lung function. Commenters including Collegium Ramazzini, LHSFNA, and BCTD requested that the standard include requirements or instructions for longitudinal testing to compare an employee's current lung function value to his or her baseline value (Document ID 3541, p. 10; 3589, Tr. 4205; 4223, p. 129). As noted by Dr. L. Christine Oliver, associate clinical professor of medicine at Harvard Medical School, representing Collegium Ramazzini:

> Excessive loss of lung function may indicate early development of silica-related disease, even in the absence of an abnormal test result. So spirometry at one point in time may be normal, but compared to the baseline of that individual, there may have been a decline. So even though the test result itself is normal, it doesn't mean that there is not something going on with regard to that individual's lung function (Document ID 3588; Tr. 3855).

Both Collegium Ramazzini and BCTD requested that the standard require referral to a specialist for excessive losses of pulmonary function. Collegium Ramazzini recommended specialist referral for a year-to-year decline in FEV_1 of greater than 8 percent or 330 mL based on the study by Wang and Petsonk discussed above (Document ID 3541, pp. 3, 9-10; 3636). BCTD recommended specialist referral for a year-to-year decline in FEV_1 of greater than 10 percent based on ACOEM guidance (Document ID 4223, p. 129; 3634, pp. 579-580).

OSHA endorses in principle the value of longitudinal spirometry analyses to compare employees' lung function to their baseline values, but is not adopting the specific recommendation to incorporate it into the rule. Based on a review of the available evidence, OSHA is concerned about several challenges in determining an employee's change from baseline

values, which preclude the Agency from requiring longitudinal analyses with an across-the-board trigger of 8-to-10 percent loss of baseline lung function for specialist referral. First, a lung function loss of 8-to-10 percent is more stringent than general recommendations from ACOEM and ATS. OSHA notes that the complete ACOEM recommendation for evaluating longitudinal changes in lung function states:

> When high-quality spirometry testing is in place, ACOEM continues to recommend medical referral for workers whose FEV_1 losses exceed 15%, after allowing for the expected loss due to aging. Smaller declines of 10% to 15%, after allowing for the expected loss due to aging, may be important when the relationship between longitudinal results and the endpoint disease is clear. These smaller declines must first be confirmed, and then, if the technical quality of the pulmonary function measurement is adequate, acted upon (Document ID 3634, p. 580).

The ACOEM recommendation is based on ATS guidelines indicating that year-to-year changes in lung function exceeding 15 percent are probably unusual in healthy individuals. A recent ATS committee restated that position:

> ATS recommends that a decline of 15% or more over a year in otherwise healthy individuals be called "significant," beyond what would be expected from typical variability (Document ID 3632, p. 989).

As ATS indicated, actual lung function losses must be distinguished from measurement variability. Variability in spirometry findings can occur as a result of technical factors (e.g. testing procedures, technician competence, and variations in equipment) and biological factors related to employees being tested (e.g., circadian rhythms, illness, or recovery from surgery) (Document ID 3630, p. 32). The requirement for testing by a technician with a current certificate from a NIOSH-approved course improves spirometry quality and reduces variability related to

testing technique and technician competence. However, OSHA is aware that even with high quality spirometry programs, variability in results can still occur from factors such as changes in equipment and/or testing protocol.

Collegium Ramazzini noted that spirometry performed at a location other than that of the first employer may not provide an adequate baseline to evaluate lung function changes in the absence of quality control and standardized equipment, methodology, and interpretation (Document ID 3541, p. 5). OSHA is concerned about the ability to differentiate lung function changes from variability, even with standardization and quality control. ACOEM has concluded that frequent changing of spirometry providers may prevent a meaningful evaluation of longitudinal testing results (Document ID 3633, p. 1309). OSHA recognizes that changes in spirometry providers could preclude evaluating changes in lung function from baseline values and that employees in high-turnover industries, e.g., construction, could be particularly affected if they undergo spirometry testing on different types of spirometers used by different providers contracted by the different employers for whom they work.

In addressing the issue of construction employees frequently changing employers, Dr. L. Christine Oliver recommended storing spirometry results in a central database or providing them to employees to allow comparison of current results with past results (Document ID 3588, Tr. 3873-3875). As indicated above, technical quality of past spirometry should be evaluated before examining longitudinal change in lung function. Full spirometry reports should be examined for indicators of test quality (e.g., acceptability and repeatability of spirometry maneuvers). OSHA encourages PLHCPs to give employees copies of their full medical records, including spirometry

reports with numerical values and graphical illustrations of expiratory curves. Employees (including former employees) also have a right to access their medical records under OSHA's access to medical and exposure records rule (29 CFR 1910.1020). Presenting past spirometry records to a new PLHCP might allow for the interpretation of lung function compared to baseline values, but the PLHCP would have to determine if this evaluation is possible based on spirometry technical quality.

In sum, OSHA recognizes the value of longitudinal analyses that compare an individual's lung function to their baseline values. Recent studies have shown that excessive decline in lung function can be an early warning sign for risk of COPD development (Document ID 1516). Therefore, identifying employees who are at risk of developing severe decrements in lung function can allow for interventions to possibly prevent or slow progression of disease and thus justifies periodic spirometry. But because of the complexities and challenges described above, OSHA is not mandating testing to compare employees' lung function values to baseline values or specifying a lung function loss trigger for referral to a specialist. OSHA concludes that spirometry conducted every three years is appropriate to detect the possible development of lung function impairment. However, the PLHCP is in the best position to determine how spirometry results should be evaluated. Under paragraph (i)(5)(iv) of the standard for general industry and maritime (paragraph (h)(5)(iv) of the standard for construction), PLHCPs have the authority to recommend referral to a specialist if "otherwise deemed appropriate," and an informed judgment or suspicion that excessive lung function loss or an actual lung function abnormality has

occurred would be an appropriate reason for referral to a specialist with the necessary skills and capability to make that evaluation.

Information provided to the PLHCP.

OSHA received few comments regarding information to be supplied to the PLHCP. NAHB was concerned about obtaining or verifying information, such as PPE use, exposure information, and medical information, from past employers to give to the PLHCP (Document ID 2296, p. 31). Paragraph (i)(4)(iv) of the standard for general industry and maritime (paragraph (h)(4)(iv) of the standard for construction) is explicit, however, that employers must only provide the information within their control. Employers are not expected to provide information to PLHCPs on exposures experienced by employees while the employees were working for prior employers. Similarly, OSHA intends that where the employer does not have information on the employee's past or current exposure level, such as when a construction employer uses Table 1 in lieu of exposure monitoring, providing the PLHCP with an indication of the exposure associated with the task (e.g., likely to be above the PEL) fulfills the requirement.

OSHA identifies the information that the employer must provide to the PLHCP, along with information collected as part of the exposure and work history, as relevant to the purposes of medical surveillance under the rule because it can assist the PLHCP in determining if symptoms or a health finding may be related to respirable crystalline silica exposure or if the employee might be particularly sensitive to such exposure. For example, a finding of abnormal lung function caused by asthma might indicate increased sensitivity to a workplace exposure. The information will also aid the PLHCP's evaluation of the employee's health in relation to

recommended limitations on the employee's use of respirators or exposure to respirable crystalline silica. For these reasons, OSHA is retaining the proposed provisions detailing information to be provided to the PLHCP in the rule.

Written medical reports and opinions.

OSHA received a number of comments on these provisions. The majority of these comments related to the proposed contents of the PLHCP's written medical opinion and its transmission to the employer. For example, Dr. Laura Welch expressed concern that the provision that would have required the PLHCP to disclose "a medical condition that puts him or her at risk of material impairment to health from exposure to silica" could be read to require disclosure of the employee's medical diagnosis (Document ID 3581, Tr. 1580). Dr. Steven Markowitz, physician and director of the Center for Biology of Natural Systems at Queens College, representing USW, explained:

> So, for example, if I were the examining healthcare provider and I saw an employee, and he had what I identified as idiopathic pulmonary fibrosis, which is diffuse scarring of the lungs with an unknown cause, in this case, not silica, is that information that I would need to turn over to the employer because further exposure to silica might impair that person's health or not? Or what if the worker has emphysema, which is a silica-related condition, and the provider believes that that emphysema is not due to silica exposure but to the employee's long-time smoking history. Is that information that the healthcare provider is supposed to turn over to the employer? It isn't at all clear (Document ID 3584, Tr. 2518-2519).

Some commenters offered suggestions to address privacy concerns regarding the content of the proposed PLHCP's written medical opinion for the employer and the proposed requirement that the opinion be given to the employer instead of the employee. One suggestion advocated by UAW, LHSFNA, AFSCME, AFL-CIO, and BCTD was for OSHA to use a model

based on the black lung rule for coal miners (Document ID 2282, Attachment 3, pp. 20-21; 3589, Tr. 4207; 4203, p. 6; 4204, p. 88; 4223, p. 134). Under the coal miner regulations, miners receive the medical information and employers are prohibited from requiring that information from miners (30 CFR 90.3). Commenters including BlueGreen Alliance, CWA, USW, and Collegium Ramazzini also urged OSHA to require that findings from medical surveillance only be given to employers upon authorization by the employee (Document ID 2176, p. 2; 2240, pp. 3-4; 2336, p. 12; 3541, p. 13). UAW, AFL-CIO, and BCTD referred OSHA to ACOEM's recommendations for workplace confidentiality of medical information (Document ID 2282, Attachment 3, p. 20; 3578, Tr. 929; 3581, Tr. 1579-1580). The ACOEM guidelines state:

> Physicians should disclose their professional opinion to both the employer and the employee when the employee has undergone a medical assessment for fitness to perform a specific job. However, the physician should not provide the employer with specific medical details or diagnoses unless the employee has given his or her permission (Document ID 3622, p. 2).

Exceptions to this recommendation listed under the ACOEM guidelines include health and safety concerns. Collegium Ramazzini, BCTD, USW, and BAC argued that providing an employer with information about an employee's health status violates an employee's privacy and is not consistent with societal views reflected in laws, such as the Health Insurance Portability and Accountability Act (HIPAA) (Document ID 3541, p. 13; 3581, Tr. 1578-1579; 3584, Tr. 2519; 4219, p. 31).

Although HIPAA regulations allow medical providers to provide medical information to employers for the purpose of complying with OSHA standards (Document ID 4214, p. 7), OSHA has accounted for stakeholder privacy concerns in devising the medical disclosure requirements

in the rule. OSHA understands that the need to inform employers about a PLHCP's recommendations on work limitations associated with an employee's exposure to respirable crystalline silica must be balanced against the employee's privacy interests. As discussed in further detail below, OSHA finds it appropriate to distinguish between the PLHCP's recommendations and the underlying medical reasons for those recommendations. In doing so, OSHA intends for the PLHCP to limit disclosure to the employer to what the employer needs to know to protect the employee, which does not include an employee's diagnosis. Contrary to some of the comments, it was not OSHA's intent, either in the proposed rule or in earlier standards that require information on an employee's medical or health condition, to transmit diagnostic information to the employer; OSHA intended for the PLHCP merely to convey whether or not the employee is at increased risk from exposure to respirable crystalline silica (or other workplace hazards in other standards) based on any medical condition, whether caused by such exposure or not. In re-evaluating how to express this intent, however, OSHA concludes that the employer primarily needs to know about any recommended limitations without conveying the medical reasons for the limitations. Thus, in response to the weight of opinion in this rulemaking record and to evolving notions about where the balance between preventive health policy and patient privacy is properly struck, OSHA is taking a more privacy- and consent-based approach regarding the contents of the PLHCP's written medical opinion for the employer compared to the proposed requirements and earlier OSHA standards. These changes, which are reflected in paragraph (i)(6) of the standard for general industry and maritime (paragraph (h)(6)

of the standard for construction), and the comments that led to these changes, are more fully discussed below.

Reinforcing the privacy concerns, various stakeholders, including labor unions, physicians, and employees, were also concerned that employees' current or future employment might be jeopardized if medical information is reported to employers (e.g., Document ID 2282, Attachment 3, p. 20; 3581, Tr. 1582; 3583, Tr. 2470-2471; 3585, Tr. 3053-3054; 3586, Tr. 3245; 3589, Tr. 4227-4228, 4294-4295; 4203, pp. 6-7; 4214, pp. 7-8). The same concerns were expressed by Sarah Coyne, a painter and Health and Safety Director from the International Union of Painters and Allied Trades, who testified that many of her fellow union members who have silicosis refused to testify at the silica hearings because they feared they would lose their jobs if their employers found out they were ill (Document ID 3581, Tr. 1613-14). Dr. L. Christine Oliver testified that her patients do not want medical information reported to employers, and Dr. James Melius stated that LHSFNA members are leery of medical surveillance because they fear losing their jobs (Document ID 3588, Tr. 3881-3882; 3589, Tr. 4228). Deven Johnson, cement mason, described employees hiding injuries from supervisors on jobsites for fear of being blacklisted, and said that:

> The same is true with occupational illnesses, that the last thing that a worker wants is to have any information that he's somehow compromised because, even though we want to think the best of the employer, that somebody wouldn't take action against that individual, we know for a fact that it happens. It's happened to our membership (Document ID 3581, Tr. 1656).

Industry representatives indirectly confirmed that discrimination based on medical results was possible. For example, CISC noted that some employers might refuse to hire an employee

with silicosis because they might have to offer workers' compensation or be held liable if the disease progresses (Document ID 4217, pp. 22-23).

Evidence in the record demonstrates that a likely outcome of employees' reluctance to let employers know about their health status is refusal to participate in medical surveillance. For example, Dr. Rosemary Sokas stated that employees who lack job security would likely avoid medical surveillance if the employer receives the results (Document ID 3577, Tr. 819-820). In discussing the Coal Workers' Health Surveillance Program, Dr. David Weissman stated that maintaining confidentiality is critical because:

> One of the biggest reasons in focus groups that miners have given for not participating in surveillance is fear of their medical information being shared without their permission (Document ID 3579, Tr. 169).

When asked if employees would participate in medical surveillance that lacked both employee confidentiality and anti-retaliation and discrimination protection, employees Sarah Coyne, Deven Johnson, and Dale McNabb stated that they would not (Document ID 3581, Tr. 1657; 3585, Tr. 3053-3054). BAC and BCTD emphasized that employees must choose to participate in medical surveillance in order for it to be successful (Document ID 4219, p. 31; 4223, p. 131).

Industry groups, such as OSCO Industries and NAHB, commented that they or employers from their member companies are reluctant to handle or maintain confidential medical information (Document ID 1992, p. 12; 2296, p. 32). NAHB indicated:

> Members have expressed strong concerns that much of [the medical information], if not all, would be covered by privacy laws and should be between a doctor and patient. . . . Moreover, the PLHCP should provide a copy of the written medical

opinion to the employee directly, not the employer, once it is written (Document ID 2296, pp. 31-32).

However, other industry groups asserted that employers should receive detailed information from medical surveillance. In particular, NISA argued that reporting medical surveillance findings to employers would facilitate epidemiological studies to better understand hazards and the effectiveness of a new standard (Document ID 4208, p. 14).

OSHA agrees that epidemiology studies are important; indeed its health effects and significant risk findings in this rule are overwhelmingly based on epidemiological studies. However, as noted above, it was never OSHA's intent for the PLHCP's written medical opinion on respirable crystalline silica to contain specific diagnoses or detailed findings that might be useful for an epidemiology study. As noted in the summary and explanation of Recordkeeping, OSHA's access to employee exposure and medical records standard (29 CFR 1910.1020) requires employers to ensure that most employee medical records are retained for the duration of employment plus 30 years for employees employed more than one year. Such records obtained through appropriate legal means, and with personal identifying information omitted or masked, would be a possible avenue for conducting epidemiology studies.

CISC also noted that in past standards, the purpose of medical surveillance was to improve health practices by allowing employers to understand effects of hazards and, therefore, make changes to the worksite, such as implementing controls or removing employees from exposure (Document ID 4217, p. 24). Attorney Brad Hammock, representing CISC at the public hearing, stated that if OSHA expects employers to make placement decisions based on health outcomes and exposure, then there would be some value in an employer receiving the PLHCP's

opinion. However, Mr. Hammock further explained that if the purpose of surveillance is simply to educate employees about their health situation, then there would be arguably little value in the employer receiving the opinion (Document ID 3580, Tr. 1466-1467). Other commenters, including ACOEM, AOEC, and NISA, also noted the importance of medical surveillance for identifying adverse health effects among employees in order to make workplace changes or evaluate the effectiveness of regulations or workplace programs (Document ID 2080, pp. 9-10; 3577, Tr. 784; 4208, pp. 13, 16-17). Andrew O'Brien testified that if employers are not allowed to see medical findings, the first time they are made aware of a problem is when they receive a letter from the compensation system. Mr. O'Brien stated:

> Without access to that data, you can't . . . potentially see disease beginning and take preventative action to prevent it from actually having a negative health effect (Document ID 3577, Tr. 614).

In contrast to those views, USW questioned the value in providing employers with the PHLCP's medical opinion. It stated:

> Exactly what corrections in the workplace will the employer make based on newfound knowledge that one of his workers has a silica-related condition? Silicosis occurs 15 or more years following onset of exposure, so that today's silicosis is due to exposure that likely occurred decades ago. (Exceptions are acute and accelerated silicosis, which are rare and are not expected to occur at the recommended PEL.) What inference is the employer supposed to make about the magnitude or effect of current exposures under these circumstances? Indeed, to make sense of the issue, the employer would have to know about the worker's prior silica exposures, quite often at different workplaces. But the employer and, quite likely, even the worker are unlikely to have high quality data on exposures to silica that occurred decades ago. In the absence of such information, it is unclear how an employer can properly interpret current exposures as causing silicosis. By contrast, the best information on current exposures derives from current exposure monitoring, and the notion that documenting silicosis can somehow provide useful information about current exposures above and beyond what proper exposure monitoring is ill-conceived (Document ID 4214, p. 8).

Similarly, Peg Seminario, Director of Safety and Health with AFL-CIO, testified that employers should be basing their decisions on exposure levels and how well controls are working (Document ID 3578, Tr. 1008). NAHB and CISC questioned how an employer should respond if an employee has signs of lung disease and the employer has already implemented engineering controls and respirator use (Document ID 2296, p. 31; 2319, p. 117).

OSHA agrees that because of the long latency period of most respirable crystalline silica-related diseases, a diagnosis of such an illness in an employee will not provide useful information about current controls or exposure conditions. Employers should be basing their actions on exposure assessments and ensuring properly functioning controls, such as those listed and required for employers using Table 1. In the case where an employee may have disease related to respirable crystalline silica and the employer has properly implemented engineering controls, the only further action by the employer would be to follow PLHCP recommendations to protect the worker who may be especially sensitive to continuing exposure and need special accommodations. Such recommendations could include limitations on respirator use; they might also include specialist referral or limitations on respirable crystalline silica exposure (if the employee gives authorization for the employer to receive this information) (paragraph (i)(6)(i)(C) or (ii)(A) and (B) of the standard for general industry and maritime and paragraph (h)(6)(i)(C) or (ii)(A) and (B) of the standard for construction).

In taking a more consent-based approach than in the proposed rule regarding the PLHCP's written medical opinion for the employer, OSHA considered the countervailing factor that employers will not be able to report occupational illnesses to OSHA if they are not given

medical surveillance information. USW refuted the utility of employer reporting of workplace illnesses, stating:

> However, this loss is minor, because few believe that such employer-generated reporting of chronic occupational conditions does, or even could, under the best of circumstances, provide proper counts of occupational illnesses (Document ID 4214, p. 8).

On a similar note, Fann Contracting and ASSE requested clarification on what information would be reportable or recordable (Document ID 2116, Attachment 1, p. 20; 2339, p. 9).

This rule does not change OSHA reporting or recording requirements, and employers who need more information on recording or reporting of occupational illnesses should refer to OSHA's standard on recording and reporting occupational injuries and illnesses (29 CFR 1904). OSHA finds that if employees do not participate in medical surveillance because of discrimination or retaliation fears, illnesses associated with respirable crystalline silica would generally not be identified. Although not disclosing medical information to employers appears inconsistent with the objective of recording illnesses, the net effect of that decision is improving employee protections due to more employees participating in medical surveillance. Also, as noted above, OSHA never intended for employers to get specific information, such as diagnoses, and this would further limit employers' ability to report disease. Although state surveillance systems are likely to underestimate silicosis cases (see Section V, Health Effects), they are still likely to be a better way to get information on trends of silicosis cases than employer reports. Reporting of silicosis cases by health care providers is required by 25 states (see http://www.cste2.org/izenda/ReportViewer.aspx?rn=Condition+All&p1value=2010&p2value=Silicosis). PLHCPs are more likely to have the

information needed to report silicosis cases to state health authorities than employers. Thus, OSHA concludes that exclusion of health-related information from the PLHCP's written medical opinion for the employer will not have a significant impact on silicosis surveillance efforts.

An additional consideration relating to what information, if any, goes to the employer is that withholding information, such as conditions that might place an employee at risk of health impairment with further exposure, may leave employers with no medical basis to aid in the placement of employees. Although NSSGA did not want to receive confidential medical records, it stressed the importance of continuing to receive information concerning how the workplace could affect an employee's condition and on recommended respirator restrictions (Document ID 3583, Tr. 2315-2316; 4026, p. 5). NISA stated that employers should receive the results of medical surveillance because employers might be held liable if employees choose to keep working in settings that might aggravate their illnesses (Document ID 4208, p. 14). However, labor unions, such as USW, BAC, and BCTD, strongly opposed employers making job placement decisions based on employees' medical findings (Document ID 4214, pp. 7-8; 4219, pp. 31-32; 4223, p. 133). USW and BCTD noted that as long as employees are capable of performing their work duties, decisions to continue working should be theirs; BCTD further noted that the employee should make such decisions with guidance from the PLHCP, and USW noted that the employee should decide because of the significance of job loss or modifications (Document ID 2371, Attachment 1, pp. 45-46; 4214, pp. 7-8). Sarah Coyne agreed that employees should make decisions about placement. Ms. Coyne stated, "I might have silicosis. I

might have asbestosis. I know if I can work or not. Let me decide" (Document ID 3581, Tr. 1656).

OSHA agrees that employees have the most at stake in terms of their health and employability, and they should not have to choose between continued employment and the health benefits offered by medical surveillance, which they are entitled to under the OSH Act. OSHA agrees that employees should make employment decisions, following discussions with the PLHCP that include the risks of continued exposure. Before that can happen, however, employees need to have confidence that participation in medical surveillance will not threaten their livelihoods. After considering the various viewpoints expressed during the rulemaking on these issues, OSHA concludes that the best way to maximize employee participation in medical surveillance, therefore promoting the protective and preventative purposes of this rule, is by limiting required disclosures of information to the employer to only the bare minimum of what the employer needs to know to protect employee health—recommended restrictions on respirator use and, only with consent of the employee, the PLHCP's recommended limitations on exposure to respirable crystalline silica and specialist referrals. Thus, OSHA views this consent-based approach to reporting of medical surveillance findings critical to the ultimate success of this provision, which will be measured not just in the participation rate, but in the benefits to participating employees—early detection of silica-related disease so that employees can make employment, lifestyle, and medical decisions to mitigate adverse health effects and to possibly retard progression of the disease.

NISA supported providing the proposed medical opinion to employers, partly because some employers might have a better understanding of medical surveillance results than employees, who might not have the training or understanding to make health-protective decisions based on those results (Document ID 4208, pp. 13-14). OSHA recognizes that larger companies that employ health, safety, and medical personnel may have in-house expertise to answer employee questions and stress the importance of protective measures, such as work practices or proper use of respirators. However, it is not likely that owners or management of small companies would have a better understanding than their employees or would be able to provide them any additional guidance. Consequently, OSHA does not find the fact some employers might have a better understanding of medical surveillance results than employees to be a compelling argument against limiting the information that is to be reported to the employer in the absence of employee consent. In addition, OSHA expects that the training required under the rule will give employees knowledge to understand protective measures recommended by the PLHCP.

In sum, OSHA concludes that the record offers compelling evidence for modifying the proposed content of the PLHCP's written medical opinion for the employer. The evidence includes privacy concerns expressed by both employees and employers, as well as evidence on the limited utility for giving medical surveillance findings to employers. OSHA is particularly concerned that the proposed requirements would have led to many employees not participating in medical surveillance and

therefore not receiving its benefits. OSHA therefore has limited the information to be given to the employer under this rule, but is requiring that the employee receive a separate written medical report with more detailed medical information.

The requirements for the type of information provided to the employer are different from requirements of other OSHA standards, which remain in effect for those other standards. The requirements for this rule are based on the evidence obtained during this rulemaking for respirable crystalline silica, in particular that many employees would not take advantage of medical surveillance without privacy protections and because the findings of medical examinations would not likely reflect current workplace conditions in most cases. The action taken in this rulemaking does not preclude OSHA from adopting its traditional approach, or any other approach for reporting of medical findings to employers, in the future when it concludes, based on health effects information, that such an approach would contribute information that is relevant to current workplace conditions and would allow for design or implementation of controls to protect other employees.

PLHCP's written medical report for the employee.

OSHA did not propose a separate report given directly by the PLHCP to the employee, but as discussed in detail above, several commenters requested that a report containing medical information only be given to the employee. OSHA agrees and in response to those comments, paragraph (i)(5) of the standard for general industry and maritime (paragraph (h)(5) of the standard for construction) requires the employer to

ensure that the PLHCP explains the results of the medical examination and provides the employee with a written medical report within 30 days.

The health-related information in the PLHCP's written medical report for the employee is generally consistent with the proposed PLHCP's written medical opinion for the employer, with two notable exceptions. Because only the employee will be receiving the PLHCP's written medical report, the written medical report may include diagnoses and specific information on health conditions, including those not related to respirable crystalline silica, and medical conditions that require further evaluation or follow-up are not limited to those related to respirable crystalline silica exposure. Although the focus of the examination is on silica-related conditions, the PLHCP may happen to detect health conditions that are not related to respirable crystalline silica exposure during the examination, and could include information about such conditions in the written medical report for the employee. The employer, however, is not responsible for further evaluation of conditions not related to respirable crystalline silica exposure. A minor difference from the proposed written medical opinion for the employer and the written medical report for the employee in the rule is that it specifies limitations on respirator use rather than PPE because respirators are the only type of PPE required by the rule. The requirements for the PLHCP's written medical report for the employee are consistent with the overall goals of medical surveillance: to identify respirable crystalline silica-related adverse health effects so that the employee can consider appropriate steps to manage his or her health; to let the employee know if he or she can be exposed to respirable crystalline silica in his or her workplace without increased risk of experiencing adverse health effects; and to determine the

employee's fitness to use respirators. By providing the PLHCP's written medical report to employees, those who might be at increased risk of health impairment from respirable crystalline silica exposure will be able to consider interventions (i.e., health management strategies) with guidance from the PLHCP. Dr. Laura Welch testified that her recommendations to a patient diagnosed with silicosis would include employment choices to limit exposures, using a respirator for additional protection, quitting smoking, and getting influenza and pneumonia vaccines (Document ID 3581, p. 1663).

The requirement for a verbal explanation in paragraph (i)(5) of the standard for general industry and maritime (paragraph (h)(5) of the standard for construction) allows the employee to confidentially ask questions or discuss concerns with the PLHCP. The requirement for a written medical report ensures that the employee receives a record of all findings. As noted by BCTD, giving the employee the written report will ensure the employee understands medical conditions that require follow-up and could affect decisions of where and how to work; BCTD also noted that employees would be able to provide the PLHCP's written medical report to future health care providers (Document ID 2371, Attachment 1, p. 48); this would include PLHCPs conducting subsequent periodic examinations under the rule.

PLHCP's written medical opinion for the employer.

As discussed in detail above, many commenters objected to OSHA's proposed content for the PLHCP's written medical opinion for the employer based on employee privacy concerns. OSHA agrees with these privacy concerns and is thus revising the contents of the written medical opinion. In developing the contents of the PLHCP's written medical opinion for the

employer, OSHA considered what type of information needs to be included to provide employers with information to protect employee health, while at the same time protecting employee privacy. Commenters representing labor unions and the medical community stated that the only information that employers need to know is limitations on respirator use (Document ID 2178, Attachment 1, p. 5; 2240, pp. 3-4; 2282, Attachment 3, p. 21; 2336, p. 12; 3589, Tr. 4207; 4196, p. 6; 4203, p. 6; 4204, p. 89; 4219, pp. 31-32; 4223, p. 133). Dr. Laura Welch stated that giving the employer information on an employee's ability to use a respirator, but not specific medical information, strikes the appropriate balance between the employee's privacy and the employer's right to know; she noted that employees who are not fit to wear a respirator and then do can be at risk of sudden incapacitation or death (Document ID 3581, Tr. 1582, 1662).

BCTD further noted that the medical surveillance model it is recommending for respirable crystalline silica presents a different circumstance than what it advocated for regarding asbestos in Industrial Union Department, AFL-CIO v. Hodgson. There, the union was not granted its request for results of medical examinations to be given to the employer only with the employees' consent under the asbestos standard. The court ruled that employers needed the medical results because the asbestos standard requires employers to reassign employees without loss of pay or seniority if the employee was found unable to safely wear a respirator. For respirable crystalline silica, BCTD has concluded that providing employers with information regarding limitations on respirator use and nothing else that is medically related is reasonable if the employee is not requesting accommodations or additional examinations from the employer (Document ID 4223, pp. 134-135).

Based on record evidence, OSHA has determined that for the respirable crystalline silica rule, the PLHCP's written medical opinion for the employer must contain only 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. These requirements are laid out in paragraphs (i)(6)(i)(A)-(C) of the standard for general industry and maritime (paragraphs (h)(6)(i)(A)-(C) of the standard for construction). OSHA is persuaded by arguments to include limitations on respirator use, and no other medically-related information, in the PLHCP's written medical opinion for the employer. The Agency notes that the limitation on respirator use is consistent with information provided to the employer under the respiratory protection standard (29 CFR 1910.134). OSHA concludes that only providing information on respirator limitations in the PLHCP's written medical opinion for the employer is consistent with the ACOEM confidentiality guidelines that recommend reporting of health and safety concerns to the employer (Document ID 3622, p. 2). The date and statement about the examination meeting the requirements of this section are to provide both the employer and employee with evidence that requirements for medical surveillance are current. Employees would be able to show this opinion to future employers to demonstrate that they have received the medical examination, as was recommended by LHSFNA and BCTD **(**Document ID 4207, p. 5; 4223, p. 125).

OSHA is convinced that routinely including recommended limitations on respirable crystalline silica exposure and specialist referrals in the PLHCP's written medical opinion for the employer could adversely affect employees' willingness to participate in medical surveillance. The requirements for this paragraph are consistent with recommendations from labor unions. For

example, UAW, BAC, and BCTD suggested letting the employee decide to forward the recommendation for an examination by a specialist if the employee wanted the employer to cover the costs of that examination (Document ID 3582, Tr. 1909; 4219, p. 32; 4223, pp. 133-134). BAC and BCTD also stated the employee should decide whether recommended accommodations (i.e., recommended limitations on exposure) should be reported to the employer. As both BAC and BCTD emphasized, information given to the employer should only indicate that a referral is recommended and the nature of the limitation on exposure, not an underlying diagnosis. OSHA considers this reasonable. Non-mandatory Appendix B contains an example of a PLHCP's written medical opinion for the employer.

OSHA finds that this new format for the PLHCP's medical opinion for respirable crystalline silica will better address concerns of NAHB and Dow Chemical, who feared they would be in violation if the PLHCP's written medical opinion for the employer included information that OSHA proposed the PLHCP not report to the employer, such as an unrelated diagnosis (Document ID 2270, p. 4; 2296, pp. 31-32). OSHA finds that removing the prohibition on unrelated diagnoses and instead specifying the only information that is to be included in the PLHCP's written medical opinion for the employer remedies this concern because it makes the contents of the opinion easier to understand and less subject to misinterpretation. The new format also addresses NAHB's request that PLHCPs' opinions be standardized so that employers could understand the results (Document ID 2296, pp. 31-32).

OSHA recognizes that some employees might be exposed to multiple OSHA-regulated substances at levels that trigger medical surveillance and requirements for written opinions. The

PLHCP can opt to prepare one written medical opinion for the employer for each employee that addresses the requirements of all relevant standards, as noted in preambles for past rulemakings, such as chromium (VI) (71 FR 10100, 10365 (2/28/06)). However, the combined written medical opinion for the employer must include the information required under each relevant OSHA standard. For example, if the PLHCP opts to combine written medical opinions for an employee exposed to both chromium (VI) and respirable crystalline silica in a workplace covered by construction standards, then the combined opinion to the employer must contain the information required by paragraphs (i)(5)(A)-(C) of the chromium (VI) standard for construction (29 CFR 1926.1126) and the information required by paragraphs (h)(6)(i)(A)-(C) (and paragraphs (h)(6)(ii)(A)-(B), with written authorization from the employee) of the respirable crystalline silica standard for construction.

Other commenter recommendations for information to be included in the PLHCP's written medical opinion for the employer were not adopted by OSHA. Collegium Ramazzini and BCTD requested that the PLHCP's written medical opinion for the employer contain a statement that the employee was informed that respirable crystalline silica increases the risk of lung cancer, and Collegium Ramazzini also requested that the opinion indicate that the employee was told that smoking can compound the risk of developing lung cancer with exposure to respirable crystalline silica (Document ID 3541, p. 14; 4223, p. 137). On a similar note, Collegium Ramazzini also requested that employers establish smoking cessation programs (Document ID 3541, p. 4). OSHA notes that training provisions in paragraph (j)(3)(i)(A) of the standard for general industry and maritime (paragraph (i)(2)(i)(A) of the standard for construction) already

require employers to ensure that each employee can demonstrate knowledge of the health hazards associated with exposure to respirable crystalline silica, which include lung cancer. OSHA concludes that the training required under the respirable crystalline silica rule is sufficient to inform employees about lung cancer risk.

Labor unions including UAW, CWA, USW, AFL-CIO, and BCTD requested that the rule prohibit employers from asking employees or the PLHCP for medical information (Document ID 2282, Attachment 3, p. 21; 2240, pp. 3-4; 2336, p. 12; 4204, p. 90; 4223, p. 134); as most of these commenters noted, a similar prohibition is included in the black lung rule for coal miners (30 CFR 90.3). OSHA is not including such a prohibition in the rule because employers may have legitimate reasons for requesting medical information, such as X-ray findings, to conduct epidemiology studies, and if employees are not concerned about discrimination or retaliation, they could authorize the employer to receive such information.

The proposed written medical opinion for the employer called for a statement that the PLHCP had explained to the employee the results of the medical examination, including findings of any medical conditions related to respirable crystalline silica exposure that require further evaluation or treatment, and any recommendations related to use of protective clothing or equipment. As noted above, OSHA has retained the requirement that the employer ensure that the PLHCP explains the results to the employee in paragraph (i)(5) of the standard for general industry and maritime (paragraph (h)(5) of the standard for construction), but no longer requires the PLHCP to include a statement of this fact in the written medical opinion for the employer. OSHA is not mandating how the employer ensures that the employee gets the required

information because there are various ways this could be done, such as in a contractual agreement between the employer and PLHCP. PLHCPs could still include the verification in the PLHCP's written medical opinion for the employer if that is a convenient method for them to do so.

As indicated above, the rule requires that employers ensure that employees get a copy of the PLHCP's written medical report and opinion and that they get a copy of the PLHCP's opinion within 30 days of each medical examination (paragraphs (i)(5), (6)(i), and (6)(iii) of the standard for general industry and maritime, paragraphs (h)(5), (6)(i), and (6)(iii) of the standard for construction). By contrast, the proposed rule would have required that the employer obtain the PLHCP's written medical opinion within 30 days of the medical examination and then provide a copy to the employee within 2 weeks after receiving it. Dow Chemical expressed concern about compliance if a PLHCP took more than 30 days to deliver the PLHCP's written medical opinion, which is a situation that is out of the employer's control (Document ID 2270, p. 4). Ameren and EEI requested 30 days for the employer to give the employee a copy of the PLHCP's written medical opinion (Document ID 2315, p. 4; 2357, p. 35).

The purpose of these requirements is to ensure that the employee and employer are informed in a timely manner. To ensure timely delivery and demonstrate a good faith effort in meeting the requirements of the standard, the employer could inform PLHCPs about the time requirements and follow-up with PLHCPs if there is concern about timely delivery of these documents. Similar 30-day requirements are included in other OSHA standards, such as chromium (VI) (1910.1026) and methylene chloride (1910.1052). Because the PLHCP will be

providing the employee with a copy of the PLHCP's written medical report, he or she could give the employee a copy of the written medical opinion at the same time. This would eliminate the need for the employer to give the employee a copy of the PLHCP's written medical opinion for the employer, but the employer would still need to ensure timely delivery.

Additional examinations with a specialist.

Paragraph (i)(7)(i) of the standard for general industry and maritime (paragraph (h)(7)(i) of the standard for construction) sets time limits for additional examinations to be made available. Specifically, it requires that the employer make available a medical examination by a specialist within 30 days of receiving a written medical opinion in which the PLHCP recommends that the employee be examined by a specialist. This requirement is unchanged from the proposed rule. Some commenters, including Dow Chemical, Ameren, and EEI, commented that it might take more than 30 days to get an appointment with a specialist (e.g., Document ID 2270, p. 5; 2315, p. 4; 2357, p. 36). OSHA does not expect this will be the case based on the numbers of available specialists in the U.S. As of March 10, 2015, the American Board of Internal Medicine (ABIM) reported that 13,715 physicians in the U.S. had valid certificates in pulmonary disease (see http://www.abim.org/pdf/data-candidates-certified/all-candidates.pdf). ABIM does not report how many of these physicians are practicing. However, ABIM does report that more than 400 new certificates in pulmonary disease were issued per year from 2011 to 2014 and a total of 4,378 new certificates in pulmonary disease were issued in the period from 2001 to 2010 (see http://www.abim.org/pdf/data-candidates-certified/Number-Certified-Annually.pdf). Because physicians are likely to practice for some time after receiving their certification, the

numbers indicate that a substantial number of pulmonary disease specialists are available in the U.S. The American Board of Preventative Medicine reports that between 2001 and 2010, 863 physicians passed their examinations for board certification in occupational medicine (see https://www.theabpm.org/pass_rates.cfm). In a comparison with total numbers of physicians who were board certified in pulmonary disease during 2001 to 2010, the addition of board certified occupational medicine physicians will likely increase specialist numbers by approximately 20 percent. The expansion of the specialist definition to board certified occupational medicine physicians will mean that more physicians will be available for referrals, making appointments easier to get. Consequently, OSHA considers the 30-day period to be reasonable, and expects that this deadline will ensure that employees receive timely examinations.

E. Communication of Respirable Crystalline Silica Hazards to Employees

Paragraph (j) of the standard for general industry and maritime (paragraph (i) of the standard for construction) sets forth requirements intended to ensure that the dangers of respirable crystalline silica exposure are communicated to employees. Employees need to know about the hazards to which they are exposed, along with associated protective measures, in order to understand how they can minimize potential health hazards. As part of an overall hazard communication program, training serves to explain and reinforce the information presented on labels and in safety data sheets (SDSs). These written forms of communication will be effective and relevant only when employees understand the information presented and are aware of the actions to be taken to avoid or minimize exposures, thereby reducing the possibility of experiencing adverse health effects. Numerous commenters, including industry stakeholders and

dozens of construction employees and concerned individuals, generally supported inclusion of a hazard communication requirement in the rule (e.g., Document ID 2039; 2113; 2116, Attachment 1, p. 45; 2302, p. 1; 2315, p. 4; 2345, p. 3; 3302, p. 1; 3295; 4217, p. 25).

Paragraph (j)(1) of the standard for general industry and maritime (paragraph (i)(1) of the standard for construction) requires the employer to (1) include respirable crystalline silica in the program established to comply with the hazard communication standard (HCS) (29 CFR 1910.1200); (2) ensure that each employee has access to labels on containers of crystalline silica and SDSs, and is trained in accordance with the provisions of the HCS and the provisions on employee information and training (contained in paragraph (j)(3) of the standard for general industry and maritime, paragraph (i)(2) of the standard for construction), and (3) ensure that at least the following hazards are addressed: cancer, lung effects, immune system effects, and kidney effects. These requirements remain unchanged from the proposed rule, after OSHA considered comments addressing these requirements (discussed below).

Some stakeholders agreed with OSHA that additional hazard communication provisions are needed in this rule. For example, the National Industrial Sand Association (NISA) generally agreed with OSHA's approach for communication of hazards to employees and indicated that the generic training elements of the HCS alone are insufficient (Document ID 2195, p. 45). In addition, labor unions such as the United Automobile, Aerospace and Agricultural Implement Workers of America (UAW), International Union of Operating Engineers (IUOE), American Federation of Labor and Congress of Industrial Organizations (AFL-CIO), International Union of Bricklayers and Allied Craftworkers (BAC), and Building and Construction Trades Department,

AFL-CIO (BCTD) generally agreed that employees exposed to respirable crystalline silica need additional information and training (Document ID 2282, Attachment 3, p. 24; 3583, Tr. 2367; 4204, p. 98; 4219, p. 22; 4223, p. 114).

However, other stakeholders expressed the view that OSHA's existing HCS requirements are sufficient, and that hazard communication provisions in this rule are not warranted. For example, the National Stone, Sand, and Gravel Association (NSSGA) asserted that requiring information and training under the respirable crystalline silica rule would be duplicative and unnecessary because OSHA's existing HCS adequately addresses communication of hazards and training of employees (Document ID 2327, Attachment 1, p. 11). The Portland Cement Association and National Association of Home Builders (NAHB) expressed similar views (Document ID 2284, p. 6; 2296, p. 44).

OSHA understands that the HCS already addresses communication of hazards but, after reviewing rulemaking record comments, reaffirms that employees exposed to respirable crystalline silica need additional training and information. Therefore, OSHA has decided to include in the rule the approach set forth in the proposed rule. The rule thus requires compliance with the HCS and the additional requirements that address aspects of employee protection that are not specified in the HCS but are relevant to these standards; examples of these provisions include health hazards specific to respirable crystalline silica, signs at entrances to regulated areas, training on medical surveillance, and training on engineering controls. Specific comments on these requirements and OSHA's rationale for their inclusion in the rule are discussed below. OSHA expects this approach will reduce the administrative burden on employers who must

comply with both the HCS and this rule, while providing employees with adequate information and effective training on respirable crystalline silica hazards.

Which hazards should be addressed in employers' HCS programs was a matter of debate among commenters. For example, the American Coatings Association (ACA) asserted that OSHA's listing of health effects associated with crystalline silica was contrary to the revised HCS, which ACA argued allows qualified health professionals to established hazard classifications based on actual data (Document ID 2239, p. 2). Associated Builders and Contractors, Inc. and the Construction Industry Safety Coalition (CISC) did not support the inclusion of cancer, immune system effects, and kidney effects on the list of hazards to be addressed, asserting that OSHA did not meet its burden of showing a link between these diseases and exposure to crystalline silica (Document ID 2289, p. 8; 2319, p. 120).

OSHA does not find these arguments persuasive. As discussed in Section V, Health Effects, OSHA evaluated the best available published, peer-reviewed literature on respirable crystalline silica and considered comments from stakeholders to determine that exposure to respirable crystalline silica is associated with silicosis and other non-malignant respiratory disease, lung cancer, immune system effects, and kidney effects. Inclusion of a minimum list of health effects to address as part of hazard communication, based primarily on information from OSHA's rulemakings, is consistent with the 2012 revision of all substance-specific standards (77 FR 17574, 17749-17751, 17778-17785 (3/26/2012)). Therefore, the Agency concludes that including a list of hazards to be addressed, and the specific hazards listed, are appropriate.

IUOE requested a requirement to affix warning labels listing the health hazards of respirable crystalline silica on enclosed cabs to remind operators not to work with windows open (Document ID 2262, pp. 34-35). Where enclosed cabs are used to limit exposures to respirable crystalline silica, the employer must ensure that these controls are properly implemented (paragraph (c)(1) of the standard for construction) and that employees can demonstrate knowledge of the controls (paragraph (i)(2)(i)(C) of the standard for construction). Therefore, OSHA concludes that a general requirement to affix warning labels to cabs is unwarranted and construction employers are in the best position to determine if there is a need for warning labels in their workplaces as a reminder to properly implement controls. As a result, OSHA has not included such a requirement in the standard.

OSHA's proposed rule required the employer to make a copy of the standard readily available without cost to each employee covered by the respirable crystalline silica rule, and OSHA has retained this requirement in paragraph (j)(3)(ii) of the standard for general industry and maritime (paragraph (i)(2)(ii) of the standard for construction). This is a common requirement in OSHA standards such as chromium (VI) (29 CFR 1910.1026), acrylonitrile (29 CFR 1910.1045), and cotton dust (29 CFR 1910.1043). The provision leaves employers free to determine the best way to make the standard available, such as a printed or electronic copy in a central location that employees can easily access. OSHA concludes that employees need to be familiar with and have access to the respirable crystalline silica standard for general industry and maritime or construction, as applicable, and be aware of the employer's obligations to comply with it.

OSHA did not propose a requirement for labels or signs in languages other than English. Ameren requested the rule include a requirement that labels include appropriate languages for employees who do not understand English (Document ID 2315, p. 4). Charles Gordon and BAC requested that warning signs be presented in a language or manner that employees can understand, and, as noted by BAC, the method could include graphics (Document ID 3588, Tr. 3805; 4219, p. 27). Requirements for labels on hazardous chemicals are set forth in paragraph (f) of the HCS, which does not require languages other than English. However, the HCS requires the inclusion of certain information on labels on shipped containers, including pictograms (29 CFR 1910.1200 (f)(1)(iv)), and mandates that containers in the workplace be labeled either in accordance with the rules for shipping containers or with product identifier and combinations of words, pictures, or symbols to warn of hazards. OSHA has concluded that with training required under the HCS (29 CFR 1910.1200 (h)(3)(iv)), even employees who are not literate in English will have sufficient knowledge of respirable crystalline silica hazards. Likewise, with training, employees will be able to recognize the meaning of signs at the entrances to regulated areas and the need for respiratory protection in these areas.

OSHA did not include a requirement for employees to be certified as having received training in the proposed rule. Commenters including Dr. Ruth Ruttenberg, representing the AFL-CIO, have voiced support for a portable training record or certification-based approach; Dr. Ruttenberg noted that this would reduce costs by avoiding the need for each new employer to conduct full training (Document ID 1950, pp. 11-12; 2256, Attachment 4, p. 5; 4235, p. 14). OSHA is not including a requirement for a portable training record in the rule. This approach is

consistent with the HCS, which neither requires nor precludes a training record that could be portable. Employee training requirements might be partially fulfilled by training obtained through trade associations, unions, colleges, or professional schools. However, the employer is always ultimately responsible for ensuring that employees are adequately trained, regardless of the method relied upon to comply with the training requirements.

OSHA concludes that a portable training record is unlikely to eliminate the need for employer-specific or site-specific training. For example, Barbara McCabe, Program Manager for IUOE, testified that IUOE local unions train employees but employees would need site-specific training when they report to the worksite (Document ID 3583, Tr. 2368). An example of a case where site-specific training is needed was noted by BAC, who commented that an employee who operated a saw with water controls at one site may be given a saw with vacuum controls at another site (Document ID 4219, p. 23).

In the Notice of Proposed Rulemaking, OSHA asked whether labeling of substances containing more than 0.1 percent crystalline silica was appropriate, as required by the HCS, or if the threshold for labeling should be greater than 1 percent crystalline silica (78 FR at 56291). A number of industry groups suggested a threshold for including respirable crystalline silica on labels or SDSs. With the exception of NISA, who favored a 0.1 percent threshold, the commenters requested a threshold of 1 percent or greater or thought that a 0.1 percent threshold could be problematic (Document ID 1785, p. 4; 2179, pp. 3-4; 2101, pp. 8-9; 2284, p. 10; 2296, p. 44; 2312, p. 3; 2317, p. 3; 2319, p. 120; 2327, Attachment 1, p. 14; 4208, pp. 19-20). The International Diatomite Producers Association agreed with NISA that the threshold for hazard

communication should be 0.1 percent for respirable crystalline silica but requested an exception for respirable crystalline silica in natural (uncalcined) diatomaceous earth, according to OSHA's current policy (Document ID 4212, pp. 6-7).

The classification of hazardous chemicals, including chemicals containing silica, is determined by the HCS. As explained in Section V, Health Effects, OSHA has determined, consistent with the National Toxicology Program and International Agency for Research on Cancer classifications, that respirable crystalline silica is a carcinogen. Under the HCS, a mixture that contains a carcinogen must itself be classified as a carcinogen when at least one ingredient in it has been classified as a Category 1 or Category 2 carcinogen and is present at or above the appropriate cut-off value/concentration limit specified in HCS Table A.6.1 (29 CFR 1910.1200, Appendix A, A.6.3.1). Table A.6.1 sets the cut-off value at greater than or equal to 0.1 percent. Footnote 7 to 1910.1200, Appendix A, A.6.3 notes that the cut-off value is the primary means of classification of carcinogens and may only be modified on a case-by-case evaluation based on available test data for the mixture as a whole. Classification of a chemical under the HCS triggers labeling requirements under that standard, and OSHA does not find it appropriate to impose different requirements in this rule. To do so would be at odds with the concept of harmonizing national and international requirements for classification and labelling of chemicals that is the basis of the GHS and HCS.

OSHA also did not propose requirements related to the creation and retention of training records, but some commenters expressed opinions on this issue. For example, CISC commented that they would agree to document that employees completed training and demonstrated

knowledge (Document ID 4217, p. 25). Consistent with the HCS, employers are not required to keep records of training under the rule for respirable crystalline silica, but employers may find it valuable to do so. Comments on this issue and OSHA's rationale for this decision are discussed in the summary and explanation of Recordkeeping.

F. Recordkeeping

Paragraph (k) of the standard for general industry and maritime (paragraph (j) of the standard for construction) requires employers to make and maintain air monitoring data, objective data, and medical surveillance records. The recordkeeping requirements are in accordance with section 8(c) of the Occupational Safety and Health (OSH) Act (29 U.S.C. 657(c)), which authorizes OSHA to require employers to keep and make available records as necessary or appropriate for the enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational accidents and illnesses.

Paragraph (k)(1)(i) of the standard for general industry and maritime (paragraph (j)(1)(i) of the standard for construction) is substantively unchanged from the proposed rule. It requires the employer to make and maintain accurate records of all exposure measurements taken to assess employee exposure to respirable crystalline silica, as prescribed in paragraph (d) of the standard for general industry and maritime (paragraph (d)(2) of the standard for construction). OSHA has added the words "make and" prior to "maintain" in order to clarify that the employer's obligation is to create and preserve such records. This clarification has also been made for other records required by the silica rule. In addition, OSHA now refers to "measurements taken to assess employee exposure" rather than "measurement results used or

relied on to characterize employee exposure." This change is editorial, and is intended to clarify OSHA's intent that all measurements of employee exposure to respirable crystalline silica be maintained. Paragraph (k)(1)(ii) of the standard for general industry and maritime (paragraph (j)(1)(ii) of the standard for construction) requires that such records include the following information: the date of measurement for each sample taken; the task monitored; sampling and analytical methods used; the number, duration, and results of samples taken; the identity of the laboratory that performed the analysis; the type of personal protective equipment, such as respirators, worn by the employees monitored; and the name, social security number**,** and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

OSHA has made one editorial modification that differs from the proposed rule in paragraph (k)(1)(ii)(B) of the standard for general industry and maritime (paragraph (j)(1)(ii)(B) of the standard for construction) and that is to change "the operation monitored" to "the task monitored." Both "task" and "operation" are commonly used in describing work. However, OSHA uses the term "task" throughout the rule, and the Agency is using "task" in the recordkeeping provision for consistency and to avoid any potential misunderstanding that could result from using a different term. This editorial change neither increases nor decreases an employer's obligations as set forth in the proposed rule.

The recordkeeping provision that received the most comments was proposed paragraph (j)(1)(ii)(G) (now paragraph (k)(1)(ii)(G) of the standard for general industry and maritime, paragraph (j)(1)(ii)(G) of the standard for construction), which, consistent with existing

recordkeeping requirements in OSHA health standards, requires the employer to include in the standard's mandated records the employee's social security number. Morgan Electro Ceramics, National Electrical Carbon Products, Inc. (NECP), Southern Company, the National Tile Contractors Association (NTCA), Dow Chemical Company, the Asphalt Roofing Manufacturers Association (ARMA), the American Petroleum Institute (API), the Marcellus Shale Coalition, Ameren Corporation, the North American Insulation Manufacturers Association (NAIMA), Edison Electric Institute (EEI), the Tile Council of North America (TCNA), the American Foundry Society (AFS), the Nevada Mining Association (NMA), Newmont Mining Corporation (NM), and others opposed the requirement (e.g., Document ID 1772, p.1; 1785, pp. 9-10; 2185, pp. 8; 2267, p. 7; 2270, p. 3; 2291, p. 26; 2301, Attachment 1, pp. 80-81; 2311, p. 3; 2315, p. 7; 2348, Attachment 1, p. 39; 2357, pp. 36-37; 2363, p. 7; 2379, Appendix 1, p. 73; 2107, p. 4; 1963, p. 3). The commenters, citing employee privacy and identity theft concerns, wanted to be allowed to use an identifier other than the social security number, such as an employee identification number, an employee driver's license number, or another unique personal identification number. For example, NAIMA stated "Using social security numbers is a dangerous threat to personal privacy and identify theft that OSHA should affirmatively discourage" (Document ID 2348, Attachment 1, p. 39). Commenters acknowledged that social security numbers must be used for some reports to the government and thus are present in some employer records, but that access to these records is usually more restricted than to air monitoring records.

OSHA has considered the comments it received on this issue and has decided to retain the requirement for including the employee's social security number in the recordkeeping requirements of the rule. The requirement to use an employee's social security number is a long-standing OSHA practice, based on the fact that it is a number that is both unique to an individual and is retained for a lifetime, and does not change as an employee changes employers. The social security number is therefore a useful tool for tracking employee exposures, particularly where exposures are associated with diseases such as silicosis that generally have a long latency period and can develop over a period of time during which an employee may have several employers.

OSHA is cognizant of the privacy concerns expressed by commenters regarding this requirement, and understands the need to balance that interest against the public health interest in requiring the social security identifier. Instances of identity theft and breeches of personal privacy are widely reported and concerning. However, OSHA has concluded that this rule should adhere to the past, consistent practice of requiring employee social security numbers on exposure records mandated by every OSHA substance-specific health standard, and that any change to the Agency's requirements for including employee social security numbers on exposure records should be comprehensive. Some employers who are covered by this rule, such as employers who perform abrasive blasting on surfaces coated with lead, cadmium, or chromium (VI), will be covered by more than one OSHA standard. OSHA examined alternative forms of identification in Phase II of the Agency's Standards Improvement Project, but did not revise requirements for the use of social security numbers (70 FR 1111-1144 (1/5/2005)). Nevertheless, given increasing concerns regarding identity theft and privacy issues, as evidenced by stakeholder comments in

this rulemaking record, OSHA intends to examine the requirements for social security numbers in all of its substance-specific health standards in a future rulemaking. In the meantime, the requirement to use and retain social security numbers to comply with this rule remains.

The remaining requirements of paragraph (k)(1)(ii) of the standard for general industry and maritime (paragraph (j)(1)(ii) of the standard for construction) are generally consistent with those found in other OSHA standards, such as the standards for methylene chloride (29 CFR 1910.1052) and chromium (VI) (29 CFR 1910.1026). The additional requirement to include the identity of the laboratory that performed the analysis of exposure measurements is for the reason stated in the preamble to the Notice of Proposed Rulemaking (NPRM), which is that analysis of crystalline silica samples must conform with the requirements listed in the rule (i.e., in Appendix A), and that can only be determined by knowing the identity of the laboratory that performed the analysis.

Fann Contracting, Inc. commented that OSHA's proposed rule would create a "recordkeeping nightmare" and raised concerns about the difficulties of managing air monitoring data for over 200 employees scattered around the state, with 7 to 8 ongoing projects and 12 to 15 total projects per year (Document ID 2116, Attachment 1, p. 11). The American Subcontractors Association expressed concerns about the high costs of transferring data to new technology or keeping records in paper format (Document ID 2187, p. 7).

OSHA understands that, as with any recordkeeping requirement in a comparable rule, there will be time, effort, and expense involved in developing and maintaining records. However, OSHA expects that even employers who manage multiple projects will have a system for

maintaining these records, just as they do for their other business records. As for high expenses of transferring data to new technology, the Agency understands that there are multiple ways to maintain these records and there are expenses involved in doing so. Therefore, the Agency is allowing employers the option to use whatever method works best for them, paper or electronic.

Paragraph (k)(1)(iii) of the standard for general industry and maritime (paragraph (j)(1)(iii) of the standard for construction) is unchanged from the proposed rule. It requires the employer to ensure that exposure records are maintained and made available in accordance with OSHA's access to employee exposure and medical records standard, which specifies that exposure records must be maintained for 30 years (29 CFR 1910.1020(d)(i)(ii)). Commenters addressed the issue of how long an employer should maintain exposure records. The National Industrial Sand Association (NISA) noted that its occupational health program requires NISA members to retain employee air monitoring records indefinitely (Document ID 2195, p. 35). NISA supported the proposed requirement that air monitoring records be retained for 30 years (Document ID 2195, p. 46). Other commenters advocated recordkeeping durations ranging from 10 years to 40 years (e.g., Document ID 2210, Attachment 1, p. 8; 2319, p. 122; 2339, p. 10; 4025, pp. 8-9). The American Society of Safety Engineers (ASSE) recommended that air monitoring records should be retained for 40 years or the duration of employment plus 20 years, whichever is longer, due to latency periods of some silica-related illnesses (Document ID 2339, p. 10). The International Union of Operating Engineers indicated that 10 years is more than adequate time to retain air monitoring data; it commented that British Columbia, Canada requires retention for 10 years (Document ID 4025, pp. 8-9). The Construction Industry Safety Coalition

and the National Federation of Independent Business (NFIB) expressed the view that 30 years is too long, but did not make recommendations for what they considered a suitable duration (Document ID 2319, pp. 121-122; 2210, Attachment 1, p. 8). NFIB alleged that employers will have to maintain and make available records of all activities relating to each requirement of the rule if the company wants to ensure it can show a good-faith effort to comply, and indicated that keeping records for 30 years would lead to a "staggering" amount of paperwork (Document ID 2210, Attachment 1, p. 8).

After reviewing the comments in this record, OSHA has concluded that the best approach is to maintain consistency with 29 CFR 1910.1020 and its required time period for retention of exposure records of 30 years. OSHA explained in that rulemaking that it is necessary to keep exposure records for this extended time period because of the long latency period between exposure and development of silica-related disease (45 FR 35212, 35268-35271 (5/23/80)). For example, silicosis is often not detected until 20 years or more after initial exposure. The extended record retention period is therefore needed because establishing causality of disease in employees is assisted by, and in some cases can only be made by, having present and past exposure data (as well as any objective data relied on by the employer and present and past medical surveillance records, as discussed below).

In retaining the 30-year retention period, OSHA does not agree with commenters who recommended extending it to at least 40 years, or even indefinitely. The Agency concludes that the 30-year retention period specified in 29 CFR 1910.1020 represents a reasonable balance between the need to maintain exposure records and the administrative burdens associated with

maintaining those records for extended time periods. Because the 30-year records-retention requirement is included in 29 CFR 1910.1020, this duration is consistent with longstanding Agency and employer practice. Other substance-specific rules are also subject to the retention requirements of 29 CFR 1910.1020, such as the standards addressing exposure to methylene chloride (29 CFR 1910.1052) and chromium (VI) (29 CFR 1910.1026). The Agency also disagrees that the 30-year retention requirement will lead to a "staggering" amount of paperwork. as NFIB commented (Document ID 2210, Attachment 1, p. 8). Electronic recordkeeping has become commonplace. Commenters such as the Association of Energy Service Companies and ASSE support the use of electronic or digital records to ease paperwork burdens (Document ID 2344, p. 2; 2339, p. 5). Thus, OSHA finds that the 30-year retention period is necessary and appropriate for air monitoring data.

Paragraph (k)(2)(i) of the standard for general industry and maritime (paragraph (j)(2)(i) of the standard for construction) is substantively unchanged from the proposed rule. It requires employers who rely on objective data to keep accurate records of the objective data. Paragraph (k)(2)(ii) of the standard for general industry and maritime (paragraph (j)(2)(ii) of the standard for construction) requires the record to include: the crystalline silica-containing material in question; the source of the objective data; the testing protocol and results of testing; a description of the process, task, or activity on which the objective data were based; and other data relevant to the process, task, activity, material, or exposures on which the objective data were based. Paragraphs (k)(2)(ii)(D) and (E) of the standard for general industry and maritime (paragraphs (j)(2)(ii)(D) and (E) of the standard for construction) have been modified from the

proposed rule to substitute the word "task" for "operation" and to clarify the requirements for records of objective data. These changes are editorial, and do not affect the employer's obligations as set forth in the proposed rule.

Since the rule allows objective data to be used to exempt the employer from monitoring requirements and to provide a basis for selection of respirators, OSHA considers it critical that the use of objective data be documented. As authorized in the rule, reliance on objective data is intended to provide the same degree of assurance that employer monitoring of employee exposures by taking air samples does. The specified content elements are required to ensure that the records are capable of demonstrating to OSHA a reasonable basis for the conclusions drawn by the employer from the objective data.

OSHA considers objective data to be employee exposure records that must be maintained. Paragraph (k)(2)(iii) of the standard for general industry and maritime (paragraph (j)(2)(iii) of the standard for construction) is unchanged from the proposed rule. It requires the employer to ensure that objective data are maintained and made available for 30 years in accordance with 29 CFR 1910.1020(d)(1)(ii)).

The National Asphalt Pavement Association recommended that OSHA clarify that ". . . for an operation provided the controls outlined in Table 1, no further records of objective data would be required" (Document ID 2181, p. 13). OSHA confirms that an employer who fully and properly implements the control measures in Table 1 does not need to have objective data since no exposure assessment (including those based on objective data) is required when the employer

is following Table 1. Therefore, following Table 1 does not trigger a recordkeeping or retention requirement.

Associated Builders and Contractors, Inc. (ABC) and ASSE addressed the issue of retaining objective data records for 30 years (Document ID 2289, p. 8; 2339, p. 10). ABC expressed concerns that data could be lost or destroyed during the 30-year period, and thought it would be difficult to enforce this provision. Furthermore, it commented that there is a ". . . large and burdensome amount of records that an employer would need to store and maintain" (Document ID 2289, p. 8). ABC did not make a recommendation on how long employers should maintain objective data records. ASSE commented that 30 years is too short and recommended that objective data records be retained for 40 years or the duration of the employment plus 20 years, whichever is longer, due to latency periods of some silica-related illnesses (Document ID 2339, p. 10). For the same reasons noted in the explanation above for retaining air monitoring data pursuant to paragraph (k)(1)(iii) of the standard for general industry and maritime (paragraph (j)(1)(iii) of the standard for construction), OSHA finds that the 30-year retention period is necessary and appropriate for objective data.

Paragraph (k)(3)(i) of the standard for general industry and maritime (paragraph (j)(3)(i) of the standard for construction) requires the employer to make and maintain an accurate record for each employee subject to medical surveillance under paragraph (i) of the standard for general industry and maritime (paragraph (h) of the standard for construction). Paragraph (k)(3)(ii) of the standard for general industry and maritime (paragraph (j)(3)(ii) of the standard for construction) lists the categories of information that an employer is required to record: the name and social

security number of the employee; a copy of the PLHCPs' and specialists' written medical opinions for the employer; and a copy of the information provided to the PLHCPs and specialists where required by paragraph (i)(4) of the standard for general industry and maritime (paragraph (h)(4) of the standard for construction). The information provided to the PLHCPs and specialists includes the employee's duties as they relate to crystalline silica exposure, crystalline silica exposure levels, descriptions of personal protective equipment used by the employee, and information from employment-related medical examinations previously provided to the employee (paragraph (i)(4) of the standard for general industry and maritime, paragraph (h)(4) of the standard for construction).

In paragraph (k)(3)(ii)(B) of the standard for general industry and maritime (paragraph (j)(3)(ii)(B) of the standard for construction), OSHA has changed the "PLHCP's and pulmonary specialist's written opinions" to the "PLHCPs' and specialists' written medical opinions." The change, consistent with paragraph (i) of the standard for general industry and maritime (paragraph (h) of the standard for construction), is made to reflect the revised definition for the term "specialist" included in the rule.

Paragraph (k)(3)(iii) of the standard for general industry and maritime (paragraph (j)(3)(iii) of the standard for construction) is unchanged from the proposed rule. It requires that medical records must be maintained for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020(d)(1)(i), which governs application of the retention requirements in this rule. Pursuant to 29 CFR 1910.1020(d)(1)(i)(C), medical records of employees who have worked for less than one year for the employer need not be retained beyond

the term of employment if they are provided to the employee upon the termination of employment. This exception allows employers flexibility and the option not to retain medical records in these circumstances (53 FR 38140, 38153-38155 (9/29/88)). This provision greatly reduces the recordkeeping burden on employers of short-term employees, including many construction employees covered by this rule. Of course, neither this rule nor 29 CFR 1910.1020 prohibits employers from keeping the medical records of employees who worked less than one year, and some employers may choose to keep the records. As indicated earlier, employers have the option to keep records in electronic or paper form.

The employer is responsible for the maintenance of records in his or her possession (e.g., the PLHCP's written medical opinion for the employer described in paragraph (i)(6) of the standard for general industry and maritime (paragraph (h)(6) of the standard for construction)). The employer is also responsible for ensuring the retention of records in the possession of the PLHCP (e.g., the written medical report for the employee described in paragraph (i)(5) of the standard for general industry and maritime (paragraph (h)(5) of the standard for construction)) that are created pursuant to this rule's medical surveillance requirements. This responsibility, which derives from 29 CFR 1910.1020(b), means that employers must ensure that the PLHCP retains a copy of medical records for the employee's duration of employment plus 30 years. The employer can generally fulfill this obligation by including the retention requirement in the agreement between the employer and the PLHCP.

Commenters objecting to the recordkeeping requirements for medical records were concerned with privacy and costs. OSCO Industries asserted that the medical recordkeeping

provisions would be subject to the Health Insurance Portability and Accountability Act (HIPAA), and thus employers would be denied access to the records (Document ID 1992, p. 12). The National Electrical Contractors Association (NECA) also expressed concerns about the application of HIPAA (Document ID 2295, p. 2). NECA indicated that the recordkeeping requirements would ". . . inundate most businesses with paperwork . . ." and would be ". . . an economic burden to employers in the construction industry . . ." (Document ID 2295, p. 2). Fann Contracting and Leading Builders of America said that medical records would be very expensive and difficult to maintain (Document ID 2116, Attachment 1, p. 11; 2269, p. 19). Fann Contracting commented that they have multiple projects, as many as 7 to 8 ongoing and 12 to 15 per year, with over 200 employees scattered around the state, which makes the new requirements "a recordkeeping nightmare" (Document ID 2116, Attachment 1, p. 11).

As to the expense and difficulty of maintaining the medical records, OSHA recognizes that there will be time, effort, and expense involved in maintaining medical records. However, as stated earlier, OSHA expects that employers who manage multiple projects will have a system for maintaining these records, just as they do for their other business records. The adverse health effects associated with crystalline silica are very serious, and OSHA has concluded that the recordkeeping requirements are necessary to ensure that records are available to assist PLHCPs in identifying health conditions that may place employees at increased risk from exposure, as well as identifying and treating adverse health effects that may develop among employees. Therefore, OSHA concludes that the requirements for making and maintaining medical records are reasonable, and are essential for the health and safety of employees.

As to the concerns expressed regarding the application of HIPAA, the requirement for retention of medical records in this standard (like those in other OSHA standards) is consistent with HIPAA. HIPAA allows for disclosure of certain health information to an employer where needed to comply with OSHA requirements for medical surveillance (45 CFR 164.512). Moreover, this standard's requirement that medical surveillance reports be provided to workers rather than to employers eliminates much of this concern.

Morgan Electro Ceramics, NECP, Southern Company, NTCA, Dow Chemical, ARMA, API, the Marcellus Shale Coalition, Ameren, NAIMA, EEI, TCNA, AFS, NMA, NM and others also questioned the requirement that the employee's social security number be included in medical records (Document ID 1772, p. 1; 1785, pp. 9-10; 2185, pp. 8; 2267, p. 7; 2270, p. 3; 2291, p. 26; 2301, Attachment 1, pp. 80-81; 2311, p. 3; 2315, p. 7; 2348, Attachment 1, p. 39; 2357, pp. 36-37; 2363, p. 7; and 2379, Appendix 1, p. 73; 2107, p. 4; 1963, p. 3).

As noted above in the discussion on air monitoring data, OSHA finds the privacy and security issues associated with the required use of social security numbers are of concern. However, for the same reasons discussed above with regard to employee exposure records, the Agency has decided to retain the requirement for use of social security numbers in medical records. As stated above, OSHA intends separately from this rulemaking to examine the requirements for social security numbers in all of its substance-specific health standards in order to address the issue comprehensively and ensure consistency among standards.

In total, the recordkeeping requirements fulfill the purposes of Section 8(c) of the OSH Act, and help protect employees because such records contribute to the evaluation of employees'

health and enable employees and their healthcare providers to make informed health care decisions. These records are especially important when an employee's medical condition places him or her at increased risk of health impairment from further exposure to respirable crystalline silica. Furthermore, the records can be used by the Agency and others to identify illnesses and deaths that may be attributable to respirable crystalline silica exposure, evaluate compliance programs, and assess the efficacy of the standard. OSHA concludes that medical surveillance records, like exposure records, are necessary and appropriate for protection of employee health, enforcement of the standard, and development of information regarding the causes and prevention of occupational illnesses.

Commenters, such as NISA and ASSE, addressed the issue of duration of retention of medical records (Document ID 2339, p. 10; 2195, p. 35). NISA indicated that 30 years is an appropriate retention period (Document ID 2195, p. 35). ASSE indicated that medical records should be retained for 40 years or the duration of the employment plus 20 years, whichever is longer, due to latency periods of some silica-related illnesses (Document ID 2339, p. 10).

As with exposure records and objective data records, OSHA has concluded that the best approach is to maintain consistency with 29 CFR 1910.1020 and its required retention period for medical records; that period is the duration of employment plus 30 years. It is necessary to keep medical records for this extended time period because of the long latency period between exposure and development of silica-related disease (45 FR at 35268-35271). OSHA recognizes that in some cases, the latency period for silica-related diseases may extend beyond 30 years. However, the Agency concludes that the retention period specified in 29 CFR 1910.1020

represents a reasonable balance between the need to maintain records and the administrative burdens associated with maintaining those records for extended time periods. Because the duration of employment plus the 30-year records retention requirement is currently included in 29 CFR 1910.1020, this time period is consistent with longstanding Agency and employer practice.

Charles Gordon, a retired occupational safety and health attorney, advocated for a provision for trade associations, unions, and medical practices to provide medical exams and keep medical records (Document ID 2163, Testimony 1, p. 14). After considering this suggestion, OSHA decided not to incorporate it into the rule. OSHA anticipates that, in some cases, employers may be able to work with unions or trade associations to ensure that medical examinations are provided that meet the requirements of the rule, and that records are maintained. However, in many cases, unions and trade associations will not be available to provide such services. And in any case, the employer is ultimately responsible for ensuring that medical examinations are provided in accordance with the rule. Consistent with OSHA's access to employee exposure and medical records standard (29 CFR 1910.1020), the rule therefore requires the employer to maintain such records, and the employer must ensure the PLHCP retains the medical records for the employee's duration of employment plus 30 years. As stated earlier, the employer can generally fulfill this obligation by including the retention requirement in the contractual agreement between the employer and the PLHCP.

Commenters such as the International Union of Bricklayers and Allied Craftworkers (BAC) and ASSE stated that records should be made available to the employee and the

employee's designated representative(s), at the request of the employee (e.g., Document ID 2329, p. 8; 2339, p. 5). OSHA agrees, and employees and their representatives are permitted to obtain a copy of exposure and medical records pursuant to 29 CFR 1910.1020(e)(iii).

Commenters such as the Building and Construction Trades Department, AFL-CIO (BCTD) and BAC requested the addition of a provision for retaining training records in the rule (e.g., Document ID 2371, Attachment 1, p. 50; 2329, p. 8). BAC recommended that employers in the construction industry could use a portable training management system that is designed to track employees' training throughout their career (Document ID 4053, Attachment 1 and Exhibit 2). To keep track of training records, BCTD recommended that employers could use the same portable training management system recommended by BAC or use a portable database, as described in a report by the Mount Sinai Irving J. Selikoff Center for Occupational and Environmental Medicine (Document ID 4223, p. 126; 4073, Attachment 2b).

OSHA is not including a provision for retaining training records in the rule because the Agency has concluded that requiring such records is not necessary. The performance-oriented requirements for training in paragraph (j) of the standard for general industry and maritime (paragraph (i) of the standard for construction) specify that employees must be able to demonstrate knowledge of the health hazards associated with exposure to respirable crystalline silica; tasks that could result in exposure; procedures to protect employees from exposure; as well as the silica standard and the medical surveillance program it requires. These requirements will be sufficient to ensure that employees are adequately trained with regard to recognizing silica hazards and taking protective measures. Moreover, adding a provision for retention of

training records would involve additional paperwork burdens for employers. The absence of a requirement for retention of training records in the rule is consistent with OSHA's hazard communication standard (29 CFR 1910.1200), addressing training for all hazardous chemicals, as well as the most recent OSHA substance-specific health standards, addressing exposure to 1,3-butadiene (29 CFR 1910.1051), methylene chloride (29 CFR 1910.1052), and chromium (VI) (29 CFR 1910.1026).

The recordkeeping requirements of the rule are also generally consistent with the recordkeeping provisions of the industry consensus standards, ASTM E 1132 – 06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica and ASTM E 2625 – 09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities. The main substantive differences are related to the use of social security numbers and duration of retention of records. ASTM E 1132 – 06 and ASTM E 2625 – 09 specify that the employer should include an identification number for each employee monitored for dust exposure, but do not indicate that the number must be a social security number, whereas OSHA's rule requires the employer to include the employee's social security number. As noted above, although OSHA intends to reconsider this policy for all standards in a future rulemaking, the Agency has determined that the use of social security numbers is appropriate for this rule. ASTM E 1132 – 06 specifies that medical and exposure records should be retained for 40 years or the duration of employment plus 20 years, whichever is longer. ASTM E 2625 – 09 does not specify a duration for retaining exposure or medical records. OSHA has determined that the retention requirements of 29 CFR

1910.1020 are appropriate for exposure and medical records collected under this rule, because the requirements represent a reasonable balance between the need to maintain records and the administrative burdens associated with maintaining those records, and are consistent with longstanding practice by the Agency with which employers are familiar and to which they are accustomed; changing the duration of retention requirement for this one rule could therefore cause confusion.

Dates

Paragraph (l) of the standard for general industry and maritime (paragraph (k) of the standard for construction) sets forth the effective date of the standard and the date(s) for compliance with the requirements of the standard. OSHA proposed identical requirements for both standards: an effective date 60 days after publication of the rule; a date for compliance with all provisions except engineering controls and laboratory requirements of 180 days after the effective date; a date for compliance with engineering controls requirements, which was one year after the effective date; and a date for compliance with laboratory requirements of two years after the effective date.

The United Steelworkers supported the proposed effective and start-up dates, arguing that they provide adequate time for employers to come into compliance with the rule (Document ID 2336, p. 16). Employers and industry representatives such as the American Exploration and Production Council, the Tile Council of North America, and Ameren requested that the effective date of the rule be extended (e.g., Document ID 2147, p. 2; 2267, p. 7; 2315, p. 4; 2375, Attachment 1, p. 3; 2363 p. 7).

OSHA sets the effective date to allow sufficient time for employers to obtain the standard, read and understand its requirements, and undertake the necessary planning and preparation for compliance. Section 6(b)(4) of the OSH Act allows the effective date of a standard to be delayed for up to 90 days from the date of publication in the Federal Register. Given the requests by commenters, OSHA's interest in having employers implement effective compliance efforts, and the minimal effect of an additional 30 day delay, the Agency has decided that it is appropriate to set the effective date at 90 days from publication, rather than at 60 days. Accordingly, the rule will become effective 90 days after publication in the Federal Register.

Paragraphs (l)(2), (3) and (4) of the standard for general industry and maritime (paragraphs (k)(2) and (3) of the standard for construction) establish dates for compliance with the requirements of the standard. Employers and industry representatives such as the American Petroleum Institute, the National Industrial Sand Association, Dow Chemical Company, the Glass Association of North America (GANA), and the American Foundry Society (AFS) contended that substantially more time was needed to implement engineering controls than the one year from the effective date that had been proposed (e.g., Document ID 2195, pp. 8, 22; 2147, p. 1; 2267, p. 3; 2149, p. 2; 2277, p. 1; 1992, pp. 4, 12; 2023, p. 4; 2315 pp. 4, 9; 2137; 2047; 2215, p. 10; 2311, p. 3; 2291, p. 16; 2105. p. 1; 2348, Attachment 1, p. 40; 2357, p. 18; 2365, pp. 10-22; 2301, Attachment 1, pp. 64, 82; 2302, p. 9; 2327, Attachment 1; 2270, p. 1; 2279, pp. 6, 11; 2290, pp. 3-4; 2296, p. 36; 2384, p. 6; 2493, p. 5; 2379, Appendix 1, pp. 22, 73-74; 2544, p. 11).

Attachment A - Summary of Major PRA-related Public Comments from Respirable Crystalline Silica Final Rule (Excerpts from Chapter XV. *Summary and Explanation of the Standards*)

General industry employers and trade associations were concerned with the length of time needed for the design, approval, and installation of engineering controls. For example, the AFS provided examples of how implementation of engineering controls could take longer than one year for foundries:

> The proposed compliance period fails to account for the substantial time required for a comprehensive engineering evaluation of the overall silica exposure at the facility and the design of a proposed engineering control system. The engineering phase alone for a 10,000 cfm or larger system typically takes 4 to 6 months -- longer for large or complex exposure problems. This issue is further complicated by the fact that the current national economy has substantially reduced the number of firms offering these environmental services, and all of the affected foundries will be competing for these limited services. The compliance period also fails to take into effect the fact that to attempt to meet the proposed PEL with local exhaust ventilation would require custom control equipment (primarily baghouses) which are not stock items and are custom built for each application. These control systems typically require a minimum of 2 to 4 months for manufacture after the completion of the engineering specifications and submission of an order. This period is significantly longer for specialized or large orders (Document ID 2379, Attachment B, p. 37).

Another issue raised by general industry representatives and employers such as Morgan Electro Ceramics, the Asphalt Roofing Manufacturers Association, the Fertilizer Institute, and the National Association of Manufacturers, was the potential length of time involved in environmental permitting processes (e.g., Document ID 1772, p. 1; 1992, Attachment 1, p. 4; 2291, Attachment 1, pp. 16-17; 3487, pp. 26-27; 3492, Attachment 1, pp. 5-6; 3584, Tr. 2845; 2290, Attachment 1, p. 3; 2380, Attachment 2, p. 20). The AFS testified on the permitting issue:

> Because many of the controls involve additions or changes to ventilation systems, OSHA must recognize the additional time required for modelling and permitting by state or federal EPA authorities. The proposed one year compliance period is totally unrealistic. In some states, the mandatory permitting requirement for both

> new and modified systems requires up to 18 months, and this does not include the design and modelling work necessary to prepare the permit application, or the construction and installation time after approval. For foundries which have a Title V permit, the approval includes an additional time period for the US EPA to review and make comments, and if the facility is subject to the federal Prevention of Significant Deterioration (PSD) or Lowest Achievable Emission Rate (LAER) rules the permit approval can take an additional 6 to 18 months for the detailed review and approval necessary (Document ID 3487, p. 26).

OSHA is persuaded that the concerns expressed by commenters regarding the time needed to implement engineering controls are reasonable, and is extending the compliance deadline for general industry and maritime to allow two years from the effective date for employers to comply with the standard. In extending the proposed compliance date for engineering controls in the general industry and maritime standard by one year, OSHA has concluded that engineering controls can be implemented within two years of the effective date in most general industry and maritime workplaces. However, because permit requirements and application processes vary by jurisdiction, OSHA is willing to use its enforcement discretion in situations where an employer can show it has made good faith efforts to implement engineering controls, but has been unable to implement such controls due to the time needed for environmental permitting.

OSHA understands that some general industry employers may face difficulties in implementing engineering controls due to continuous operation of facilities in particular industries. Trade associations such as the North American Insulation Manufacturers Association (NAIMA) and the GANA noted that their industries have plants that run constantly and shut down only on rare occasions, making installation of engineering controls, which would require a

shutdown, unusually difficult and expensive (e.g., Document ID 2348, Attachment 1, p. 40; 2215, Attachment 1, p. 10). OSHA is willing to provide latitude and work with such employers on an individual basis to schedule implementation of engineering controls during shutdowns, provided they are working in good faith toward compliance and that they provide and assure employees use appropriate respirators until engineering controls are installed.

Paragraph (l)(3)(ii) of the standard for general industry and maritime allows five years from the effective date – four years more than the proposed standard – for employers to comply with obligations for engineering controls in hydraulic fracturing operations in the oil and gas industry. Additional time is provided to implement engineering controls in this industry to allow employers to take advantage of further development of emerging technologies discussed in Chapter IV of the Final Economic Analysis and Regulatory Flexibility Analysis (FEA). Paragraph (l)(3)(iii) specifies that obligations for medical surveillance in paragraph (i)(l)(i) commence in accordance with paragraph (l)(4) for hydraulic fracturing operations in the oil and gas industry. Paragraph (l)(4) is discussed below.

Paragraph (k)(2) of the standard for construction allows one year after the effective date to come into compliance with all obligations other than the requirements for methods of sample analysis. This extends the time (one year compared to 180 days) for compliance with the standard's ancillary provisions and retains the one year period after the effective date for engineering controls. Commenting on the proposed compliance dates for construction work, several stakeholders raised issues that might impact the ability of employers to implement engineering controls within one year after the effective date (e.g., Document ID 2296,

Attachment 1, p. 36; 2357, p. 18). OSHA expects that the vast majority of construction employers will choose to implement the controls specified in paragraph (c) of the construction standard. These controls are generally commercial products that are readily available and can be purchased and put into use in a very short period of time. For the limited number of construction tasks that require more sophisticated controls (e.g., enclosed cabs on heavy equipment used during the demolition of concrete or masonry structures), the controls are already either commonly in use or could be implemented within one year. Moreover, by implementing the controls specified in paragraph (c) of the construction standard, employers will not be required to assess employee exposures to respirable crystalline silica, so no time will be needed for assessing employee exposures prior to implementing engineering controls. OSHA finds that the ready availability of engineering controls for construction will enable construction employers to implement engineering controls within one year of the effective date, and the Agency is therefore requiring that construction employers implement engineering controls required by the standard within one year of the effective date.

In requiring that general industry and maritime employers comply with most obligations of the standard two years after the effective date, and in requiring that construction employers comply with all ancillary and engineering controls one year after the effective date, OSHA has aligned the compliance dates for other provisions of the standards with the compliance dates for engineering controls. This will allow employers to focus their efforts on implementation of engineering controls. OSHA decided that staggering the compliance dates for some provisions of the rule could serve to divert attention and resources away from the implementation of

engineering controls. For example, if respiratory protection were to be required six months after the effective date (as OSHA proposed), employers would need to assess employee exposures, and would need to develop a respiratory protection program and provide appropriate respirators to employees exposed above the PEL, while simultaneously working to implement engineering controls. A requirement for respiratory protection prior to implementation of engineering controls would be particularly problematic where construction employers implement the controls specified in paragraph (c) of the construction standard. This is because those employers would not otherwise be required to assess employee exposures.

In determining the compliance dates for provisions other than engineering controls, OSHA considered the relatively short time period before engineering controls must be implemented in construction work. The Agency recognizes the longer time period allowed for general industry and maritime employers to implement engineering controls. However, general industry employers must comply with a PEL that is approximately equivalent to 100 $\mu g/m^3$ during the period before compliance with the revised PEL of 50 $\mu g/m^3$ is required, whereas construction work will be subject to a higher PEL of approximately 250 $\mu g/m^3$. The lower PEL of approximately 100 $\mu g/ m^3$ that will apply to general industry will mitigate respirable crystalline silica exposures in this sector to some extent during the interim period. Moreover, because employers will be using this time to implement engineering controls, OSHA expects that exposures will continue to decline during this period. Construction will continue to be subject to the higher PEL of approximately 250 $\mu g/m^3$ during this interim, but that period will only be one year from the effective date, compared to two years from the effective date for general industry

and maritime. OSHA finds that establishing consistent compliance dates for engineering controls and other provisions of the standards is less confusing, more practical, and will better enable employers to focus their time and resources on implementing the control measures that will best protect employees. For hydraulic fracturing operations in the oil and gas industry, OSHA is providing an extra three years– a total of five years from the effective date – for employers to implement engineering controls for hydraulic fracturing operations. During these additional three years, employers must comply with all other requirements of the standard, including requirements for respiratory protection to protect employees exposed to respirable crystalline silica at levels that exceed the revised PEL of 50 μg/m^3.

The issue of how much time to allow for laboratories to come into compliance with respect to methods of sample analysis received considerable comment during the rulemaking. Employers and trade and professional associations such as the National Tile Contractors Association, the Fertilizer Institute, OSCO Industries, Edison Electric Institute, and Fann Contracting, Inc. expressed concerns about the proposed rule's provisions that gave all employers one year to implement engineering controls and allowed two years before employers would be required to follow requirements for methods of sample analysis (e.g., Document ID 2267, pp. 6-7; 2149, p. 2; 1992, pp. 10, 12; 2179, p. 3; 2312, p. 2; 2317, p. 2; 2314, p. 3; 2357, pp. 18-19; 2365, p. 22; 2116, Attachment 1, p. 48; 2327, p. 29; 2368, p. 3; 2379, Attachment B, p. 37; 3398, pp. 1-2; 3487, p. 27; 3491, p. 5; 2363, p. 6). For example, Andy Fulton of ME Global stated:

> OSHA is giving laboratories 2 years to improve their procedures for accurate silica analysis. However, OSHA is requiring foundries to install expensive

> engineering controls within one year, before accurate exposure levels are available. This does not make sense, especially when it could involve millions of dollars (Document ID 2149, p. 2).

In proposing to require employers to implement engineering controls and comply with other provisions of the rule before the laboratory requirements came into effect, OSHA intended to allow time for laboratory capacity to develop. As indicated in Chapter IV of the FEA, OSHA finds that it is feasible to measure exposures to respirable crystalline silica at the revised PEL and action level with a reasonable degree of accuracy and precision using methods that are currently available. Many laboratories are capable of analyzing samples in accordance with the laboratory requirements of the silica rule; OSHA encourages employers to follow these requirements prior to the time that they are mandated. There are approximately 40 laboratories that are accredited by AIHA Laboratory Accreditation Programs for the analysis of crystalline silica (Document ID 3586, Tr. 3284). These laboratories are already capable of analyzing samples in accordance with the laboratory requirements of the silica rule.

OSHA anticipates that the additional demand for respirable crystalline silica exposure monitoring and associated laboratory analysis with the rule will be modest. Most construction employers are expected to implement the specified exposure control measures in paragraph (c) of the construction standard, and will therefore not be required to assess employee exposures, thus placing no demands on laboratories. The performance option for exposure assessment provided in both the general industry and maritime standard at paragraph (d)(2) and the construction standard at paragraph (d)(2)(ii) also serves to lessen the anticipated volume of exposure monitoring. The additional time allowed for compliance with the general industry and maritime

standard further serves to diminish concerns about laboratory capacity by providing additional time for laboratory capacity to increase and distributing demand for sample analysis over an extended period of time. OSHA therefore concludes that the compliance date for methods of sample analysis of two years after the effective date is reasonable in both the general industry/maritime and construction standards. OSHA also anticipates that construction employers who perform air monitoring before the laboratory requirements go into effect (see paragraph (k)(3) of the construction standard) will be able to obtain reliable measurements of their employees' exposures to respirable crystalline silica.

Paragraph (l)(4) of the standard for general industry and maritime specifies that obligations in paragraph (i)(1)(i) regarding medical surveillance take effect for employees who will be occupationally exposed to respirable crystalline silica above the PEL for 30 or more days per year beginning two years after the effective date. Obligations in paragraph (i)(l)(i) for employees who will be occupationally exposed to respirable crystalline silica at or above the action level (but at or below the PEL) for 30 or more days per year will commence four years after the effective date. In other words, medical surveillance will be triggered by exposures above the PEL for 30 or more days per year, beginning two years after the effective date and continuing through four years after the effective date, and will then be triggered by exposures at or above the action level for 30 or more days per year beginning four years after the effective date. As indicated in the Summary and Explanation for Medical Surveillance, this approach focuses initial medical surveillance efforts on those employees who are at greatest risk, while giving most employers additional time to fully evaluate the engineering controls they have

implemented in order to determine which employees meet the action level trigger for medical surveillance.

Commenters such as NAIMA and the National Concrete Masonry Association voiced concerns about the proposed rule's effects on small businesses, and asked for compliance extensions for small businesses (e.g., Document ID 2348, Attachment 1, p. 41; 2279, Attachment 1, p. 10). OSHA has considered these concerns, and has found that the compliance dates set forth in this section are reasonable for employers of all sizes. Therefore, OSHA has not created exceptions extending the compliance period for specific business classes or sizes.

OSHA also considered comments from the U.S. Chamber of Commerce and the National Stone, Sand, and Gravel Association, among others, expressing concern that the rule would create increased demand for health and safety professionals and for medical professionals; they alleged there are not enough professionals in those fields to service the demand that would be created by the rule (e.g., Document ID 2365, Attachment 1, p. 10; 2237, Attachment 1, p. 4; 3578, Tr. 1127). The Agency does not find these arguments convincing. Most of the provisions of the rule do not generally require the involvement of a health or safety professional, or require only limited oversight from a health or safety professional. For example, exposure monitoring does not need to be performed by certified industrial hygienists; technicians and other trained employees can perform this task. Employer compliance with the specified exposure control methods in paragraph (c) of the construction standard can generally be accomplished without the involvement of a health or safety professional. Compliance with other obligations, such as housekeeping and training requirements, can also be achieved without the involvement of a

health or safety professional or with minimal oversight from them. There are a sufficient number of medical professionals available for employers to implement the medical surveillance provisions of the rule. The availability of medical professionals is confirmed and discussed in detail in the summary and explanation of Medical Surveillance in this preamble. Therefore, the Agency finds no evidence in the record that a shortage of available health and safety professionals, or a shortage of medical professionals, will preclude employers from complying with the rule by the dates set forth in this paragraph.

Thus, the effect of changes made to the proposed rule is that: (1) all obligations (i.e., exposure assessment and other ancillary provisions, engineering controls) for general industry and maritime employers (other than hydraulic fracturing operations in the oil and gas industry and an action level trigger for medical surveillance for all general industry and maritime employers) will become enforceable two years after the 90-day effective date of the rule; (2) all obligations for hydraulic fracturing operations in the oil and gas industry (except obligations for engineering controls and an action level trigger for medical surveillance) will become enforceable two years after the 90-day effective date; (3) obligations for engineering controls for hydraulic fracturing operations in the oil and gas industry will become enforceable five years after the 90-day effective date; (4) obligations for an action level trigger for medical surveillance in the standard for general industry and maritime, including hydraulic fracturing operations in the oil and gas industry, will become enforceable four years after the 90-day effective date; (5) all obligations (other than requirements for methods of sample analysis) for construction employers will become enforceable one year after the 90-day effective date; and (6) requirements for

methods of sample analysis, applicable to laboratories covered by paragraph (d)(2)(v) of the standard for construction, become enforceable two years after the effective date, i.e., one year after the other requirements in the construction standard and on the same date as all obligations in general industry and maritime (other than hydraulic fracturing).

Appendix A

Appendix A, which addresses methods of sample analysis, is incorporated as part of this standard and imposes additional mandatory obligations on employers covered by this standard.

OSHA proposed analysis requirements that it had included as part of paragraph (d) of both standards. The Southern Company recommended that OSHA require use of accredited laboratories and move all other laboratory requirements to an Appendix as a guide for laboratories that analyze silica samples (Document ID 2185, p. 7).

OSHA has retained the substance of the proposed provisions addressing analysis of samples, but has moved these provisions to a new mandatory appendix. The Agency has decided that segregating these requirements in a mandatory appendix in the final rule provides greater clarity for both employers and the laboratories that analyze samples.

Appendix A specifies procedures for the laboratories conducting the analysis, but employers must ensure samples taken to satisfy the monitoring requirements of the standard are analyzed by an accredited laboratory using the methods and quality control procedures described in this Appendix. Putting the requirements in a separate appendix, rather than in the regulatory text, facilitates the communication of these requirements to the laboratory analyzing samples. The mandatory appendix approach is also meant to clarify that an employer who engages a

laboratory to analyze respirable crystalline silica samples may rely on an assurance from that laboratory that the specified requirements were met. For example, the laboratory could include a statement that it complied with the requirements of the standard along with the sampling results provided to the employer, or the employer could obtain the information from the laboratory or industrial hygiene service provider.

Appendix A of the final rule describes the specific analytical methods to be used, as well as the qualifications of the laboratories at which the samples are analyzed. As discussed in greater detail in Chapter IV of the Final Economic Analysis and Regulatory Flexibility Analysis (FEA), the sampling and analysis methods required by the rule are technologically feasible in that they are widely used and accepted as the best available methods for measuring individual exposures to respirable crystalline silica. The Agency has determined that the provisions in Appendix A are needed to ensure the accuracy of monitoring required by the rule to measure employee exposures.

OSHA has typically included specifications for the accuracy of exposure monitoring methods in substance-specific standards, but has not always specified the analytical methods to be used or the qualifications of the laboratory that analyzes the samples. Exceptions are the asbestos standards for general industry (29 CFR 1910.1001, Appendix A) and construction (29 CFR 1926.1101, Appendix A), which specify the sampling and analytical methods to be used, as well as quality control procedures to be implemented by laboratories.

Consistent with the evaluation of sampling and analysis methods in the FEA, under the Appendix (A.1), all samples taken to satisfy the monitoring requirements of this section must be

evaluated 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. OSHA has determined based on inter-laboratory comparisons that laboratory analysis by either X-ray diffraction (XRD) or infrared (IR) spectroscopy is required to ensure the accuracy of the monitoring results. The specified analytical methods are the XRD or IR methods for analysis of respirable crystalline silica that have been established by OSHA, NIOSH, or MSHA.

To ensure the accuracy of air sampling data relied on by employers to achieve compliance with the standard, the standard requires that employers must have air samples analyzed only at laboratories that meet requirements listed in A.2 through A.6.3. The requirements were developed based on recommendations for quality control procedures to improve agreement in analytical results obtained by laboratories (Eller et al., 1999, Document ID 1688, pp. 23-24). According to Dr. Rosa Key-Schwartz, NIOSH's expert in crystalline silica analysis, NIOSH worked closely with AIHA Laboratory Accreditation Programs to implement a silica emphasis program for site visitors who audit accredited laboratories to ensure that these quality control procedures are being followed (Document ID 3579, Tr. 153). As discussed in the FEA, analysis of recent data from the AIHA Proficiency Analytical Testing (PAT) program showed that laboratory performance has improved in recent years, resulting in greater agreement between labs, and this has been attributed to improvement in quality control procedures (Document ID 3998, Attachment 8; see also Section IV of the FEA).

A.2 requires employers to ensure that samples taken to monitor employee exposures are analyzed by a laboratory that is accredited to ANS/ISO/IEC Standard 17025 "General

requirements for the competence of testing and calibration laboratories" (EN ISO/IEC 17025:2005) by an accrediting organization that can demonstrate compliance with the requirements of ISO/IEC 17011 "Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies" (EN ISO/IEC 17011:2004). ANS/ISO/IEC 17025 is a consensus standard that was developed by the International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) and approved by the American Society for Testing and Materials (ASTM). This standard establishes criteria by which laboratories can demonstrate proficiency in conducting laboratory analysis through the implementation of quality control measures. To demonstrate competence, laboratories must implement a quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error (SAE) when reporting samples. ISO/IEC 17011 establishes criteria for organizations that accredit laboratories under ISO/IEC 17025. For example, the AIHA accredits laboratories for proficiency in the analysis of crystalline silica using criteria based on the ISO 17025 and other criteria appropriate for the scope of the accreditation.

Appendix A.3-A.6.3 contain additional quality control procedures for laboratories that have been demonstrated to improve accuracy and reliability through inter-laboratory comparisons. The proposed rule would have required that laboratories participate in a round robin testing program with at least two other independent laboratories at least every six months. OSHA deleted this requirement in the final rule since accredited laboratories must participate in the AIHA PAT program. The laboratory must use the most current National Institute of

Standards and Technology (NIST) or NIST-traceable standards for instrument calibration or instrument calibration verification (Appendix A.3). The laboratory must have an internal quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error (Appendix A.4). The laboratory must characterize the sample material by identifying polymorphs of respirable crystalline silica present, identifying the presence of any interfering compounds that might affect the analysis, and making the corrections necessary in order to obtain accurate sample analysis (Appendix A.5). The laboratory must analyze quantitatively for respirable crystalline silica only after confirming that the sample matrix is free of uncorrectable analytical interferences, and corrects for analytical interferences (Appendix A.6). The laboratory must perform routine calibration checks with standards that bracket the sample concentrations using five or more calibration standard levels to prepare calibration curves, and use instruments optimized to obtain a quantitative limit of detection that represents a value no higher than 25 percent of the PEL (Appendix A.6.1 – A.6.3).

Several stakeholders commented that requiring employers to analyze samples for all polymorphs (e.g., quartz, cristobalite, tridymite) would be unnecessarily burdensome, especially where the employer knows that some polymorphs are not present in its operations (Document ID 2215, p. 9; 2291, p. 24; 2348, Attachment 1, pp. 33-34; 4213, p. 4; 3588, Tr. 3968). OSHA does not intend for A.5 to require analysis for all polymorphs for every sample. Employers can consult with their laboratories or industrial hygiene service providers to determine which polymorphs are likely to be present in a sample given the nature of the material and processes employed. For example, if a material used by an employer is known to contain only quartz, and

that material is not subjected to high temperatures, it is unlikely that cristobalite is present. Likewise, if prior sampling results failed to find cristobalite in airborne dust, there would be no need to analyze samples for cristobalite on a continuing basis. OSHA expects that laboratories and industrial hygiene service providers will be able to guide employers on the sample analyses necessary to ensure compliance with the rule without having to incur unnecessary analytical costs.

Appendix B

Non-mandatory Appendix B of the respirable crystalline silica rule contains medical surveillance guidelines to assist in complying with the medical surveillance provisions and provides other helpful recommendations and information. 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. In addition, this appendix is not intended to detract from any obligation that the rule imposes. American College of Occupational Medicine (ACOEM), National Institute for Occupational Safety and Health (NIOSH), American Public Health Association, and the National Consumers League supported the inclusion of a non-mandatory appendix for medical surveillance guidelines (Document ID 2080, p. 2; 2177, Attachment B, p. 41; 2178, Attachment 1, p. 4; 2373, p. 4).

The medical surveillance guidelines were in Appendix A of the proposal but were moved to Appendix B of the rule, following the addition of a mandatory Appendix A for sampling and analysis. OSHA received some comments recommending corrections or clarifications to Appendix B. For example, NIOSH and the National Industrial Sand Association requested that

OSHA update the discussion of digital radiography to include the most recent International Labour Office policy, as was done in the preamble, and NIOSH suggested several clarifications to the discussions on silicosis, specialists and specialist referrals, and tuberculosis (Document ID 2177, Attachment B, pp. 41, 48-50; 2195, pp. 44, 46). OSHA considered those comments and made changes as needed. In addition, OSHA revised Appendix B to make it consistent with the updates to the rule.

American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) requested that the appendix discuss medical confidentiality and provide guidance on information that may be provided to the employer without the employee's informed consent (Document ID 4204, p. 90). OSHA agrees that it is important to discuss this type of information in Appendix B because the information that the physician or licensed health care professional (PLHCP) is to provide to the employer under this rule has changed substantially from the proposal, and Appendix B may serve as the PLHCP's primary source of information about medical surveillance under the rule. Therefore OSHA has included a discussion on medical confidentiality. In addition, OSHA has included examples of the PLHCP's written medical report for the employee, the PLHCP's written medical opinion for the employer, and an authorization form to allow limitations on respirable crystalline silica exposure or recommendations for a specialist examination to be reported to the employer. OSHA expects the example report, opinion, and authorization form will greatly clarify the type of information that is to be reported to the employer.

Some commenters requested that additional information be added to the appendix. ACOEM, NIOSH and Building and Construction Trades Department, AFL-CIO requested that the appendix include spirometry guidelines or reference values (Document ID 2080, p. 9; 2177, Attachment B, pp. 45-46; 4223, pp. 128-130). Collegium Ramazzini requested that the appendix include a standardized medical and exposure history (Document ID 3541, pp. 3, 6). AFL-CIO recommended that the appendix include a discussion on low dose computed tomography (LDCT) screening for lung cancer (Document ID, 4204, p. 82). OSHA is not including the information requested by these commenters in Appendix B for reasons discussed more fully in the summary and explanation for Medical Surveillance. OSHA is not including spirometry guidance because of the widespread availability of useful guidance, including an OSHA spirometry guidance available through OSHA's website. Instead of including a standardized medical and exposure history form, Appendix B includes a discussion of the information to be collected as part of a history that will allow PLHCPs to easily update their current history forms. Appendix B also does not include a discussion about LDCT screening for lung cancer because too little is currently known about the risks and benefits of such screening for employees exposed to respirable crystalline silica.