February 9, 2014

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

AB36-COMM-50-2

Re: Comments/Testimony of the National Industrial Sand Association on OSHA's Proposed Rule Regarding Occupational Exposure to Respirable Crystalline Silica -- Docket No. OSHA–2010–0034

Dear Sir or Madam:

The National Industrial Sand Association (NISA) presents these comments on OSHA's proposed rule regarding occupational exposure to crystalline silica.[1] NISA represents the major North American producers and processors of industrial sand.[2] The crystalline silica rulemaking is as significant as any initiative that OSHA has launched during this Administration, and NISA is pleased to offer a unique perspective on the issue and an optimal solution to the challenge facing OSHA.

NISA and four of its members belong to the American Chemistry Council's Crystalline Silica Panel (the Panel).[3] The Panel has filed comments separately in this docket that focus on the appropriateness of OSHA's proposed permissible exposure level (PEL). Those comments address issues of significant risk and issues of economic and technological feasibility (including feasibility of measurement). In brief, they show that OSHA has not established that a significant risk of material health impairment from crystalline silica exists at the current permissible exposure limit (PEL) of 100 $\mu g/m^3$, or that any such risk would be substantially reduced by a PEL of 50 $\mu g/m^3$. The Panel's comments also demonstrate that the proposed standard, with a PEL of 50 $\mu g/m^3$, is not

[1] 78 Fed. Reg. 56274 (Sept. 12, 2013).
[2] The list of NISA's member companies can be found at www.sand.org/NISA-members.
[3] Information about the Panel is available at http://www.americanchemistry.com/ProductsTechnology/Crystalline-Silica.

technologically or economically feasible. NISA supports and hereby adopts those comments, although we offer some additional comments below regarding the costs of exposure assessment.[4]

NISA and the International Diatomite Producers Association (IDPA) are both members of the International Minerals Association - North America (IMA-NA) – NISA is the sole member of the industrial sand section of IMA-NA, and IDPA is the sole member of the diatomite section of IMA-NA.[5] IDPA has also filed comments separately in this docket that focus primarily on the appropriate PEL and action level for cristobalite, the predominant polymorph of crystalline silica found in calcined (as opposed to natural) diatomaceous earth products. The comments commend OSHA for proposing to treat quartz and cristobalite alike for purposes of this rulemaking and, in particular, for setting the same PEL and action level for both quartz and cristobalite. As OSHA explains in the preamble to the proposal, and as further substantiated by the comments of IDPA and their consultant Kenneth A. Mundt, PhD, there is no basis in experimental toxicology or epidemiology to believe that the two polymorphs pose materially different health risks in the workplace or warrant differential treatment. To the contrary, all available evidence militates in favor of treating them alike – as OSHA has correctly proposed to do. NISA supports and hereby adopts those comments as well.

This document goes beyond the scope of the Panel's and IDPA's comments and focuses primarily on OSHA's proposed action level and ancillary provisions and their integration with the PEL. In sum, NISA strongly supports the "NISA Solution": a comprehensive standard, in the form of a variant of OSHA's Alternative #1: the current PEL of 100 $\mu g/m^3$ and an action level of 50 $\mu g/m^3$, with exposure monitoring and medical surveillance triggered by exposures *above the action level* (not the PEL).[6] NISA commends OSHA for offering Alternative #1 as its first alternative and for stating that it "will strongly consider alternatives that would reduce the economic impact of the rule."[7] As these comments demonstrate, this alternative would substantially reduce any risks of material health impairment from workplace exposure to crystalline silica arising from the persistently high level of noncompliance with the current PEL, and is economically and technologically feasible.

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[4] NISA also encourages OSHA to give careful consideration to comments of particular industry sectors regarding feasibility; e.g., the discussion of hydraulic fracturing contained in the comments of the American Petroleum Institute.

[5] Additional information regarding IMA-NA is available at http://www.ima-na.org/.

[6] Neither the preamble nor the preliminary economic analysis for the proposal expressly states when medical surveillance would be triggered under Alternative #1, but since OSHA assumes cost savings for medical surveillance under that alternative versus the proposed approach (of between $28-29 million – *see* Table SI-2, 78 Fed. Reg. 56279), NISA assumes that OSHA intends for medical surveillance under Alternative #1 to be triggered at the PEL of 100 $\mu g/m^3$. As explained above, NISA opposes that approach and instead advocates for medical surveillance *in any case* to be triggered at the action level.

[7] 78 Fed. Reg. 56284.

Following an Executive Summary, these comments provide more information about NISA and the Silicosis Prevention Program (SPP) that NISA members have voluntarily implemented for more than three decades. This includes the results of the SPP, as shown by some two decades of chest X-ray data collected by participating NISA member companies and shared among the membership. These data – presented publicly in this fashion for the first time – show that implementation of the NISA Solution has resulted in the elimination of new silicosis cases among participating NISA member company employees. Finally, we discuss an ongoing epidemiology study being conducted with dust measurements and chest X-ray data collected over almost four decades by NISA's two largest member companies. With that essential background, these comments then turn to OSHA's list of issues and respond to the relevant ones.

NISA has filed a notice of intention to appear at the hearing in this rulemaking currently scheduled for March 18. Given the sheer size and complexity of the proposed rule and the record thus far in this rulemaking, and OSHA's refusal to grant a full 90-day extension of the original comment deadline as requested by NISA and others, NISA is compelled also to designate these comments as NISA's testimony for the hearing. In the intervening days, NISA expects to develop a more concise oral statement for the hearing, but it will be based upon these comments.

Finally, these comments necessarily reflect only the current views of NISA with respect to the issues specifically identified by OSHA in its notice. NISA's views on those and other issues may evolve over time. These comments should not be interpreted as expressing any views on any broader issues not directly relevant to the rulemaking.

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The NISA Solution

NISA strongly supports the "NISA Solution": a comprehensive standard, in the form of a variant of OSHA's Alternative #1: the current PEL of 100 μg/m^3 and an action level of 50 μg/m^3, with exposure monitoring and medical surveillance triggered by exposures *above the action level* (not the PEL).

As documented by the comments of the American Chemistry Council's Crystalline Silica Panel (the Panel), OSHA has not established that a significant risk of material health impairment from crystalline silica exists at the current permissible exposure limit (PEL) of 100 μg/m^3, or that any such risk would be substantially reduced by a PEL of 50 μg/m^3. The Panel's comments also demonstrate that the proposed standard, with a PEL 50 μg/m^3, is not technologically or economically feasible.

By contrast, the NISA Solution would substantially reduce any risks of material health impairment from workplace exposure to crystalline silica arising from the persistently high level of noncompliance with the current PEL, and is economically and technologically feasible.

NISA expects all its member companies to implement and manage a comprehensive Silicosis Prevention Program (SPP) – including exposure monitoring and medical surveillance – at all worksites sufficient to eliminate silicosis among its employees. NISA's own data, drawn from 11 NISA members over a period of 19 years, show that implementation of the SPP by those companies has eliminated the creation of new silicosis cases among those companies' employees. This experience demonstrates that the current PEL is adequate to substantially reduce significant risk of material health impairment from silicosis sufficient to meet the requirements of Section 6(b) of OSH Act if supported by the proposed ancillary provisions, triggered by an action level of 50 μg/m^3, and if the current PEL is strictly complied with.

The Need for Exposure Monitoring and Medical Surveillance, Triggered by a 50 μg/m3 Action Level

OSHA frankly acknowledges that noncompliance with current PEL within general industry has stubbornly remained at roughly 30%. This great degree and extent of noncompliance may be substantially or largely to blame for the continued observed incidence of silicosis and other silica-related health effects. OSHA really has no basis to say that the 100 μg/m^3 PEL is not protective for general industry given the likelihood that one-third of all workplaces exposures are actually in excess of the PEL.

The most likely cause of such sustained, significant noncompliance is that, in the absence of any requirement to do exposure monitoring, many employers have no idea what the levels of RCS are in their workplaces. Personal dust sampling of employees is thus key to ensuring compliance with any PEL. Medical surveillance is needed as well. NISA therefore supports

OSHA's proposed inclusion of these ancillary provisions as part of a comprehensive crystalline silica standard.

Value of an Action Level

NISA strongly supports the inclusion of an action level in the crystalline silica rulemaking. In the absence of an action level, employers have to comply with all requirements of a standard no matter what level of exposure they achieve. On the other hand, if staying below the action level frees an employer from having to comply with the rule at all, the employer has a powerful economic incentive to do so. After 17 years of intensive OSHA focus on crystalline silica, it would be a tragic missed opportunity if the rule were to fail to incorporate an action level coupled with appropriate ancillary provisions.

Exposure monitoring

Given the great variability that can occur in crystalline silica exposures, in order to maintain individual employees' exposures below the PEL, it is necessary to monitor those exposures at an action level. Monitoring only when exposures are expected to be at the PEL or higher would substantially defeat the purpose of such monitoring.

OSHA's economic analysis assumes that employers will use outside contractors to conduct initial and periodic exposure assessments. NISA members have all found that it is more cost-effective for them to conduct exposure assessments in-house. We urge OSHA to analyze scenarios in which some percentage of regulated establishments do their own exposure assessments. To facilitate that exercise, NISA has supplied cost data from five of its member companies.

Medical surveillance

NISA supports OSHA's proposal for medical surveillance, with the proviso that it be required for all employees likely to be exposed above the recommended 50 $\mu g/m^3$ action level, not the PEL. NISA's medical surveillance program is more demanding, but we can support the proposed medical surveillance requirements as an appropriate regulatory mandate.

Other Ancillary Provisions

Recordkeeping

NISA believes the proposed recordkeeping requirements have utility and are not unduly burdensome.

Hazard Communication

NISA supports the hazard communication elements of the proposed standard.

Training

NISA supports OSHA's proposed training requirements. The generic training elements of the Hazard Communication Standard alone are insufficient.

Other Issues

Applicability/scope

If OSHA retains its proposed approach of having crystalline silica concentrations of 0.1% trigger the hazard communication provisions of the rule then NISA can support a rule that an employer can rely on a safety data sheet that does not list crystalline silica and assume that it is not covered by the rule. NISA would oppose a framework under which the crystalline silica standard only applied to materials containing 1.0% crystalline silica, but the Hazard Communication Standard applied to any materials containing 0.1% crystalline silica.

NISA supports OSHA's proposal to allow an employer to rely on objective data in lieu of initial air monitoring. If crystalline silica must be listed on an SDS at a concentration of 0.1% or greater, and an SDS does not list crystalline silica as a constituent in a material, no calculations should be required to substantiate a conclusion that a PEL will not be exceeded. The definition of "objective data" should more generally authorize competent persons to make judgments about the possibility of a PEL being exceeded.

NISA strongly supports exempting facilities in general industry from engineering and work practice control requirements for exposures lasting less than 30 days, provided employees are required to use PPE. This exemption has enormous potential to reduce the compliance costs of any crystalline silica standard without any reduction in employee health benefits.

Contaminated clothing

NISA does not support OSHA's proposed trigger for requirements regarding contaminated clothing, which it finds to be too vague and subjective, even as explained at 78 Fed. Reg. 56451. NISA would support these requirements being triggered in cases where contaminated clothing can be shown to be the cause of exceedences of the PEL.

Prohibition on rotation

NISA opposes this prohibition, which flies in the face of long-standing, widely-accepted industrial hygiene practice. Regardless of how silica-related illnesses are caused, rotation helps protect against them.

Medical removal protection

NISA agrees with OSHA that medical removal protection is inappropriate for this rulemaking because "respirable crystalline silica-related health effects (e.g., silicosis) are generally chronic conditions that are not remedied by temporary removal from exposure."

Compliance date

OSHA should give regulated entities at least three years to install engineering controls. Bringing a facility into compliance with a PEL can be a major operation involving multiple outside industrial hygiene, engineering, architectural, and construction firms, and can easily take multiple years – especially since the work has to be retrofitted onto currently-operating processes.

OSHA should not be greatly concerned about the length of time allowed for compliance, since, under proposed paragraph (g)(1)(i), employers would be required to provide respiratory protection in areas where exposures exceed the PEL while engineering controls are being installed and validated.

OSHA Should Reopen the Docket When NISA Completes Its Ongoing Silica Study

NISA has commissioned a case-control radiology study, conducted by world-class scientists, to reduce the considerable uncertainty regarding the dose/response relationship of silica exposure and silicosis. The exposure data include about 50,000 dust measurements collected systematically since the mid-1970s, with personal identifiers that will facilitate construction of a job-time-exposure matrix. The chest X-ray data similarly encompasses thousands of chest x-rays, generally taken at the beginning of the individual's employment in the industrial sand industry and every two years thereafter. For most of them, the database includes more than 10 chest X-rays for each. We strongly urge OSHA to defer finalizing this rulemaking until it and others can have an opportunity to review the report of the study.

I. NISA and the NISA Solution

A. NISA and Its Interest in this Rulemaking

NISA is a nonprofit 501(c)(6) trade association representing the major North American producers and processors of industrial sand (sometimes called silica sand). Founded in 1936, NISA is committed to advancing research and maintaining a dialogue with industry, legislators, regulatory agencies and the scientific community with respect to issues of concern to the industrial sand industry, including the potential health effects associated with the inhalation of respirable crystalline silica. NISA currently has 31 member companies and is the oldest and largest trade association representing the industrial sand industry in the United States and Canada.[8]

As predominantly mining operations, NISA members' workplaces are typically regulated by MSHA, not OSHA, for purposes of occupational safety & health. (A few NISA member company workplaces are regulated by OSHA; *see* NISA's response to Issue #8, below.) NISA has a substantial stake in the outcome of the OSHA crystalline silica rulemaking, however, for several reasons:

1. Because OSHA is proceeding first, is a sister agency within the Department of Labor, and has substantially greater resources to devote to this project than does MSHA, it is likely that MSHA, in its own upcoming rulemaking on crystalline silica, will give great deference to OSHA's conclusions, both proposed and (especially) final.

2. NISA member companies have a substantial business interest in the financial well-being of our customers, who are OSHA regulated. A standard that is more costly than is necessary to reduce significant risks,[9] or that is infeasible, could subject our customers to significant economic hardship, some proportion of which would likely translate into reduced revenues for NISA members.

3. Most important, NISA members strongly believe that the exposure monitoring and medical surveillance that they implement under the NISA Silicosis Prevention Program are the right thing to do to protect the health of their employees and are good for their businesses' bottom line. They also believe that personal dust sampling of employees is the key to ensuring compliance with any PEL for crystalline silica, and that the absence of an exposure assessment requirement from the current crystalline silica PEL is the principal reason for the persistently high rates of noncompliance with the current PEL that OSHA continues to witness despite years of focused enforcement. NISA therefore

[8] *See* footnote 2 above.
[9] *Cf.* 29 U.S.C. § 652(8) (workplace safety and health standards must be "reasonably necessary and appropriate to provide safe or healthful employment"); Industrial Union Dep't, AFL-CIO v. API, 448 U.S. 607, 614-15, 639, 642 (1980). A standard that goes beyond what is necessary to eliminate significant risk is not authorized by the statute.

supports OSHA's proposed inclusion of exposure monitoring and medical surveillance as part of a comprehensive crystalline silica standard.

For all these reasons, NISA members have a vital interest in the outcome of this OSHA rulemaking.

B. The NISA Silicosis Prevention Program

1. Origin of the Silicosis Prevention Program

Industrial sand companies produce essentially 100% pure crystalline silica. As a result, NISA members have one of the longest histories of working with silica, and more direct contact with silica, than anyone else in industry. It is also why, beginning in the late 1970s, NISA and its member companies worked with occupational health experts to establish an Occupational Health Program for Exposure to Crystalline Silica in the Industrial Sand Industry (OHP), a voluntary program of employee exposure assessment and medical surveillance.

In 1993, the NISA Board of Directors adopted the goal of preventing any "new" cases of silicosis among their employees – with "new" defined as cases of silicosis produced by exposures at NISA member company workplaces commencing in 1994.[10] As a result of this decision, and influenced by the widespread establishment of management systems approaches, NISA and its members subsequently incorporated the OHP into a broader Silicosis Prevention Program (SPP). We discuss these two programs in reverse order below.

2. Elements of the Silicosis Prevention Program

The scope and elements of the SPP are set out in a guide entitled *National Industrial Sand Association Silicosis Prevention Program*.[11] The SPP declares that "NISA expects all member companies to implement and manage a comprehensive Silicosis Prevention Program at all worksites sufficient to eliminate silicosis among its employees."[12] As it describes, such a program

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[10] This definition of "new" recognized that some number of NISA member company employees might have had silicosis at that time, or might subsequently develop it, based on exposures occurring (i) before that date, whether at NISA member companies or elsewhere; or (ii) after that date, but before employment at a NISA member company.

[11] This document is available at http://www.sand.org/nisa/files/ccLibraryFiles/Filename/000000000027/%20SPP.pdf. A pdf copy is attached as Appendix A. NISA uses the term "Silicosis Prevention Program" to refer to both this document and the program that NISA member companies implement pursuant to it.

[12] *Id*. at 4. As with any voluntary industry self-regulatory program, membership uptake of the SPP has not been instantaneous. Currently, 15 of NISA's 31 member companies have formally committed to the SPP. On December 19, 2013, NISA's Board approved an amendment to the NISA Bylaws that would make commitment to, and implementation of, the SPP conditions of membership. This change will be submitted to the NISA membership for a vote in May 2014.

comprises seven steps:

1. *Strong management commitment to implement a silicosis prevention program.* This commitment includes not only a commitment to performing both dust exposure assessment and medical surveillance, but to sharing data on both dust measurements and chest X-ray results with other NISA member companies at annual benchmarking sessions.

2. *Implementation of the OHP*. The OHP prescribes in great detail how dust monitoring and medical surveillance are to be conducted by NISA members. (The next section of these comments summarizes the OHP.)

3. *Periodic assessments of the amount of workers' exposure to silica dust.* The SPP states: "It is crucial that NISA member companies implement and manage a silica exposure program to collect personal breathing samples from all employees exposed to industrial sand so that periodic measurements of silica exposure and cumulative exposure assessments can be made."[13]

4. *Routine medical surveillance to assess worker health and to look for indications of silica-related health effects.* The SPP explains that medical surveillance serves multiple purposes:
    a. Establishing a baseline for future measurements (so that each employee serves as his or her own control);
    b. Detecting abnormalities that might be consistent with the health effects of silica exposure at an early stage, when intervention can lead to the prevention of disease progression;
    c. Preventing the development of silicosis that could produce pulmonary impairment in the worker;
    d. Preventing the development of other occupational conditions that might be associated with exposure to silica;
    e. Disclosing to the worker occupationally and non-occupationally related abnormalities for appropriate medical follow-up; and
    f. Developing data on which epidemiological studies of crystalline silica exposure can be based.

5. *Implementation of dust control equipment or processes.* The SPP requires NISA member

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The fact that not all NISA members currently participate in all aspects of the SPP is not relevant to these comments, however. The point of the comments is not how successful NISA has been in spurring implementation of the SPP across its entire membership, but rather how successful the companies that *have* implemented it have been in preventing new cases of silicosis in their workplaces.

[13] *Id*. at 11-12.

companies to undertake a program to anticipate, recognize, evaluate and control hazardous dust exposures and to continually monitor the effectiveness of control strategies. It emphasizes that "[t]he control of hazards from exposures to respirable crystalline silica and the elimination of silicosis is the primary and single most important reason for developing a comprehensive silicosis prevention program."[14]

6. *Employee involvement in all stages of SPP implementation.* The SPP recognizes that "[a] workforce fully involved in health and safety management, and a system of workers operating in partnership with management, are essential parts of an effective health and safety program."[15] It describes steps for promoting employee engagement and provides example actions management can take.

7. *Smoking cessation programs*. The principal goal of such programs is to reduce the added impact of smoking on silica-related health effects, but a related goal is to diminish the serious adverse health effects that are directly caused by smoking and by second-hand smoke.

3. Occupational Health Program

The historic core of the NISA SPP, the OHP builds out Steps 3 and 4 of the SSP by "providing mechanisms by which individual NISA member companies can properly and systematically monitor the environmental aspects of dust exposures at their operations and the respiratory health status of employees."[16] The OHP Manual – the current description of the program – begins with an overview of the state of the science regarding the range of potential health effects of silica exposure. It then provides detailed guidance on both dust sampling and medical surveillance:

- *Dust sampling.* The goal of this section is to provide sufficient detail, in sufficiently clear terms, that "a safety officer, laboratory technician, quality control analyst, or any person within a company who has responsibility for the industrial hygiene program [can] collect sufficient personal breathing zone samples from all employees exposed to industrial sand so that cumulative individual exposure assessments can be made."[17]
- *Medical surveillance*. This section provides guidance for both baseline and periodic medical surveillance of employees. While it is principally intended for health professionals, it is also written for any member company employee with responsibility for a safety and health program, since such individuals should have a working knowledge

[14] *Id*. at 12.
[15] *Id*. at 13.
[16] *Occupational Health Program for Exposure to Crystalline Silica in the Industrial Sand Industry* (2d ed. 2010) (OHP Manual) at 12. The OHP Manual is available at https://www.hightail.com/dl?phi_action=app/orchestrateDownload&rurl=https%3A%2F%2Fwww.hightail.com%2Ftransfer.php%3Faction%3Dbatch_download%26batch_id%3DcnJnYUo5WkI1R05jR0E9PQ. A pdf copy is attached as Appendix B.
[17] *Id*. at 12-13, 35-36.

of the elements of the medical surveillance program. NISA's responses to Issues #69-80 below present the elements of this section in great detail.

Multiple citations to the OHP Manual in the preamble confirm the obvious fact that OSHA's proposed medical surveillance requirements are substantially derived from NISA's OHP Manual.[18] NISA is proud of these references and appreciates being able to provide a model for such an important element of silica workplace health. It is also obvious from the same preambular discussions that OSHA's proposed requirements are in several respects less comprehensive and less demanding than the OHP Manual. (These differences are discussed at greater length in response to Issues ##69-70.)

4. Member Company Annual Reporting

As noted above, part of the management commitment that is Step 1 of the SPP is a commitment to sharing data on both dust measurements and chest X-ray results with other NISA member companies at annual benchmarking sessions. Prompted by the 1993 Board meeting that gave rise to the SPP, these annual sessions have occurred every year since 1994. The sessions are held in September, in connection with the NISA Annual Meeting. By August 1 of each year, participating NISA members report employee personal dust sampling and chest X-ray data for the previous year to NISA staff. That information is compiled and presented on a blinded basis to the membership.

- Dust measurements are presented as total measurements, average percent quartz and average exposure (as a percentage of the PEL) for ten different operations (e.g., mining, bagging, administrative), and company-wide.
- Chest X-ray data are presented as number of individuals with chest X-rays classified (generally by more than one certified B-reader) as ≥1/1 on the ILO scale.
- Summary slides are also presented for each category of data.

These presentations allow the membership to evaluate how they are doing, individually and collectively, at controlling exposures and eliminating new cases of silicosis.

5. The Silicosis Prevention Program Solution Has Eliminated New Cases of Silicosis at Participating NISA Member Companies

As just explained, since 1994, NISA has tracked the number of individuals at participating member companies with chest X-rays classified (generally by more than one certified B-reader) as ≥1/1 on the ILO scale. This data has been reported for 11 companies. Over this 19-year period, medical surveillance at these eleven companies has yielded eight cases with radiographic evidence of silicosis meeting that standard, occurring at three companies. Those companies advise NISA that they do not regard these as "new" cases – meaning that, in each case, the company judges that the silicosis was attributable to exposures occurring (i) before 1994, either at that company or elsewhere; or (ii) after that date, but before employment at the

[18] *See, e.g.*, 78 Fed. Reg. 56294, 56469-71.

company. (Several NISA members have grown substantially by acquisition.) Accordingly, NISA's own data show that implementation of the SPP by participating companies has eliminated the creation of new silicosis cases among those companies' employees.[19]

NISA draws two key lessons from this experience:

- *First, there is a huge disparity between the observed incidence of silicosis at participating NISA member companies and the amount that one would have predicted to occur at a PEL based on the silicosis portion of OSHA's quantitative risk assessment (QRA). Admittedly, the QRA's silicosis risk estimate (between 2-77% of employees)[20] is based on a 45-year working life exposure at 100 μg/m^3, while the average NISA member's employee's tenure is much shorter, his or her exposures have averaged far less, and NISA members do not conduct post-employment medical surveillance. Even adjusted to match NISA's circumstances, however, OSHA's QRA would doubtless predict many new cases of silicosis – not none. NISA believes that its data is more reliable, and more probative, than the underlying studies that OSHA has used as inputs to the model it that produced its morbidity estimates. Our experience shows that, as the Panel's comments argue, OSHA's modeling exercise is overly conservative and too heavily skewed by uncertainty, principally as regards exposure estimation.*[21]
- *Second, eleven NISA members over a period of 19 years have found only eight cases of silicosis, none new, while operating under the current PEL of 100 μg/m^3. This experience demonstrates that the NISA Solution – OSHA's Alternative #1, with exposure assessment and medical surveillance triggered at the action level rather than the PEL – reduces significant risk of material health impairment from silicosis sufficient to meet the requirements of Section 6(b) of the OSH Act.*[22]

C. Ongoing NISA Silica/Silicosis Dose/Response Study

While the association between silicosis and exposure to respirable crystalline silica has long been recognized and is indisputable, there is still considerable uncertainty regarding the

[19] NISA recognizes that there is an inherent degree of art or subjectivity among interpretation of chest X-rays for evidence of silicosis, and hence use of other or additional B-readers over the years at the 11 participating companies might have produced somewhat more or fewer diagnoses. Such variance may well be produced by the re-review of two companies' chest X-ray data databases as part of the silica study discussed in the next part of these comments. However, NISA would expect such variance to be a matter of degree, and not the sort of exponential difference that would be required to undermine the basic conclusions stated in italics immediately below.

[20] *See* 78 Fed. Reg. 56319

[21] Part II of the Panel's comments documents in exhaustive detail these shortcomings of OSHA's QRA. *See also* Part I.C of these comments, immediately below.

[22] NISA is aware that OSHA justifies the proposed rule on the basis of health effects beyond silicosis. Part II of the Panel's comments, which NISA adopts, explains why these asserted health effects do not give rise to a significant risk of material health impairment.

dose/response relationship of this association, particularly in the case of chronic simple silicosis, by far the most common form. It is unclear, for example, whether there is an effect threshold, or whether instead the dose/response curve is linear at even the lowest doses. The slope of that curve is also uncertain. As a result, there is uncertainty regarding the degree of risk remaining at various 8-hour time-weighted average exposures, including, most importantly, the current PEL of 100 $\mu g/m^3$.

In NISA's view, this degree of uncertainty is unacceptable for a rulemaking of this magnitude. NISA believes that regulatory standard-setting ought to be based on high-quality, reliable science. That is especially true where data of sufficient quality and quantity exist to produce that science.

The principal shortcoming affecting all published studies of silicosis risk – and hence undermining the reliability of resulting quantitative risk estimates, including OSHA's – is their reliance on poor-quality and uncertain exposure measurements. Many were based on very high exposures to quartz, and lack data on low exposures – so that estimated dose/response conclusions have to be extrapolated to low doses.[23] Others lack data for early exposure years, and so early exposures are based on inferred or extrapolated concentrations.[24] Others are based on area sampling rather than personal sampling.[25] Even those that include personal dust sampling of individuals generally involve measurements taken using the obsolete particle count approach for all or part of the period evaluated.[26] This latter defect is a serious limitation, because it has become increasingly clear that there is no single, defensible conversion factor

[23] *E.g.*, Buchanan et al. (2003), Miller et al. (1995, 1998); *see* 78 Fed. Reg. 56318 (miners "experienced 'unusually high concentrations of freshly cut quartz in mixed coalmine dust.'"); *see also* Park et al. (2002) (mean respirable crystalline silica exposure in the diatomaceous earth worker cohort was 0.29 mg/m^3). (Unless otherwise noted, references in these comments to studies are to those listed in the NPRM at 78 Fed. Reg. 56476-56486.)

[24] *E.g.*, Park et al. (2002); Steenland et al. (2001); Kreiss and Zhen (1996). The latter study assumed (counter to the general trend of improved industrial hygiene over the years) that the exposures prior to when dust measurements began were identical to exposures after dust measurements began. Thus, if there had been an improving hygiene trend regarding exposure, the authors seriously underestimated pre-dust monitoring exposures, resulting in a serious overestimate of disease at a specified exposure level. Attfield & Costello (2004) assumed particularly low exposures for sandblasters (0.06 mg/m^3 prior to 1940, 0.05 mg/m^3 from 1940-1950, and 0.04 mg/m^3 after 1950), even though OSHA estimates that more than 57% of abrasive blasters in the cut stone industry are currently exposed above 0.05 mg/m^3, while 43% are exposed above 0.10 mg/m^3, and 28.6% are exposed above 0.25 mg/m^3. *See* OSHA's Preliminary Economic Analysis at III-51, Table III-5.

[25] *E.g.*, Chen et al. (2001).

[26] *See* Peer Review Comments of Kenny Krump, Silica Docket Item OSHA-2010-0034-1716, p. 162. Hnizdo and Sluis-Cremer (1993) suffers from this problem, for example. *See* Preliminary QRA at 308.

from particle count measurements to gravimetric measurements.[27] For example, the simple principles of geometry demonstrate that one dust particle with a diameter of four micrometers has the same mass as eight similarly-shaped dust particles that each have a diameter of two micrometers, so the use of a single number to convert particle count to gravimetric mass can be subject to an enormous error. No published study involves decades of dust data collected rigorously and consistently via personal samplers and evaluated gravimetrically, with percentage quartz assessed with X-ray diffraction (XRD).

On the other hand, NISA's two largest member companies possess an extensive database comprising decades of gravimetric dust sampling and chest X-ray data generated by those companies' implementation of the SPP. The exposure data include about 50,000 dust measurements collected systematically since the mid-1970s, with personal identifiers that will facilitate construction of a job-time-exposure matrix. Exposure samples encompass a large number of job codes with low to high quartz concentrations, which should ensure a wide range of exposures for analyses of exposure/response. Measurements are all reported gravimetrically, with quartz analysis by XRD. The chest X-ray data similarly encompasses thousands of chest x-rays, generally taken at the beginning of the individual's employment in the industrial sand industry and every two years thereafter. For most of them, the database includes more than 10 chest X-rays for each.

Given the quality and quantity of this data, and the importance of having a more reliable dose/response function for crystalline silica, NISA has commissioned a case-control radiology study, conducted by world-class scientists, to compare the silica exposures of an exposed cohort of employees with radiographic evidence of silicosis (as identified by a panel of three radiologists) to the silica exposures of three times as many matched controls without radiographic evidence of silicosis. Roughly 1,670 employees and former employees from 14

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[27] Rando, R.J., "Estimates of Exposure to Crystalline Silica in Epidemiological Investigations of Industrial Sand Production Workers: Critical Review and Comparison of the Papers by Rando, et al. and Sanderson, et al." (July 24, 2004)(attached to the comments filed by the Panel). Rather, it appears that the conversion factor depends on the average particle size in samples taken at particular operations. *Id*. Indeed, OSHA itself recognizes that the range of negative and positive associations of silicosis (and other health effects) with particular calculated concentrations of respirable silica that one finds in the literature may in large measure reflect the degree of error one way or the other in the conversion factor used:

> It may also be that exposure estimates for some cohorts were subject to systematic misclassification errors resulting in under- or over-estimation of exposures due to the use of assumptions and conversion factors that were necessary to estimate mass respirable crystalline silica concentrations from exposure samples analyzed as particle counts or total and respirable dust mass.

78 Fed. Reg. at 56330. Complicating matters, few individuals with expertise in counting under the old methods remain alive to comment on the issue.

plants in 10 states fit the criteria for inclusion in the study (at least 10 years of employment, with a chest X-ray taken at least 10 years after commencement of employment), ensuring a robust study population. The study will assess:

- The relative risk of radiographic silicosis at cumulative and average exposures, and duration of exposure;
- The absolute risk of radiographic silicosis at average exposures of 0.05, 0.1 and 0.2 mg/m^3 over a working lifetime; and
- Factors associated with the progression of radiographic silicosis, in cases in which chest X-ray changes have occurred.

The research team contracted by NISA to conduct the study are highly-regarded experts affiliated with major universities, with significant academic credentials and publications, and experience with silica issues.[28] Their study employs a common, well-respected epidemiological study design. (The study protocol is attached as Appendix C). To help ensure that the study is viewed as objective and that the study's results are useful to government scientists, the research team submitted a draft of the protocol to seven reviewers selected by NIOSH.

NISA fully intends for the research team to work independently. The research team is charged to conduct the best study possible with the available data to advance understanding of the silica/silicosis dose-response issue. The grant agreement provides that "[t]he sponsor will be given sufficient time to review the draft study report and offer technical comment. However, the scientific conclusions and professional judgments arising out of performance of the study shall be the responsibility of the investigative team and shall not be subject to control by the sponsor." A parallel agreement with one of the institutions conducting the work also clarifies that "[t]he Sponsor and the Contractor agree to full disclosure of any scientific information developed in the performance of this Agreement."

The agreements with the research team require them to submit for publication an article based upon their report in the peer-reviewed medical literature. NISA anticipates that the research team will issue their final report sometime during the first quarter of 2015. While the record for this rulemaking will most likely have closed by that time, NISA intends to submit the report to the docket, and will request OSHA to publish a Federal Register notice reopening the record for some short period of time (NISA suggests 30 days) and requesting comment on the report.[29] (To minimize the effect on OSHA's timetable for issuing a final rule, we would expect OSHA to limit commenters to that single topic and not otherwise reopen the record.) As noted above, NISA does not know what the conclusion of this study will be, but we strongly believe that, upon release, it will be the strongest single work in the public domain on the issue of the

[28] Biosketches for the research team are presented at pp. 22-23 of the protocol attached as Appendix C.

[29] It is common practice for agencies to reopen rulemaking dockets and seek comment on specific issues when similarly significant data has become available. MSHA last year published such a request for information. *See, e.g.*, 78 Fed. Reg. 48592 (Aug. 8, 2013) (reopening the record in the refuge alternatives rulemaking at the suggestion of a federal judge).

silica/silicosis dose-response relationship. We strongly urge OSHA to defer finalizing this rulemaking until it and others can have an opportunity to review the report of the study.

II. OSHA Should Finalize Alternative #1 with Exposure Assessment and Medical Surveillance Triggered by Exposures Above the Action Level – Comments on Issues Identified by OSHA

As OSHA requests, NISA has organized its specific comments on the NPRM by reference to the numbered issues on pp. 56284-91:

- NISA adopts the comments submitted by the Panel with respect to issues involving the health effects of occupational exposure to crystalline silica, the existence of significant risk from those health effects at particular exposure levels, and the economic feasibility and technological feasibility of the proposed PEL (including both engineering and work practice controls and issues of measurement). We have added NISA-specific comments below on the costs of exposure assessment.
- The bulk of the following comments, therefore, focus on the issues of an action level and ancillary provisions, particularly exposure monitoring and medical surveillance. As those comments explain, NISA strongly supports the NISA Solution: a comprehensive standard, in the form of variant of OSHA's Alternative #1: the current PEL of 100 $\mu g/m^3$ and an action level of 50 $\mu g/m^3$, with exposure assessment and medical surveillance triggered by exposures above the action level (not the PEL).

Health Effects

1. *Are there any additional studies that would affect the information discussed or significantly change the determination of significant health impairment*?

NISA adopts the Panel's comments. Also, the findings of NISA's ongoing silica study may well affect OSHA's findings regarding the risk of silicosis at a PEL of 100 $\mu g/m^3$. As explained in Part II.C above, that study, when completed, will almost certainly represent the most authoritative conclusion regarding the dose/response relationship between respirable crystalline silica and silicosis. For that reason, OSHA should add it to the record upon its completion and publish a notice seeking comments on it.

2. *Are OSHA's risk determinations correct?*

NISA adopts the Panel's comments. Also, the findings of NISA's silica study may well affect OSHA's determination of significant risk at exposure concentrations of 100 and 50 $\mu g/m^3$.

Risk Assessment

3. *Is cumulative exposure the correct metric?*

NISA adopts the Panel's comments.

4. *Are silicosis and lung cancer risk non-linear at very high doses? Are there other models for identified risk?*

NISA adopts the Panel's comments.

5. *Should OSHA have included additional studies in its quantitative risk assessment?*

NISA adopts the Panel's comments; see also NISA's response to Issue #1 above.

6. *Quantitative risk assessments of lung cancer.*

NISA adopts the Panel's comments.

7. *Feasibility of conducting a quantitative risk assessment for autoimmune disease, stomach cancer, etc.*

NISA adopts the Panel's comments.

Profile of Affected Industries

8. *The profile of NISA member companies' worker populations*.

NISA members' facilities are principally engaged in mining or processing silica for industrial uses. As such, they are regulated for purposes of occupational safety and health by MSHA. A few NISA member facilities are regulated by OSHA. These are primarily (i) facilities where sand is resin-coated and (ii) transloading facilities (where the contents of railcars of sand originating from NISA member mines or processing plants are unloaded and transferred to trucks).

While most of the operations at most NISA member facilities do not occur at OSHA-regulated facilities (e.g., mining, crushing, drying), the essential workplace experiences and dynamics are the same as in an OSHA-regulated facility. Employees work in settings where they can be or are exposed to respirable crystalline silica (RCS), potentially well beyond the PEL in many cases. Indeed, because NISA members produce essentially 100% pure crystalline silica, high potential exposures to RCS are a fundamental and prominent feature of those workplaces, not an incidental hazard. Moreover, many NISA member company employees work at their workplaces for all or much of their worklives. In 2004, a study calculated the mean tenure for NISA member company employees fitting the definition of the study's cohort to be 19.7 years.[30]

[30] *See* McDonald et al. (2005). Cohort members were those who had worked at least three years at one of the nine study plants, including at least one month of employment during the period 1940-1979.

NISA member companies therefore addressed the health risks of those exposures long ago, and are leaders in the systematic management of RCS exposures in the workplace. Under the SPP, NISA member companies apply engineering and work practice controls to limit those exposures, and employ exposure monitoring and medical surveillance to assure that exposures are maintained at low levels and that any silica-related health effects are promptly detected. Accordingly, NISA is qualified to comment on the issues raised in this NPRM.

Technological and Economic Feasibility of the Proposed PEL

9. *Job categories.*

See response to Issue #8.

10. *Work environments or processes that expose workers to cristobalite*

C.E.D. Process Minerals, Inc., a NISA member company, manufactures cristobalite products from industrial sand using a proprietary, solid-state, high-heat process and further downstream processes. Some of these downstream processes can expose workers to cristobalite in manners not substantially different than the ways other NISA member companies' processes can expose workers to quartz. C.E.D. participates in NISA's SPP and, in its experience, that participation has eliminated any cases of silicosis in its cristobalite operation. C.E.D.'s experience also tends to indicate that both quartz and cristobalite are appropriately addressed through compliance with the same PEL, supplemented by exposure monitoring and medical surveillance.[31]

11. *Technological changes in your industry affecting magnitude, frequency and duration of RCS exposure in your industry*

As discussed in NISA's response to Issue #8, NISA members' industries are regulated by MSHA rather than OSHA. One similarity that is relevant to this question, however, is an inexorable trend toward automation of processes that historically were conducted manually. OSHA notes this "shift from manually operated to automated processes,"[32] but all the examples it cites give the impression that OSHA believes automation is principally a process whereby a single exposed worker is moved to an enclosure where he or she continues to do the same operation in relative isolation.[33] In fact, the shift to an automated process typically results in a net reduction of workers. It is virtually certain that a 50 $\mu g/m^3$ PEL would accelerate the trend toward automation significantly, with net adverse effects on employment levels. It does not appear that OSHA took this reality into account in its analysis of the employment effects of the proposed rule. It should do so for the final rule, however. It should also focus carefully on

[31] Leland Cole, Vice President and Director of C.E.D. was a member of the OSHA SBREFA panel that addressed OSHA's crystalline silica rulemaking a decade ago.
[32] *See* 78 Fed. Reg. 56453.
[33] *Id*. at 56453-44.

Alternative #1, which would retain the 100 μg/m^3 PEL but substantially reduce significant risk through operation of ancillary provisions – an approach that would not hasten automation and could potentially result in net job creation.

12. *Trends to reduce/eliminate RCS from your workplaces*

Not applicable, since NISA member company processes involve mining and processing silica sand.

13. *Outsourcing or contracting out high-RCS exposure positions*

The great preponderance of NISA member workplaces are staffed by member company employees. This includes cleaning baghouses, at companies that use them. The most significant use of contracting is at transloading facilities, which typically are owned but not operated by NISA member companies. As noted earlier, transloading facilities are OSHA-regulated. The only major function frequently performed by contractors at many NISA member company sites is the removal of overburden (i.e., the layer of earth material lying over the geological layer of industrial sand).

14. *Job categories or exposures with RCS exposures not adequately captured by air monitoring data*

As discussed in Part I.B.4 above, NISA members annually report employee exposure and chest X-ray data to NISA staff and that information is compiled and presented on a blinded basis to the membership. These presentations sometimes note that some companies should consider taking a greater number of dust samples each year to adequately assess employee exposures.

15. *Engineering/work practice controls in your industry*

Except for questions g and h, this issue is not applicable to NISA, since most NISA member company processes involve mining and processing sand and are not OSHA-regulated.

g/h. *What amount of time is needed to develop, install, and implement these additional controls? Are there any processes or operations for which it is not reasonably possible to implement engineering and work practice controls within one year to achieve the proposed PEL? If so much additional time would be necessary?*

NISA supports retention of the existing 100 μg/m^3 PEL. Currently regulated plants therefore should not need to install any additional engineering controls – although, given OSHA's robust observations of roughly 30% noncompliance, NISA expects that there are many facilities outside its membership that will have to install controls in order to comply even with the existing PEL.

If OSHA lowers the PEL as proposed, one year is not enough time for OSHA-regulated activities to install engineering controls. Implementing controls involves conducting sufficient dust monitoring to properly characterize the dust and the locations/jobs affected; determining which jobs present or may present overexposures; conducting detective work to determine the sources of dust; designing an engineered dust control system; building it; commissioning it; and optimizing its performance. As NISA members have learned from bringing into compliance facilities that they have acquired, this can be a major operation involving multiple outside industrial hygiene, engineering, architectural, and construction firms, and can easily take multiple years – especially since the work has to be retrofitted onto currently-operating processes. Even three years can be a tight timeframe to do all this work in some complex circumstances. As a result, OSHA should give regulated entities at least three years to install engineering controls.

OSHA should not be greatly concerned about the length of time allowed for compliance, since, under proposed paragraph (g)(1)(i), employers would be required to provide respiratory protection in areas where exposures exceed the PEL while engineering controls are being installed and validated.

16. *Any specific job conditions/tasks where it is not reasonably possible to meet the proposed PEL within one year?*

NISA has no comments on this issue at this time.

17. *Reasonableness of OSHA's findings re ability to meet 50 μg/m^3 most of the time through E/WPCs; technological feasibility*

NISA adopts the Panel's comments.

Compliance Costs

18. *Comment on methodological and analytical assumptions in OSHA's cost analysis, especially unit cost estimates*

NISA generally adopts the Panel's comments regarding OSHA's cost analysis, although we offer some qualifying comments regarding exposure assessment.

In its cost analysis, OSHA assumes that employers will use outside contractors to conduct initial and periodic exposure assessments. The Panel's comments adopt that approach, but then conclude that OSHA has underestimated the costs of such exposure assessments.

NISA's member companies all conduct exposure assessments using in-house personnel. We recognize that it is unclear to what extent the industries covered by OSHA's proposed standard for general industry will adopt that approach versus using contractors. Clearly, activities involving potential crystalline silica exposures are absolutely central to what NISA

members do, whereas such activities may be more or less tangential for other regulated industries. Also, NISA members have been doing exposure assessment under the SPP since the 1970s, so they have developed substantial expertise in how to do so cost-effectively.

Nonetheless, we believe that some substantial percentage of OSHA-regulated establishments will internalize the function, either at the outset of the rule's effectiveness or as they gather experience under the rule. We do not believe the issue is purely one of business or establishment size; many NISA member companies are small businesses. They have nonetheless found that it is more cost-effective for them to train particular staff, and acquire the relevant equipment, so as to be able to conduct exposure assessments in-house.

We urge OSHA to analyze scenarios in which some percentage of regulated establishments do their own exposure assessments. To facilitate that exercise, NISA has gathered cost data from five of its member companies. Three of these companies are among the largest NISA members (on a revenue basis); another meets the SBA's size standard for a small business.

Perhaps the most telling fact about these companies' cost experience is that even the two largest companies, one of which is publicly-held, regard these costs as sufficiently minor that the companies, which rigorously track all elements of their operating costs, do not bother to track the employee costs associated with dust exposure monitoring.

While NISA's member companies do not track all their ongoing costs of exposure monitoring, they have been able to estimate them according to a common format that takes into account both direct costs and an allocated share of indirect or overhead costs. The ranges of those costs are reflected in the table contained on the following page. NISA believes the relative narrowness of the ranges supports their reliability. We also note that the value used by the Panel's consultant for per-sample analytical costs is close to the top of the range of NISA's experience – so that we do not regard our unit cost estimates and the Panel's to be significantly divergent. The issue is not unit costs per se, but whether establishments will incur them directly or hire consultants who do.

Costs Experienced by Five NISA Member Companies for Exposure Assessment

# of samples annually – 30 - 517
Analytical costs
Per sample - $49 - $129
Total $3,870 - $25,333

Equipment costs
Sampling pump - $900 - $1,000
Electronic calibrator - $1,100 - $1,500
Tygon tubing - $32 - $48
Cyclone - $100 - $270
Average life of equipment – 8-10 years
Total annual equipment costs - $255 - $280

Indirect Costs
Sampler
Hourly rate - $25 - $62
Hours invested per sample – 1, 2 hours
Sampler cost per sample - $50 - $68

Corporate IH management
Hourly rate - $46
Hours invested per sample – 0.1 - 0.15
CIH cost per sample – $5 - $7

Total indirect cost per sample - $57 - $73
Total annual indirect costs per company– $1,860 - $29,417

Total annual costs - $12,515 - $55,031
Cost per sample - $106 - $127

Finally, NISA also notes that OSHA's cost estimates for the ancillary provisions are based on all of them (except medical surveillance) being triggered by exposures above a 25 $\mu g/m^3$ action level. By contrast, NISA is urging that the trigger for exposure assessment and medical surveillance be an action level of 50 $\mu g/m^3$. Adopting that approach would reduce the aggregate impact on employers of exposure assessment costs by $62 million according to OSHA's estimates.[34]

Effects on Small Entities

19. NISA has no comments on this issue at this time.

Economic Impacts

20. *Comments on OSHA's estimates of revenue, profit and impact of costs*

NISA adopts the Panel's comments.

21. *Can firms finance first-year costs out of cash flow?*

NISA adopts the Panel's comments.

22. *Comment on employment impacts of proposed rule*

NISA adopts the Panel's comments.

Outreach and Compliance Assistance

23. *What materials would be useful*?

NISA has no comments on this issue at this time.

Benefits and Net Benefits

24. *Comments on any aspects of benefits/net benefits estimates*.

NISA adopts the Panel's comments.

Overlapping and Duplicative Regulations

25. *Overlapping and duplicative regulations*

NISA has no comments on this issue at this time.

[34] *See* 78 Fed. Reg. 56282-83.

Alternatives/Ways to Simplify a New Standard

26. *Comments on whether simply improving outreach and enforcement of existing standard would reduce significant risks from RCS*

OSHA has devoted extensive outreach and enforcement resources for almost twenty years to increasing compliance with the current PEL:

- OSHA instituted a Special Emphasis Program (SEP) in August 1996 that continued through 2007. During this time, "[i]n 1998 and again in 2003, under [its] Strategic Plan, OSHA identified crystalline silica as one of the focused hazards."[35]
- "[I]n October 1996, OSHA launched a joint silicosis prevention effort with MSHA, NIOSH and the American Lung Association,"[36] including a major national conference in 1997.
- OSHA began a National Emphasis Program (NEP) in January 2008 that "expands and builds upon the 1996 SEP"[37] and continues to this day.

Notwithstanding all this activity, the preamble frankly acknowledges that noncompliance with current PEL within general industry remains stubbornly widespread. Essentially, in general industry, OSHA found 34% noncompliance from 1997-2002 and 30% noncompliance from 2003-2009. The highest levels of noncompliance (three or more times the PEL) actually increased, from 13% of general industry samples during the first period to 19% during the latter period.[38] The Panel's comments provide substantial consistent documentation of noncompliance, as detected by CDC, NIOSH, OSHA and others.[39]

Given this continuing high degree of observed noncompliance, one would expect OSHA to say more about why its outreach and enforcement efforts have not lowered it, or to speculation about what it might try to do better. But the preamble's discussion here is very cursory.[40]

NISA thinks the most likely cause of such sustained, significant noncompliance is that, in the absence of any requirement to do exposure monitoring, many employers have no idea what the levels of RCS are in their workplaces. NISA members' own experience is that exposure levels can vary dramatically across time due to process variability, whether building doors and

[35] OSHA Directive CPL 03-00-007 (Jan. 24, 2008).
[36] 78 Fed. Reg. 56293.
[37] *Id*.
[38] *Id*. at 56294 (Tables III-1 and III-2).
[39] *See* Panel comments at 10-16.
[40] *Id*. at 56429, 56433.

windows are open or shut at different times of day, etc. They can vary widely even between employees at the same work station, due to the idiosyncratic behavior of different employees.[41]

Right now, the overwhelming majority of OSHA-regulated employers with silica exposure in their workplaces elect not to measure the silica in the air that their employees breath. Due to OSHA's resource constraints, most of those employers are unlikely to see an OSHA inspector within any given year, within any given decade, or perhaps ever. While those employers have the legal obligation to comply with the PEL for respirable crystalline silica rather than wait for OSHA to arrive and enforce applicable regulations, they are probably not violating regulations by simply remaining ignorant of their employees' silica exposures. As OSHA compliance data has shown, many of them are exposing their employees to levels of respirable crystalline silica in excess of the current PEL.

Imagine, for a moment, that almost no cars were equipped with speedometers and motorists were unlikely to see a traffic cop even once a decade. What incentive would they have to learn whether they were observing the posted speed limits? That is effectively the situation under the current OSHA regulations.

NISA also believes that the great degree and extent of noncompliance across general industry (and construction) may be substantially or largely to blame for the continued observed incidence of silicosis and other silica-related health effects. OSHA really has no basis to say that the 100 $\mu g/m^3$ PEL is not protective for general industry given the likelihood that one-third of all workplaces exposures are actually in excess of the PEL.

This fact means that a PEL standing alone is inadequate to protect workers from material health risks attributable to silica. Exposure monitoring and medical surveillance are needed as well. Indeed, simply lowering the PEL, in the absence of ancillary provisions – as Alternative #7 would do – is unlikely to provide workers with much additional protection. A PEL of 50 $\mu g/m^3$, standing alone, will not in NISA's view reduce significant risks from workplace exposure to RCS. It certainly would be a far less cost-effective approach than exposure monitoring and medical surveillance.[42]

NISA's view is supported by an editorial by Noah Seixas, a noted epidemiologist whose work is cited in the NPRM. Summarizing the results of a UK program designed to improve compliance with occupational exposure limits (OELs), he states:

> In a detailed analysis of the projected burden of lung cancer due to RCS exposure (and other carcinogens) in the UK, increasing the rate of compliance with the current silica

[41] OSHA obliquely recognizes these facts when it proposes that sampling must be conducted during the same shift for one employee's exposure levels to be considered representative of another's. *Id*. at 56288.
[42] *See* 78 Fed. Reg. 56284 ("OSHA will strongly consider alternatives that would reduce the economic impact of the rule . . . .").

OEL to 90% was predicted to prevent substantially more disease than lowering the OEL without changing the rate of compliance (Hutchings et al., 2012).[43]

Conversely, NISA believes that its members' own experience demonstrates that the current PEL is adequate to substantially reduce significant risk if supported by exposure monitoring and medical surveillance triggered by an action level of 50 $\mu g/m^3$. Exposure monitoring, in particular, would also improve compliance significantly. It is far more difficult to exceed the PEL when a facility is gathering sufficient personal samples to characterize the exposures of all potentially exposed employees. OSHA seems to agree: "OSHA anticipates that the ancillary provisions in the proposed standard, including requirements for regulated areas and medical surveillance, will further reduce the risk beyond the reduction that would be achieved by the proposed PEL alone."[44]

NISA expands on all these points in its responses to Issues ##38, 40, and 69-79 below.

This is not to say that outreach will not help promote compliance with a revised crystalline silica rule. A rule involving ancillary provisions will be more complicated than the current rule, and many employers would benefit from assistance in understanding its requirements. The OSHA-funded State Consultation Program would be a particularly effective way of conducting this outreach.

27. *Other ways to simplify the proposed rule*

NISA has no comments on this issue at this time.

Environmental Impacts

28. *Data/comments on possible environmental impacts from proposal*

NISA has no comments on this issue at this time.

29. *Limitations on use of water as control measure/costs to filter out metals, etc.*

NISA has no comments on this issue at this time.

Provisions of the Standards

30. *Should OSHA issue separate general industry/maritime and construction standards*?

NISA has no comments on this issue at this time.

[43] Noah S. Seixas, "Monumental Hazards," 58 ANN. OCCUP. HYG. 1, at 3 (2013).
[44] *See* 78 Fed. Reg. at 56446.

31. *Scope of applicability of construction standard*

NISA has no comments on this issue at this time.

32. *Exclusion of agriculture*

NISA has no comments on this issue at this time.

33. *Should rule be limited to materials containing ≥ 1% CS?*

NISA believes that the applicability of the rule should be determined by the potential for exposures at a given workplace to exceed the action level. If OSHA retains its proposed approach of having crystalline silica concentrations of 0.1% trigger the hazard communication provisions of the rule,[45] then NISA can support a rule that an employer can rely on a safety data sheet that does not list crystalline silica and assume that it is not covered by the rule. By contrast, we believe that, depending upon the material and how it is processed, it is entirely feasible for a material containing 1% crystalline silica to result in exposures above 50 $\mu g/m^3$.

Also, NISA would particularly oppose a framework under which the crystalline silica standard only applied to materials containing 1.0% crystalline silica, but the Hazard Communication Standard applied to any materials containing 0.1% crystalline silica. This would place materials containing between 0.1 and 1.0% crystalline silica, and employers handling them, into a bizarre limbo that would give rise to significant compliance challenges. The illogical distinction would also undermine the credibility of any hazard communications associated with such materials.

34. *Any different provisions warranted for shipyards?*

NISA has no comments on this issue at this time.

Definitions

35. *Competent persons*

NISA has no comments on this issue at this time.

36. *Respirable crystalline silica*

[45] *See* 78 Fed. Reg. 56291. NISA presumes this is because OSHA regards crystalline silica as a known human carcinogen and the Hazard Communication Standard is ordinarily triggered by materials containing at least 0.1% of a carcinogen. *See* 29 C.F.R. § 1900.1200, Appendix A, Table A.6.1.

NISA does not oppose OSHA's definition. However, we also direct OSHA to the Panel's comments, which explain that, by referencing the ISO/CEN definition of respirable particle mass, OSHA will as a practical matter have reduced the stringency of any given PEL by 20-25%.[46]

37. *Tridymite found in any of your workplaces*?

While tridymite exposure is believed to be uncommon, NISA does not believe that it is impossible to encounter tridymite in workplace settings. NISA believes that tridymite should be treated in the same manner as quartz and cristobalite for purposes of OSHA regulations.

PEL and Action Level

38. *Is a 50 μg/m^3 PEL appropriate? If not, what PEL would be? Comments on retaining the existing PEL.*

NISA adopts the Panel's comments regarding the lack of significant risk at 50 μg/m^3 and the economic and technical infeasibility of a PEL at that level.

Additionally, NISA submits that its members' experience demonstrates that the current 100 μg/m^3 PEL is sufficiently protective if supplemented by exposure assessment and medical surveillance triggered at an action level of 50 μg/m^3. OSHA has, of course, proposed those two ancillary provisions – but while the proposal has exposure monitoring triggered by the (25 μg/m^3) action level, it only requires medical surveillance for exposures expected to exceed the (50 μg/m^3) PEL. NISA urges OSHA to retain the existing PEL – which, as noted in response to Issue #36, will effectively become 80 μg/m^3 with the adoption of the ISO/CEN convention for respirable particle mass. We also urge OSHA to require both exposure assessment and medical surveillance for exposures expected to exceed a 50 μg/m^3 action level.

NISA recognizes that silicosis continues to be diagnosed in the United States under the current PEL. Some of those cases have been among NISA employees over the past 20 years, as explained in Part II above. However:

- As we also explained there, we believe that the very few silicosis cases still being diagnosed among NISA's membership are the result of historic exposures occurring when the individuals' employers were not implementing the SSP. We do not believe NISA members implementing the SSP are currently generating any new cases of silicosis.
- As we explained in response to Issue #26, we believe the observed incidence of silicosis outside NISA's membership is most likely due to the high degree of current noncompliance with the current PEL outside of NISA's membership.

[46] *See* Panel comments at 18-19.

As noted earlier, however, it is insufficient just to retain the current PEL. To eliminate significant risk at the PEL, OSHA needs also to require exposure assessment and medical surveillance where exposures are expected to exceed a 50 $\mu g/m^3$ action limit.

39. *Is a single PEL appropriate for quartz, cristobalite and tridymite?*

Yes, for the reasons OSHA provides at 78 Fed. Reg. 56304-05 and 56442. As noted at the outset, NISA also adopts the comments of IDPA with respect specifically to the equivalent toxicity of quartz and cristobalite.

40. *Support concept of AL? Is 25 $\mu g/m^3$ right, or what number would be better?*

A. Action levels are basic good industrial hygiene.

NISA strongly supports the inclusion of an action level in the crystalline silica rulemaking. OSHA has included one in multiple other substance-specific standards, including inorganic arsenic, ethylene oxide, benzene, methylene chloride, acrylonitrile, and vinyl chloride,[47] and the same considerations that motivated doing so there are applicable here: action levels "encourage lower exposures for employees and . . . reduce administrative burdens on employers."[48]

Action levels are justified by basic industrial hygiene considerations: If the PEL is the maximum acceptable level of exposure, employers ought not to be exposing employees to just below that level. Rather, they should seek to maintain exposures sufficiently below that level to ensure some margin of safety. That margin serves multiple purposes. It provides a buffer so that, where exposures spike due to variations in materials or process operations, the resulting concentration is more likely to remain below. It also lessens the need for certainty about the toxicology or epidemiology underlying the PEL, or for conservatism in estimating that toxicity – even if it were later to emerge that the science supports a slightly lower PEL, the operation of the action level would have increased the likelihood that employees' exposures were still below even that lower value.[49]

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[47] *See* 78 Fed. Reg. 56281.
[48] 52 Fed. Reg. 34460 (Sept. 11, 1987) (final benzene rule).
[49] *See* ILO, ENCYCLOPEDIA OF OCCUPATIONAL HEALTH & SAFETY, Goals, Definitions & General Information (2011) ("In the practice of occupational hygiene, exposure assessment results are often compared with adopted occupational exposure limits which are intended to provide guidance for hazard evaluation and for setting target levels for control. Exposure in excess of these limits requires immediate remedial action by the improvement of existing control measures or implementation of new ones. In fact, preventive interventions should be made at the "action level," which varies with the country (e.g., one-half or one-fifth of the occupational exposure limit). A low action level is the best assurance of avoiding future problems.")

By definition, an "action" level should trigger some action on the part of employers if they expect exposures to exceed it. In the proposal, OSHA has proposed exposure monitoring for such exposures, but it has not proposed medical surveillance to be triggered until exposures "will be" above the PEL for 30 or more days a year. By contrast, the NISA Solution triggers both practices whenever exposures are expected to exceed the action level. Again, this is justified by basic industrial hygiene considerations.

1. Exposure assessment should be triggered at the action level

Given the great variability that can occur in crystalline silica exposures, in order to have any certainty about whether individual employees' exposures are above or below the PEL, it is necessary to monitor those exposures. Monitoring only when exposures are expected to be at the PEL or higher would substantially defeat the purpose of such monitoring, as it would fail to prevent exposures that were not expected to exceed the PEL but did. Only monitoring at the action level serves the buffering purpose noted above.

2. Medical surveillance should be triggered at the action level

Triggering medical surveillance only at the PEL or higher similarly defeats much of the purpose it is intended to serve. Depending on how variable the operation in question is, some degree of risk remains that exposures above the PEL will occur even if the employer seeks to keep them well below. Also, different individuals may have unusual susceptibility to illness, either genetically or because of prior work experience, smoking, etc. Medical surveillance at the action level provides a greater degree of confidence that if these phenomena lead to the incidence of silicosis, that incidence will be caught early – likely before any decrease in pulmonary function or other symptoms can become evident – and steps can be taken to avoid progression. Triggering medical surveillance at the PEL converts it into a mechanism for catching work-related illnesses after they have unnecessarily been produced. Especially given the irreversible nature of the silica-related lung disease, it is better industrial hygiene practice to maximize the preventive aspect of medical surveillance.

Every other OSHA standard that includes medical surveillance, and specifies a trigger, triggers it at the action level.[50] NISA does not think OSHA really believes its own argument for why, in this rulemaking, it is appropriate to trigger medical surveillance only when employees will be exposed above the PEL for 30 or more days a year: "employees exposed at or below the PEL, or exposed above the PEL for only a few days in a year, will be at lower risk of developing RCS-related disease than employees who are exposed above the PEL for 30 or more days a year."[51] If that is true, then why is OSHA insisting on requiring people to wear respirators whenever they enter a regulated area, no matter for how long?[52] Employees exposed above the

[50] 78 Fed. Reg. 56468.
[51] *Id*. NISA suspects that OMB is really the source of this argument.
[52] *Id*. at 56467 (citing the "potentially serious results of exposure" at any length of time above the PEL).

50 μg/m^3 proposed PEL for 30 days, or even exposed right below it, are still at significant risk, according to OSHA[53] -- OSHA just does not believe it is feasible to control exposures to below that level. But it is certainly feasible to surveil employees in that category. NISA disagrees that employees exposed to crystalline silica between 50 and 100 μg/m^3 are exposed to significant risk. But we recognize that some prior dust sampling data might not have been representative. Also, as of the effective date of the rule, many silica-exposed employees whose then-current exposures are between 50 and 100 μg/m^3 might have experienced higher exposures for a significant part of their work histories. Periodic chest X-rays and other medical oversight would provide an important margin of protection for such circumstances.

B. Action levels help keep exposures below the PEL and create an incentive for much lower exposures

1. An action level dramatically enhances the benefit of a PEL

NISA strongly agrees with OSHA that an action level provides "very real and necessary . . . further reduction in risk beyond that provided by the PEL alone."[54] But we do not believe that this reduction is "non-quantifiable."[55] OSHA's cost analysis for the proposed rule assumes that facilities comply with the current PEL 100% of the time, so that the new proposal imposes only the incremental costs of getting to the lower 50 μg/m^3 PEL.[56] Similarly, its benefit analysis assumes that facilities will comply with the proposed PEL 100% of the time, thus producing substantial benefits.[57] As noted earlier, however, noncompliance with the current PEL has stubbornly remained at about 30% of samples taken. There is no reason to think compliance will improve simply because the PEL is halved – indeed, noncompliance is bound to be even greater, as the number is harder to meet.[58] OSHA's assumptions are plainly contrary to the facts and irrational.

But OSHA *could* substantially improve compliance, with either the current PEL or a lower one, if it were to require exposure monitoring. Once facilities are required to measure employees' individual exposures, they will have a measurable basis for determining their initial level of compliance or noncompliance, for assessing what additional steps are required to bring them into compliance, and for assessing the success or failure of those steps. The Panel concurs in this view, contending that exposure monitoring (and other ancillary provisions) will "ensure reductions in risk even without changing the . . . current PEL . . . ."[59] Noah Seixas makes the same point in a recent editorial on crystalline silica:

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[53] *Id*. at 56281.
[54] *Id*.
[55] *Id.*
[56] *Id*. at 56337.
[57] *Id*. at 56384.
[58] As noted above in response to Issue #26, the lack of any requirement to monitor exposures substantially undercuts the benefit of a PEL, regardless of how stringent it is.
[59] *See* Panel comments at 19.

> Analyses of the results of this program presented at this year's Inhaled Particles symposium showed that overall there had been a 2- to 3-fold reduction of exposure concentrations since the start of [an Industrial Minerals Association - Europe] project (Kromhout et al., 2013), providing support for the concept that exposure monitoring with feedback to the affected worksites helps to support control measures.[60]

Seen this way, it is evident that exposure monitoring is really the component of the standard that deserves the lion's share of the credit for the benefits of compliance – in the same way that the speedometer, not the brake, deserves primary credit for making sure a car does not exceed the speed limit.

2. Action levels drive lower exposures than PELs

In absence of an action level, employers have to comply with all requirements of a standard no matter what level of exposure they achieve. It costs an employer just as much, and is just as burdensome, to attain 19 $\mu g/m^3$ as it does to attain 99 $\mu g/m^3$ – in fact, attaining the lower level is almost certainly more costly. So why should an economically rational employer bother doing more than just managing for reliable compliance; i.e., getting to 99 $\mu g/m^3$?

On the other hand, if staying below the action level frees an employer from having to comply with the rule at all, the employer has a powerful economic incentive to do so. Most companies focused solely on complying with a regulatory limit will devote expenditures and resources sufficient just to comply, and many will only spend enough not to violate it by much, or very often. On the other hand, if a company can completely avoid being covered by that regulatory regime altogether, it has a powerful motive to do so – and there is good evidence that companies will.[61] OSHA's preamble recognizes this incentive in at least two instances,[62] but it does not accurately describe the extent of the incentive,[63] nor does it adequately describe how

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[60] "Monumental Hazards," *supra* note 43.

[61] For example, after about 8,500 facilities provisionally "screened in" to the Department of Homeland Security's Chemical Facility Anti-Terrorism Standards, close to 3,000 of them made process changes that enabled them to remove themselves from regulation altogether. Testimony of DHS Under Secretary Rand Beers before the House Committee on Energy and Commerce, Subcommittee on Environment and the Economy hearing on "The Chemical Facility Anti-Terrorism Standards (CFATS) Program: A Progress Update" (March 14, 2013), available at http://www.dhs.gov/news/2013/03/14/written-testimony-national-protection-and-programs-directorate-house-energy-and.

[62] *Id*. at 56406, 56443.

[63] In both instances, OSHA talks about the action level (and initial monitoring) allowing employers to "avoid the costs of associated with the periodic exposure assessment provisions." *Id*. at 56406, 56443. But, as a practical matter, if all initial monitoring results are below the action level, an employer has no further obligations under the proposed standard, since all other

transformational the incentive can be in driving exposure levels to far below the PEL – to levels that otherwise employers derive no direct economic benefit from attaining. In developing the final rule, OSHA should fully characterize the economic savings to businesses and the lowered employee exposures that are created by an action level.

41. *What provisions should be triggered by an action level*?

As explained above, NISA believes that exposures above the action level should trigger medical surveillance as well as exposure monitoring.

Recordkeeping is an integral part of both of these ancillary provisions, and NISA supports OSHA's proposed recordkeeping requirements. The OHP requires NISA members to retain employee's individual dust monitoring records "indefinitely" and medical surveillance records for 30 years.[64]

42. *What if there is no action level?*

After 17 years of intensive OHSA focus on crystalline silica, it would be a tragic missed opportunity if the rule were to fail to incorporate an action level coupled with appropriate ancillary provisions. While certain provisions are customarily known as "ancillary," NISA believes that respiratory surveillance and, even more centrally, dust monitoring, are not in the least bit ancillary to the objective of eliminating silica-induced disease. They are the central features of a rule designed to achieve that objective. If, despite this, OSHA does not adopt NISA's proposal to establish an action level at 50 $\mu g/m^3$ and instead opts for a final standard with no action level, then, as a far from second-best solution, exposures that are reasonably expected to exceed the PEL at *any* time (not that "will exceed" the PEL for ≥ 30 days) should trigger the action levels discussed above.

Exposure Assessment

43. *Should OSHA allow objective data to substitute for initial air monitoring? Defined sufficiently?*

NISA supports OSHA's proposal to allow an employer to rely on objective data in lieu of initial air monitoring. There are many circumstances where an employer can tell confidently that a PEL will not be exceeded, based on Safety Data Sheets (SDS), the nature of the industrial process, prior information about the relevant operation, the likelihood of dust generation at an operation, the location of workers and their proximity to airborne dust. In these cases, risk of overexposure can be assessed qualitatively by a competent person and air monitoring would be

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obligations are triggered by exposures that are, or are reasonably expected to be, above the action level or the PEL. (Of course, if processes, etc., change, the employer may need to resample as per proposed § 1900.1053(d)(4).)

[64] *See* Appendix B at 57 and 108.

superfluous and wasteful.

Given the foregoing, NISA believes that OSHA has defined "objective data" too quantitatively, as the definition is limited to "air monitoring data from industry-wide surveys [and] calculations based on the composition or chemical or physical properties of a substance. . . ." If crystalline silica must be listed on an SDS at a concentration of 0.1% or greater, and an SDS does not list crystalline silica as a constituent in a material, no calculations should be required to substantiate a conclusion that a PEL will not be exceeded. The definition should more generally authorize competent persons to make judgments about the possibility of a PEL being exceeded. NISA believes that many companies have experienced employees with sufficient training and experience that many issues such as this one may appropriately be left to their discretion. In this connection, OSHA should review, and add to the rule's list of references, the American Industrial Hygiene Association's A STRATEGY FOR ASSESSING AND MANAGING EMPLOYEE EXPOSURES (J. Ignacio & W. Bullock, eds.) (3d ed. 2006).

Of course, the employer would bear the burden of substantiating the reasonableness and accuracy in fact of such judgments. By the same token, the utility of an "objective data" alternative will require OSHA to enforce it reasonably. The SBREFA Panel expressed a concern about whether such performance-based options would be "consistently interpreted by enforcement officers," but OSHA did not respond in the preamble.[65] It should do so in the final rule.

44. *Exposure assessment. Support having both fixed schedule and performance options? Latter phrased appropriately? Anything else?*

NISA supports having both a fixed schedule and performance option for exposure assessment. As a general matter, it is always optimal when a rule includes both:

- A fixed option for regulated entities who are looking for certainty or a safe harbor (this is frequently the case with smaller entities that do not have in-house expertise, and cannot afford consultants, to develop performance justifications); and
- A performance option for entities who have such resources, or whose circumstances give them confidence to justify some other approach.

NISA appreciates that OSHA has, for the first time, proposed both options.

Consistent with our response to the previous issue, however, the performance option be rephrased to permit sampling frequency "as determined by a competent person." NISA cautions again, moreover, that in order for the performance approach to be truly useful to employers, OSHA will have to enforce it reasonably.

45. *Do you conduct initial air monitoring or rely on objective data?*

NISA members sometimes use area sampling to document dust levels in work areas

[65] *See* 78 Fed. Reg. 56433.

thought to be relatively dust free, such as offices, laboratories, and lunchrooms. Area sampling can also be used to evaluate dust sources and the effectiveness of engineering controls, work practices, and administrative controls. Also, as noted in our response to Issue #43, NISA companies may conclude that qualitative considerations justify a conclusion that a PEL could not be exceeded.

46. *Lab requirements appropriate?*

NISA adopts the Panel's comments.

47. *Has OSHA correctly described the accuracy and precision of existing sampling & analysis methods? Can exposures be accurately measured at proposed action level and PEL?*

NISA adopts the Panel's comments. See also response to Issue #40 above.

48. *Performance of any analytical method with tridymite*

NISA has no comments on this issue at this time.

Regulated Areas and Access Control

49. *Will options of regulated areas or access control plans protect employees? When would you use an ACP instead of a regulated area*?

NISA's SPP does not require or recommend either regulated areas or access control plans. Beyond that, NISA has no comments on this issue at this time.

50. *Comments on how regulated areas/access control plans would work for multi-employer worksites*

NISA has no comments on this issue at this time.

51. *Protective clothing issues*

NISA member companies have years of experience conducting root cause analyses of exceedences of the PEL. In that experience, contaminated work clothing can be the source of such an exceedence, but such circumstances are uncommon. For that reason, NISA does not support OSHA's proposed trigger for requirements regarding contaminated clothing, which it finds to be too vague and subjective, even as explained at 78 Fed. Reg. 56451. NISA would support these requirements being triggered in cases where contaminated clothing can be shown to be the cause of exceedences of the PEL.

Methods of Compliance

52. *Are there any industries or processes where OSHA should establish "separate engineering control air limits" (SECALs)?*

NISA has no comments on this issue at this time.

53. *Should OSHA require a written exposure control program?*

OSHA correctly did not require a written exposure control program. Management of crystalline silica exposures is not so complicated as to require such a program. The ancillary provisions that NISA supports (exposure monitoring, medical surveillance, recordkeeping, and hazard communication/training) are adequate.

54 - 62. *Comments on Table 1*

NISA has no comments on these issues.

63. *Prohibit use of crystalline silica as an abrasive blasting agent?*

NISA has no comments on this issue at this time.

64. *Substitutes for crystalline silica not considered in OSHA's feasibility study*

The OHP notes that, "for most of the industrial sand used, there are no known suitable substitutes."[66]

65. *Relevant information on dust control kits in the railroad industry*?

NISA has no comments on this issue at this time.

66. *Comments on prohibition on dry sweeping*

NISA has no comments on this issue at this time.

67. *Should facilities be exempted from engineering/work practice control requirements for exposures lasting less than 30 days?*

NISA strongly supports this exemption for general industry, provided employees are required to use PPE. (It has no comments on whether the option should be available for construction.) This exemption has enormous potential to reduce the compliance costs of any crystalline silica standard without any reduction in employee health benefits. There are many

[66] *See* Appendix B at 11.

short-term projects (e.g., cleaning out baghouses) where use of PPE is cost-effective, reasonable and not an undue imposition on workers, but where engineering controls to reduce exposures to below the PEL would be extraordinarily expensive (e.g., requiring replacement of baghouses with alternative dust collection devices). As OSHA points out, this exemption was contained in the draft standard that was shared during the SBREFA process, and the SBREFA panel recommended its retention. The proposed rule does not explain why OSHA nonetheless dropped it.[67] OSHA should reinstate it in the proposed rule.

68. *Comments on the prohibition on employee rotation*

NISA cannot understand why OSHA has imposed this prohibition. It flies in the face of long-standing, widely-accepted industrial hygiene practice. Employee rotation is an established approach to hearing protection, for example. It is used in the case of potential mutagens or carcinogens; for example, radiation.

If, as OSHA believes, risks of silicosis are correlated with cumulative exposures, it does not matter whether one employee works an exposed job position eight hours in one day or two hours a day for four days. If, as the Panel's comments suggest, risks of silicosis (or any other silica-related health effect) are subject to a threshold below which exposures are without appreciable risk, then rotation to maintain exposures at low levels could only be protective. In other words, regardless of how silica-related illnesses are caused, rotation helps protect against them.

NISA urges OSHA to delete the prohibition.

If OSHA retains the prohibition, it should at a minimum confirm that it would not prohibit:

- Operations that involve employee rotation because rotation is performed for purposes other than "to achieve compliance with the PEL"; or
- Rotating employees to maintain their exposures below the *action level*, rather than the PEL.

Inclusion by OSHA of the second bulleted exception above would simply constitute sound industrial hygiene. Failure by OSHA to include the first bulleted exception above would get OHSA into the business of micro-managing operations of OSHA-regulated employers without any clearly identified benefit to workers.

[67] *See* 78 Fed. Reg. 56431.

Medical Surveillance

69. *Do you provide medical surveillance for your employees?*

Yes. Medical surveillance is a key element of the comprehensive SPP that NISA member companies implement and manage at all worksites as part of the goal of eliminating new cases of silicosis among their employees.

a. *How do you determine which employees receive surveillance?*

Under the OHP, all employees exposed to crystalline silica are required to receive medical surveillance.[68]

b. *Who administers and implements it?*

Physicians and allied health professionals employed by or under contract to NISA member companies.

c. *What examinations, tests or evaluations are included? TB? Pulmonary function?*

The elements of the medical surveillance prescribed by the SPP are:

1. A medical history that focuses on the presence of respiratory symptoms, smoking habits, and risk factors for kidney disease.

2. A comprehensive occupational history that details prior exposure to potentially harmful dusts, chemicals, and other physical agents. Any adverse effects related to these exposures must be recorded.

3. A physical examination to assess the general condition and respiratory status of the worker.

4. A 14-by-17-inch posterior anterior (PA) chest X-ray, preferably obtained using a high kilovoltage technique. Films should be classified in accordance with the 2000 Guidelines for the Use of ILO International Classification of Radiographs of Pneumoconioses. Good quality digital chest images reproduced on film are also acceptable.

5. Pulmonary function tests that include spirometric measurements of forced expiratory volume in one second (FEV_1) and forced vital capacity (FVC), performed, calculated, and interpreted in accordance with the ATS 1994 Update Standardization of Spirometry and the 2005 ATS-ERS Standardization of Spirometry guidelines.

[68] *See* Appendix B at 69.

6. TB testing:
   - Upon entry into employment: Baseline tuberculin skin test reactivity status of workers, using either the tuberculin skin test (TST) or a QuantiFERON-TB Gold test or the QuantiFERON-TB Gold In-Tube test. The TST should be performed by intradermal injection of purified protein derivative (PPD), using the Mantoux technique. A two-step TST should be performed for initial, baseline testing, following current Centers for Disease Control and Prevention (CDC) guidelines for the detection and evaluation of tuberculosis. Alternatively, initial baseline testing can use a single QF test.
   - Annually: A single TST or QF test, for workers w/ profusion 1/0 or greater.
   - Periodically ("consider"): A single TST or QF test, for workers with 25 or more years of silica exposure.

7. Three basic tests to screen for kidney disease:
   - A quantitative test for protein or albumin in the urine (proteinuria),
   - A calculation of glomerular filtration rate (GFR) based on a serum creatinine measurement, and
   - A blood pressure measurement.[69]

d. *What benefits have been achieved from your medical surveillance program (health, financial, reduction in absenteeism)*?

The NISA medical surveillance program has confirmed the elimination of new silicosis cases at workers employed at NISA member companies participating in the SPP, as documented by the annual reporting discussed in Part I.B.4 above. Baseline chest X-rays also allow for the identification of silicosis in new hires or workers coming on board via an acquisition. In a few cases, as discussed in Part I.B.5, medical surveillance has captured the emergence of silicosis from earlier exposures and enabled prompt interventions to ensure that these employees are monitored more closely and protected from factors that could promote progression.

For most employees, however, the principal benefit of the medical surveillance program has been to identify other, non-silica related health conditions that the employees were unaware of, allowing those conditions to be treated promptly and appropriately, before they progressed to morbidity or death. For example, routine medical surveillance has detected aortic aneurysms that could at any moment have killed the employee.

e. *What are the costs of your medical surveillance program*?

See response to Issue #18 above.

[69] *See* Appendix A at 10.

f. *How many employees are covered by your medical surveillance program*?

NISA's best estimate is that 2,838 persons are currently subject to medical surveillance under the SPP.

g. *What NAICS code describes your workplace*?

Predominantly 212322 ("Industrial sand mining").

70. *Comments on proposed content and frequency of medical surveillance examinations*

NISA supports OSHA's proposal for medical surveillance, with the proviso discussed earlier that it be required for all employees likely to be exposed above the recommended 50 $\mu g/m^3$ action level, not the PEL.

NISA's medical surveillance program is more demanding in several respects noted below. We can support the proposed medical surveillance requirements, however, as an appropriate regulatory mandate.

71. *Comments on content of PLHCP written medical opinion*

The proposed content of this opinion is appropriate.

72. *Appropriateness, cost-effectiveness of proposed latent TB testing*

Latent TB testing is clearly warranted as part of a crystalline silica medical surveillance program, given the increased risk of TB among persons with silicosis. For that reason, the NISA SPP requires:

- Baseline TB testing upon hire; and
- Annual testing among persons with chest X-ray evidence of silicosis (1/0 or greater profusion).

The SPP also encourages periodic testing for employees with more than 25 years of silica exposure but without evidence of silicosis.

NISA supports OSHA's proposal for TB testing as part of the medical surveillance provisions of a comprehensive crystalline silica standard.

73. *Appropriateness of pulmonary function testing*

Pulmonary function testing is clearly warranted as part of a crystalline silica medical surveillance program. NISA's experience has shown that most abnormalities on screening spirometry are due to smoking or other non-work-related disorders. Also, radiographic changes consistent with silicosis will normally precede losses detected by spirometry that result from the inhalation of respirable crystalline silica. Nonetheless, as effects on pulmonary function are the

most direct symptom of silicosis or other nonmalignant respiratory disease, PF testing is essential to early detection of these illnesses and to measuring the severity of their consequences. For that reason, the NISA SPP requires spirometric measurements of forced expiratory volume in one second (FEV1) and forced vital capacity (FVC) upon hiring and every two years thereafter.

NISA supports OSHA's proposal for pulmonary function testing as part of the medical surveillance provisions of a comprehensive crystalline silica standard.

74. *Appropriateness of proposed chest X-ray requirement*

Chest X-rays are absolutely fundamental to any crystalline silica medical surveillance program. Radiographic evidence of lung opacities is the way that silicosis is most commonly detected, and the size, shape, location and profusion of such opacities form the basis of how silicosis is defined and measured. For these reasons, the NISA SSP requires chest X-rays upon hire and every four years thereafter (except for employees above age 35 with greater than eight years of silica experience, for whom chest X-rays are required every two years).

NISA supports OSHA's proposal for chest X-rays as part of the medical surveillance provisions of a comprehensive crystalline silica standard.

75. *Should other tests be included in medical surveillance?*

NISA has no comments on this issue at this time.

76. *If you provide medical surveillance, describe your program*

See response to Issue #69.

NISA supports OSHA's proposal to require the physician or other licensed health care professional to provide the results of medical surveillance to the employer. NISA's OHP explains why it is important for the employer, as well as the employee, to receive the results of an employee's medical surveillance examination – it:

- Assists the company in developing baseline measurements on the employees;
- Informs the company about any medical condition or change in an employee's condition from exposure to silica or other job-related factor;
- Advises the company of medically-recommended restrictions regarding a worker's exposure to silica; and
- Advises the company regarding the worker's ability to wear a respirator or other protective equipment.[70]

Also, NISA member companies have generally found that medical surveillance directed toward workplace illness still turns up non-silica related illnesses not previously identified by the

[70] *See* Appendix B at 109-110.

employees' physicians. NISA companies inform employees when such conditions are identified. This is probably the greatest benefit of medical surveillance.

Providing results to the employer also enables the company to assemble a database of medical results that enables the company and others to conduct or support epidemiologic evaluations of workplace health – as indeed NISA is doing now, based on the accumulated medical records of its two largest members. OSHA also notes the usefulness of medical surveillance records for such epidemiologic research.[71] Many of the studies upon which OSHA's QRA relies are based on medical examinations paid for by the employer. NISA thus supports OSHA in rejecting the argument of at least one union that employees should be free to decide whether and what medical surveillance results to provide to their employer.[72]

77. *Appropriate triggers for medical surveillance (action level or PEL?; 30 or more days above?)*

As explained in our responses to Issues ##40 & 70, NISA believes that medical surveillance should be triggered when an employee is likely to be exposed above an action level (not the PEL), upon hiring or assignment to a job position with the potential for such exposure (not only when such exposure will occur for ≥30 days).

78. *Does your geographic area have adequate access to PLHCPs, esp. qualified B-readers?*

B-readers can be located anywhere in the United States, as they read chest X-rays that can be shipped (or transmitted electronically to them) readily and at reasonable cost.

79. *"Equivalent diagnostic study" as alternative to X-rays*

NISA has no comments on this issue, other than to note that the Appendix seems to be inconsistent with the proposal.[73]

80. *Comments on medical removal protection*

NISA agrees with OSHA that medical removal protection is inappropriate for this rulemaking because "respirable crystalline silica-related health effects (e.g., silicosis) are generally chronic conditions that are not remedied by temporary removal from exposure."[74] No medically-useful purpose would be served by removing an employee temporarily from exposure to crystalline silica.

[71] *See* 78 Fed. Reg. 56475.
[72] *Id*. at 56472.
[73] *See id*. at 56492 ("conventional chest radiographs are needed").
[74] *Id.* at 56473.

Hazard Communication and Training

81. *Trigger and training elements*

NISA supports OSHA's proposed hazard communication requirements. As for when they should be triggered, NISA believes the relationship between crystalline silica exposure and lung cancer is still not fully understood; in particular, NISA believes it has not yet been established whether crystalline silica exposure causes lung cancer in individuals who do not already have silicosis. However, NISA also recognizes that IARC, NTP, ATS and NIOSH have all classified crystalline silica as a carcinogen. On that basis, OSHA's Hazard Communication Standard presumably is already triggered by materials containing at least 0.1% crystalline silica.[75] Also, as NISA explained in response to Issue #33:

- Only if OSHA retains that threshold can NISA support the rule that an employer can rely on a safety data sheet that does not list crystalline silica as the basis for the conclusion that it is not covered by the rule; and
- NISA would particularly oppose a framework under which the crystalline silica standard only applied to materials containing 1.0% crystalline silica, but the Hazard Communication Standard applied to any materials containing 0.1% crystalline silica.

NISA supports OSHA's proposed training requirements. While employers have a responsibility to protect their employees, employees have a similar responsibility to understand how to keep themselves safe. In the context of this rule, that includes:

- Operations that could result in respirable crystalline silica exposure;
- Specific protective procedures the employer has implemented;
- The requirements of this rule, once finalized; and
- The purpose and elements of medical surveillance required by the rule or provided by the employer.

All of these topics are addressed by OSHA's proposal, and NISA supports it. Conversely, the generic training elements of the Hazard Communication Standard alone are insufficient.

NISA also supports the performance-based way in which the training requirements are specified.

82. *Is proposed training sufficient? Add anything?*

See response to Issue #81.

83. *Comment on other possible hazard communication issues (e.g., warning labels)*

NISA has no comments on this issue at this time.

[75] *See* 29 C.F.R. § 1900.1200, Appendix A, Table A.6.1.

Recordkeeping

84. *Utility of and costs associated with proposed recordkeeping requirements*

NISA believes the proposed recordkeeping requirements have utility and are not unduly burdensome. In particular, we support the 30-year retention period for dust sample results and medical surveillance records.

Dates

85. *Appropriateness of proposed compliance dates*

See response to Issue #15 g/h above.

86. *Appropriateness of two-year delay in compliance date for labs*

NISA adopts the Panel's comments.

Appendices

87. *Support inclusion of non-mandatory appendix?*

NISA has no comments on this Issue, other than to note an inconsistency between the rule and the Appendix regarding radiography (see response to Issue #79 above).

Conclusion

As the Panel's comments document, OSHA has not established that a significant risk of material health impairment from crystalline silica exists at the current permissible exposure limit (PEL) of 100 $\mu g/m^3$, or that any such risk would be substantially reduced by a PEL of 50 $\mu g/m^3$. The Panel's comments also demonstrate that the proposed standard, with a PEL of 50 $\mu g/m^3$, is not technologically or economically feasible.

To substantially reduce any risks of material health impairment from workplace exposure to crystalline silica arising from the persistently high level of noncompliance with the current PEL, NISA strongly supports the "NISA Solution": a comprehensive standard, in the form of a variant of OSHA's Alternative #1: the current PEL of 100 $\mu g/m^3$ and an action level of 50 $\mu g/m^3$, with exposure monitoring and medical surveillance triggered by exposures above the action level. The NISA Solution is economically and technologically feasible – particularly if, as NISA predicts, many establishments internalize the costs of exposure assessment.

If you have questions regarding these comments, please do not hesitate to contact me at 202-457-0200, ext. 4, or markellis@ima-na.org.

Sincerely,

Mark G. Ellis
President