COMMENTS

OF THE

NATIONAL ASSOCIATION OF MANUFACTURERS

BEFORE THE

U.S. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

Docket No. OSHA 2010-0034

78 Fed Reg. 56274 (September 12, 2013)

Proposed Revisions to Standard For

Occupational Exposure to Respirable Crystalline Silica

I. Preface Language

The National Association of Manufacturers (the NAM) appreciates the opportunity to submit these comments to the U.S. Occupational Safety and Health Administration (OSHA) in response to the Notice of Proposed Rulemaking referenced in 78 Fed Reg. 56274, Docket No. OSHA 2010-0034 (proposed revisions, standard or rule).

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs nearly 12 million men and women, contributes more than $1.8 trillion to the U.S. economy annually, provides the largest economic impact of any major sector, and accounts for two-thirds of private sector research and development. The NAM is the powerful voice of the

manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and creates jobs across the United States.

The proposed rule will have wide-reaching effects on a large number of manufacturers both directly and indirectly. The NAM and its members submit these comments to address some of the significant issues raised by this proposed rule. Our comments are focused primarily on policy issues and, though we urge OSHA to withdraw the proposed standard, we have included recommendations for changes to improve the OSHA proposal.

The NAM and its members understand that employees are the key resources in our facilities and all employees deserve a safe and healthful workplace. We support OSHA's efforts to reduce ill effects in employees from exposure to hazardous substances in the workplace, such as respirable crystalline silica (RCS). In adopting the OSH Act, Congress recognized the need to take a balanced approach to the regulation of workplace exposures to hazardous chemicals. This means, in significant part, that OSHA is required to limit the scope of its standards to those activities and employers whose employees are truly at risk and to adopt only those requirements that are necessary to materially and directly reduce the risk in the most cost-effective manner so as to provide a safe workplace while minimizing negative impacts on productivity and manufacturers' competitiveness.

In short, however, the NAM believes the proposed reduction of the permissible exposure limit (PEL) to 50 ug/m^3 with an action level of 25 ug/m^3 is an unnecessary change that will be unachievable for many employers, and will be very costly for almost all affected employers. If adopted as proposed, we believe the standard will lead to businesses having to decide whether to close their doors or move their operations elsewhere. Employers have worked for decades to achieve compliance with the current PEL and, through these efforts, have adopted the best possible and most cost-effective ways to keep all their employees safe. The NAM encourages OSHA to work with employers to address safety and health issues in a far more collaborative manner that will achieve the goals of safer workplaces and a competitive economy.

Due to the number of manufacturers that would be impacted by adoption of the proposed rule, the breadth and diversity of industries and activities, and the sheer volume of material to be analyzed, the NAM faced a huge challenge in preparing comments to be submitted to OSHA in

connection with this proposal. First, it was necessary for the NAM to develop a basic understanding of OSHA's objectives, the requirements of the proposed standard, and the justification for those requirements. Second, we needed to develop outreach materials that would assist our members in determining who could be affected by the proposed rule and how they could be affected. Third, it was necessary to identify members who had the resources and willingness to quickly develop a sufficient understanding of how they could be affected the proposed rule and complete a survey designed to assist the NAM and OSHA in evaluating current practices for controlling exposure to RCS and the impact of the proposed rule. Given the time required to complete that series of tasks, we made two requests to extend the comment period so that we would be able to develop more extensive comments on those issues, but because requests for sufficient additional time have been denied, we are, at this time, unable to fully analyze the survey results and, therefore, unable to meaningfully and extensively incorporate our survey results in these comments.

In the context of this rulemaking, we are particularly troubled by OSHA's denials of requests for meaningful extensions of the comment period. In an OSHA rulemaking proposing a comprehensive substance-specific standard, the critical scientific document relied upon to support the proposal is the health effects analysis and risk assessment. In 2008, recognizing the significance of the document, OSHA stated that it intended to make the draft health effects analysis and risk assessment for crystalline silica available for public discussion and comment in advance of the peer review of that document (see attached peer review agenda). We were understandably pleased that OSHA had decided to proceed with the development of that critical document in a more open and transparent manner.

Unfortunately, the promise of that approach was never realized. Instead, OSHA apparently opted to withhold all versions of that document from the regulated community from May 22, 2009 (when, according to the attached Fall 2013 OSHA Regulatory Agenda, OSHA initiated the peer review) to September 2014 when OSHA issued the NPRM. According to the attached Fall 2013 OSHA Regulatory Agenda, OSHA completed the peer review on January 24, 2010. We are compelled to ask: "What justification can OSHA offer for denying the regulated community the opportunity to review such a critical document -- which would be relied upon by OSHA to

regulate exposures to one of the primary components of the earth's crust and one of the most widely used chemicals in the world – for a period of five years?"

When viewed in that light, OSHA's decision to grant only nominal extensions of the comment period could reasonably be viewed as denying the regulated community the opportunity for effective participation in the rulemaking process. Furthermore, while each extension has been welcome and helpful, planning in this context is necessarily based on what is, rather than what might be. The final comments would have been significantly more informative and more helpful to OSHA if OSHA had included the last-minute extensions of 47 days and 15 days in the initial comment period.

In the end, the NAM believes assertions made by the agency of conducting an open process for this rule will prove unfounded, and that OSHA's actions will have deprived the agency and the public of the opportunity to perform a thorough review of the impact of the proposed rule prior to the agency's final action on this proposal. When considering the tens of thousands of pages of complicated studies and documents that OSHA included in the docket, it is clear that the 157 days OSHA credited in its response to our last extension request is patently inadequate. OSHA's comment that the hearings and post-hearing comment period combined with the pre-hearing comment period "will provide ten months or more for stakeholder input on the proposed rule" is an offense when OSHA has had ten plus years since the SBREFA panel to review the record and prepare the proposal.

Introduction

a. Summary Description Of Impact

In its Preliminary Economic Analysis (PEA), OSHA states there are at least 24 manufacturing industry subsectors, identified by North American Industry Classification System (NAICS) codes that would be affected by the proposed standard. Among these are asphalt paving products, asphalt roofing materials, foundries, concrete products, cut stone, dental equipment and supplies, flat glass and other glass products, hydraulic fracturing, iron foundries, jewelry, mineral processing, mineral wool, non-ferrous sand casting foundries, non-sand casting foundries, ferrous sand casting foundries, paint and coatings, porcelain enameling, pottery, ready-mix

concrete, refractories, refractory repair, shipyards, and structural clay. Collectively, the NAM has members in each of the 24 manufacturing industry subsectors, and all of them would be affected by the proposed standard.

It should be noted that, in the limited time we had to review the volumes of detailed information related to the proposal, we discovered that several NAM members have NAICS codes that OSHA did not include in the 24 subsectors listed, although these manufacturers know their employees work with RCS. Based on this finding, it is clear that the data and estimates contained in the PEA are incomplete and fundamentally flawed.

In addition, virtually every manufacturing facility, if not directly impacted because it is within these 24 subsectors, has undergone and will continue to undergo maintenance, construction, or equipment or utility installation that would potentially involve exposure to RCS. Many of these tasks will be performed by employees of the manufacturing facility. Even if these tasks are performed by outside contractors, there are several likely scenarios under which employees of the manufacturing facility would be exposed to RCS. First, many contractor activities will be subject to supervision by employees of the manufacturing facility (host employer) in its role as the general contractor. Second, many contractor activities will require the ongoing support of employees of the manufacturing facility. Third, many contractor activities are likely to be performed in the same area where the host employer's employees are working. We have not been able to identify any recognition, much less discussion or analysis, of these activities in the PEA. Again, based on this fundamental flaw, we believe the data and estimates contained in the PEA are wholly inadequate.

Thus, nearly every manufacturing employer will incur costs associated at least with assessing potential exposure from tasks that are nominally covered by the proposed standard, but for which OSHA has not shown that there is a significant risk of material impairment of health or functional capacity. The NAM is not commenting on the risk assessment OSHA has published *per se*, and believes the comments of the American Chemistry Council's (ACC) Silica Panel and of the U.S. Chamber of Commerce clearly state the problems with OSHA's analysis.

Rather, the NAM questions OSHA's assertion that there is a significant risk of material adverse health effects from RCS exposure based on extrapolations from studies of occupations

where substantial exposure has occurred in the past, to those occupations where exposure to RCS occurs infrequently and at low levels. As OSHA states, it is cumulative exposure to RCS that determines the degree of risk. It follows that OSHA must show by scientific evidence that conditions in the manufacturing industries produce RCS exposures of sufficient magnitude and for a sufficiently long period of time to warrant the additional steps OSHA proposes to impose wherever some potential for exposure to RCS occurs. The NAM does not believe OSHA has validated its assertions on this point.

The NAM recommends that OSHA withdraw the proposed rule on the ground that OSHA has failed to establish that there is a significant risk at exposure levels below the current PEL, or that the proposed rule is technically or economically feasible. The NAM believes that this is the standard Congress established for OSHA to show that its proposed regulatory scheme is "reasonably necessary and appropriate." In the alternative, the NAM recommends that OSHA maintain the existing PEL of 100 ug/m^3 and limit the application of the ancillary provisions of the proposed standard to those tasks and activities for which exposures exceed the current PEL. The basis for our conclusions is set forth in more detail below.

I. THE LEGAL CRITERIA REQUIRED TO SUSTAIN AN OCCUPATIONAL SAFETY AND HEALTH STANDARD

OSHA is generally authorized to adopt occupational safety and health standards, as defined in § 3(8) of the Occupational Safety and Health Act (OSH Act), in accordance with the procedures and criteria in § 6(b) of the OSH Act. We say "generally" because the exercise of that authority is also subject to the Administrative Procedure Act, the Paperwork Reduction Act, the Regulatory Flexibility Act, the Federal Register Act, Executive Order 12866, the Small Business Regulatory Enforcement and Fairness Act, and the U.S. Constitution.

Section 3(8) of the OSH Act defines the term "occupational safety and health standard" as follows:

> The term "occupational safety and health standard" means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, *reasonably necessary or appropriate* to

provide safe or healthful employment and places of employment. [Emphasis added.]

Generally, to sustain a standard on judicial review as being reasonably necessary or appropriate, OSHA must demonstrate the following:[1]

- Current workplace exposure levels to the identified hazards must pose a significant risk of harm to employees.[2]

- The proposed requirements must significantly or materially reduce the workplace risk to employees posed by those identified hazards.[3]

- The proposed requirements must be technically and economically feasible[4] and within the bounds of what is reasonable for each affected industrial sector.[5]

- The proposed requirements must be the most cost-effective approach for achieving the reduction in risk posed by that identified hazard.[6]

In the case of health standards proposed to address toxic substances, a proposed standard must, *to the extent technically and economically feasible*, reduce workplace exposures to a level below that which presents a significant risk of material impairment of health or functional capacity to employees. [Emphasis added].[7]

In addition to the foregoing statutory criteria, OSHA must also satisfy the following requirements:

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[1] See Control of Hazardous Energy Sources, Supplemental Statement of Reasons, 58 Fed. Reg. 16612, 16614, cols. 2 and 3 (March 30, 1993), upheld in International Union, UAW v. Occupational Safety and Health Administration U.S. Department of Labor, 37 F.3d 665 (D.C. Cir. 1994) (Lockout/Tagout III).

[2] Industrial Union Department, AFL-CIO v. American Petroleum Institute et al., 448 U.S. 607, 100 S.Ct. 2844 (1980); AFL-CIO v. OSHA, 965 F.2d 962, 973 - 975 (11th Cir. 1992).

[3] *Id.*

[4] *Id.*

[5] American Federation of Labor and Congress of Industrial Organizations v. OSHA, 965 F.2d 962 (11th Cir. 1992) (PELs), ADA v. Secretary of Labor, 965 F.2d 962 (7th Cir. 1992) (Bloodborne Pathogens).

[6] American Textile Mfrs. Inst. v. Donovan, 452 U.S. 490 at 514 (1981).

[7] Industrial Union Department, supra.

- OSHA's determinations must be supported by substantial evidence in the record taken as a whole.[8]

- OSHA's findings and decisions must be made on the basis of the best available evidence.[9] OSHA's cost estimates and demonstration of economic feasibility must be based on reasonable and reliable economic analyses[10], using the best available scientific evidence.

- The rule making must be conducted in accordance with applicable legal procedures so as to provide adequate notice and an opportunity for participation by interested parties.[11]

- OSHA must demonstrate that the Agency is fully aware of the present and future environmental impact of the proposed rule.[12]

Executive Order (EO) No. 12866, titled "Regulatory Planning and Review", sets forth the guidelines that OSHA and other executive branch agencies must follow when seeking to adopt new rules.[13] These guidelines include the following:

- When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

[8] OSH Act § 6(f), 29 U.S.C. § 655(f).

[9] OSH Act §§ 6(b)(5), 6(f), 29 U.S.C. § 655(b)(5), 655(f); Executive Order 12866, Section 1(b)(7).

[10] American Textile Mfrs. Inst., 452 U.S. at 514.

[11] OSH Act § 6(b), 29 U.S.C. §655(b)(1); Administrative Procedure Act Section 553(b), 5 U.S.C. § 553(b); U.S. Const., 5th Amend.

[12] National Environmental Policy Act (NEPA) of 1969, 42 U.S.C. § 4321 *et seq*.

[13] Exec. Order No. 12866, 58 Fed. Reg. 51735 (October 4, 1993).

- Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

- Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

- Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

- Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

- Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

Further, pursuant to the Data Quality Act,[14] Congress directed the Office of Management and Budget (OMB) to issue government-wide guidelines (and each covered agency to adopt conforming guidelines) for ensuring and maximizing the quality, objectivity, utility and integrity of information distributed by Federal agencies.[15] To ensure accurate, reliable and unbiased information in a scientific, financial or statistical context – as is this case – the original and

[14] to P.L. 106-554, (Dec. 21, 2000) (published at 44 U.S.C. § 3516).

[15] Pub. L. No. 106-554. In that document and the Department of Labor's Data Quality Guidelines, the term "quality" encompasses "objectivity", "utility" and "integrity." The term "utility" refers to the usefulness of the information to its intended users, which in this case would be primarily OSHA, the employer community and the employee community. The term "objectivity" means the information is (a) accurate, reliable and unbiased, and (b) presented in an accurate, clear, complete and unbiased manner with transparent documentation to the source (subject to confidentiality protections that we do not believe are present in this case). The term "integrity" means the information is protected from unauthorized access or revision.

supporting data must be generated and the analytical results developed using sound statistical and research methods. Where the information is "influential scientific, financial or statistical information" – information that will or does have a clear and substantial impact on important public policies or private sector decisions – as would be the case in an OSHA rulemaking, it is subject to stricter quality standards that would facilitate reproducibility by qualified third parties.

Based on the application of the aforementioned legal requirements to OSHA's proposed rule, the NAM concludes the proposed rule fails to meet those requirements and should be withdrawn. Should OSHA elect to adopt some or all of the proposed ancillary provisions, the NAM believes they could only be applied to exposures above the current PEL, and offers suggestions for addressing deficiencies in those provisions.

II. THE SIGNIFICANT RISK AND REDUCTION IN RISK REQUIREMENTS

The NAM supports the basic approach of the comprehensive comments on OSHA's health effects analyses and risk assessments for RCS filed in this proceeding by the U.S. Chamber of Commerce and American Chemistry Council's (ACC) Silica Panel (Silica Panel). Our comments will not be addressing those aspects of the significant risk issue as they relate specifically to RCS in these comments. Rather, the NAM will focus on considerations indicating that OSHA has not adequately evaluated the risk presented by exposure to RCS and has improperly extended coverage of the proposed standard beyond those industries and occupations where exposure to uncontrolled RCS presents a significant risk to health. The current standard provides an effective level of protection.[16]

Importantly, credit for this success goes to the employers who have worked over the last 75 years to control exposures to RCS in their workplaces. Whatever standard OSHA adopts, it is the efforts of employers and especially those responsible for safety and health practices in individual workplaces that deserve recognition for the changes that have resulted in such a dramatic drop in reported cases.

[16] 78 Fed. Reg. 56298 col. 2, stating "many of the deaths in the early part of the study period occurred among persons whose main exposure probably occurred before the introduction of national standards .established by OSHA and (MSHA)."

Without any justification, OSHA makes the assertion that surveillance data are insufficient for the analysis of residual risk associated with exposure to RCS and that such an analysis must be based on exposure-response data. But OSHA does not have any exposure-response data at exposures below the current PEL that show any risk of harm. In other words, rather than relying on real world evidence of residual risk from a very large exposed population, OSHA asserts that it should instead utilize theoretical models to estimate that risk based on extrapolation from the estimated risk at exposures that are far higher than the current PEL.

OSHA's analysis fails to give adequate credit to its own data showing that exposures to RCS continue to decline and that exposures in the recent past are far lower than the historical levels on which OSHA's models are based. The exposure-response relationship developed by OSHA for this purpose is based on generally unknown, roughly estimated and/or arbitrarily assumed exposures and data collected from outdated sampling methods that must be converted into a useful form through roughly estimated conversion factors. In taking this path, OSHA also ignores the data indicating that there is a threshold level of exposure below which there is no significant risk. At what point would the Agency concede that real world surveillance data from a very large exposed population is more persuasive than theoretical risk estimations based on a raft of academic assumptions? We believe the data has reached that point. We do not believe that OSHA's theoretical analysis is what Congress mandated when it required OSHA to rely on the "best available scientific evidence" to arrive at a finding of significant risk.

A. OSHA Has Arbitrarily Discounted Or Ignored Readily Available Data That Calls Into Question The Need For The Proposed Rule

Crystalline silica is one of the most common substances in the earth's crust. We believe OSHA is choosing to discount data readily available that would call into question the need for this proposed revision. For example, a study published by D.W. Porter, M. Barger, et. al asserts that fractured silica that has aged for weeks to months has long been known to pose less health risk than freshly fractured silica.[17] An analysis published by Susan E. Dudley and Andrew P.

[17] See Morris & Dudley at 278, citing Castranova, V., et al., *Enhanced Pulmonary Response to the Inhalation of Freshly Fractured Silica as Compared to Aged Dust Exposure,* 11 Applied Occupational & Envt. Hygiene 937 (1996); Castranova et al., *Role of Surface Free in the Pagogenicity of Silicosis in Silica and Silica-Induced Lung Disesases* 91 (1996); Vallyathan et al., *Freshly Fractured Quartz Inhalation Leads to Enhanced Lung Injury and Inflammation,* 152 Am. J. Critical Care Med. 1003 (1995).

Morriss asserts that, despite substantial evidence that the toxicity of RCS varies substantially with the form of the chemical, the proposed standard would regulate all workplace exposures to RCS according to the same set of requirements. OSHA must first demonstrate that all exposures to RCS that OSHA proposes to regulate present a significant risk over a worker's working lifetime and that the universally applicable requirements are reasonably necessary and appropriate to control the risk from exposure to each form of RCS.

Yet OSHA declines to use this information in forming its risk assessment, saying "OSHA preliminarily concludes that it is not yet possible to use available information on factors that mediate the potency of silica to refine available quantitative estimates of the lung cancer and silicosis mortality risks." The NAM questions whether OSHA's risk assessment represents the "best available scientific evidence" if OSHA disregards what it admits is probative information relevant to the scientific questions.

There are other examples where OSHA chooses to rely on data or studies that support its position while discounting others that contradict or undermine OSHA's conclusions. We do not believe that this approach is permissible under the Congressional directive to examine the evidence and to base its decision on "substantive evidence in the record taken as a whole." [18] The agency may not rely on selective data that supports its position and simply discount or disregard other relevant evidence in the record. Otherwise, the phrase "in the record taken as a whole" has no meaning.

We believe the quoted language should be interpreted to require OSHA to take what is today called a "weight of evidence" approach.[19] Here, that means OSHA cannot simply dismiss studies that it finds unpersuasive, but must search for all available data, as OSHA would require of classifiers of hazardous chemicals under its Hazard Communication Standard, and formulate an assessment that most adequately takes into account all of the available information. Some evidence will be more persuasive than other evidence due to limitations in methodology, data, or

[18] OSH Act § 6(f), 29 U.S.C. § 655(f).

[19] OSHA adopted the weight of the evidence approach in the changes to the Hazard Communication Standard it adopted in 2012. See 77 Fed.Reg 17574, March 26, 2012, p. 17706; see also, Krimsky, S, The Weight of Scientific Evidence in Policy and Law, Am. . Pub. Health, 2005;95:S129-136 doi: 120.2105/AJPN.2004.044727, accessed January 29, 2014; http://www.mass.gov/eopss/docs/dfs/osfm/boards/specific-meetings/j-fleming/krimskyweightevidence.pdf

any of numerous other factors that affect the quality and reliability of scientific data. We believe OSHA's current approach fails to meet this test and, therefore, is not consistent with its statutory mandate. The following summarize some of the additional facts that suggest OSHA's approach is inadequate.

III. Technical Feasibility

A. Feasibility Of Control Measures

As the NAM collects additional data from its members, it expects to have more extensive information to share with OSHA. However, as mentioned earlier in connection with our requests for additional time to develop these comments, the NAM has repeatedly advised OSHA that we have not been given sufficient time to gather information from members to provide a systematic analysis of the economic and technical feasibility issues related to the proposed rule. The NAM is surveying its members about the cost and feasibility of each section of OSHA's proposal. Unfortunately, due to the compressed calendar and holidays, we are still collecting responses. We hope to have more information available to present at the planned hearings in March.

Manufacturers generally may have employees with potential RCS exposures if maintenance and modifications to the physical facilities involve tasks where silica-containing building materials or structures have to be modified to make necessary changes. The tasks involved include drilling with hand-held tools, drywall finishing, and using tools like jackhammers and concrete saws, among others. The NAM endorses the comments of the Construction Industry Safety Coalition (CISC) on the technical feasibility of OSHA's proposed controls. Because manufacturers represented by the NAM will have employees only infrequently and sporadically involved in projects with potential RCS exposure, adopting the controls OSHA proposes will have minimal benefit because of the minimal risk such tasks involve. The NAM believes that the CISC has demonstrated the lack of feasibility for controlling these exposures.

Among the manufacturers who responded to the survey so far are some of our foundry members. These foundries are directly affected by every provision of the proposed standard. The comments filed by the American Foundry Society (AFS) demonstrate the infeasibility of the proposed PEL for the foundry industry and that OSHA has only superficially examined the experience of the industry in attempting to meet the existing PEL. Because the foundry industry

has been a focus of attention when it comes to crystalline silica, the fact that OSHA's technical feasibility conclusions as to the proposed PEL are unfounded and so far off the mark with respect to foundries suggests that OSHA's general conclusions on the feasibility of the proposed PEL are also unfounded. We briefly recount some of the pertinent facts related to this issue.

OSHA's technical feasibility analysis for foundries is purportedly based, in large part, on the outcomes of enforcement investigations of a number of foundries that resulted in citations for alleged violations of the current PEL and settlement agreements. Contrary to OSHA's assertions, those settlement agreements demonstrate OSHA's recognition and acknowledgement that it is infeasible for those foundries to achieve continued compliance with the current PEL, much less the proposed PEL, through the implementation of traditional engineering controls. Rather than acknowledging the substance of those settlements, OSHA relied on a single set of samples taken from one non-representative foundry that apparently had been able to control exposures to a lower level for the tasks that were sampled, and asserted they were representative of all tasks and activities performed by the entire industry. We strongly support the AFS position that a single set of samples from one foundry lacks any statistical significance for that facility, much less the entire industry, and reliance on a single set of samples from one foundry to represent continuing exposures for the entire industry is clearly inadequate under the "best available evidence" standard.

The NAM Believes OSHA has not accurately considered the difficulties in complying with the PEL solely through engineering controls, especially with regard to maintenance activities. We received the following comment from one member:

> "Exceedences of the PEL can and do occur in our facilities especially involving maintenance and/or cleaning activities. There are occasional conditions where maintenance cleaning is performed inside conveyor enclosures where the enclosure is ordinarily a part of the dust control systems. This is just one example of where a control would have to be breached in order to properly maintain it as well as the operating equipment. It is simply not technically feasible to establish engineering controls for all possible maintenance activities. There has to be allowances for upset conditions where maintenance and cleaning of systems is required. Respirators must be allowed for such

periods. Even the engineering controls themselves require maintenance and cleaning periodically. It is especially not feasible to have engineering controls FOR the engineering controls. Maintenance activities in all of our sand/batch handling systems have to be performed quite regularly due to the abrasive and corrosive nature of the silica itself and other materials in the process."

Proposed Paragraph (f)(3)(i) specifically require HEPA filtered vacuums. This would seem to disallow any other technology. Many glass batch houses are currently equipped with central vacuum systems that discharge external to the facility and are EPA permitted as a discharge. This would seem to be equivalent, in terms of worker exposure control, to a HEPA Vacuum and should be allowed by the new standard.

As proposed, the rule making would prohibit the use of compressed air to clean surfaces and equipment. There is some equipment that needs to be cleaned where other methods just are not effective, for example in batch houses, for scales and weighing equipment. While the NAM agrees that use of compressed air can contribute to RCS exposures, employers need the flexibility where it is necessary to clean equipment in specific, space restricted applications. Employers are in a better position to judge whether the benefits of not using compressed air exceed the costs of more difficulty in accomplishing a task that is OSHA or its contractors. The presumption should be that the employer's judgment is to be accorded deference unless OSHA can show that an alternative method is at least as effective as the use of compressed air.

B. Accuracy Of RCS Sampling And Analytical Techniques

In question 47, OSHA asked for comments on its assessment of the available sampling and analytical techniques for measuring exposure to RCS, especially at the proposed PEL and action level.

To assess compliance with the proposed PEL and action level, OSHA would have employers arrange for sampling and analysis in accordance with OSHA Method ID-142, described at https://www.osha.gov/dts/sltc/methods/inorganic/id142/id142.html. According to the OSHA web site, that method has an "overall analytical error" of +/- 26 percent and has been validated for a working range of 50 to 160 ug with a recommended sampling rate of 1.7 liters/minute, which results in a total volume of 816 liters over 8 hours. *Id.* In OSHA's preamble

discussion of analytical accuracy, OSHA states that the method has a precision error of +/- 23 percent at a working range of 50 to 160 ug, and a sampling and analytical error (SAE) of +/- 19 percent.[20] OSHA adds to the confusion by failing to explain the relationship between an "overall analytical error" of +/- 26 percent and the combination of a precision error of +/- 23percent and an SAE of +/- 19 percent. Although the agency does not acknowledge the problem, a sample of 50 ug (the bottom of the working range that has been validated for Method ID-142), yields an exposure level of 61 ug/m3. In other words, to achieve the PEL, Method ID-142 must be applied to a quantity of RCS smaller than the smallest amount for which the method has been validated. The agency then states, without explanation:

> OSHA's Salt Lake Technical Center (SLTC) evaluated the precision of ID-142 at lower filter loadings and has shown an acceptable level of precision is achieved at filter loadings of approximately 40 µg and 20 µg corresponding to the amounts collected from full-shift sampling at the proposed PEL and action level, respectively. This analysis showed that at filter loadings corresponding to the proposed PEL, the precision and SAE for quartz are ±17 and ±14 percent, respectively.

Without any foundation or basis, OSHA then also asserts that "employers can be virtually certain that the PEL is not exceeded where exposures are less than 43 µg/m^3 which represents the lower 95-percent confidence limit."

This statement is misleading. In other words, if all error other than SAE was eliminated, and SAE was 14% rather than 19%, then a test result of 43 ug/m^3 would indicate an actual exposure of between 36 and 50 ug/m3. But all other error cannot be eliminated. Even if all other error could be eliminated, OSHA is now acknowledging that the employer would have to reliably control exposure levels to 43 ug/m^3, which is 7 ug/m^3 below the proposed PEL, to be confident the PEL is not exceeded. But OSHA has already acknowledged a PEL of less than 50 ug/m^3 is technically infeasible.

[20] 78 Fed. Reg. 56,274, 56,354 (September 12, 2013).

Furthermore, OSHA's conclusion that the employer could be confident of complying with the PEL by reducing exposure levels to 43 ug/m^3 ignores the precision error. If the officially stated "overall analytical error" of 26% is applied, the employer would need to control exposures to 37 ug/m^3 rather than 43 ug/m^3 to be confident the PEL would not be exceeded! But, and this bears repeating, OSHA has already acknowledged a PEL of less than 50 ug/m^3 is technically infeasible.

Under the logic of OSHA's preamble analysis, OSHA is not proposing a PEL of 50 ug/m^3, but a PEL of 37 ug/m^3. OSHA acknowledged that a PEL of less than 50 ug/m^3 is technically infeasible, which means the proposed rule is technically infeasible.

OSHA may assert that this shortcoming can be cured by taking a sufficient number of samples to get a statistically reliable average that demonstrates compliance with the PEL, but this approach has problems that have not been considered. First, OSHA has not acknowledged that it would accept that approach to compliance. Second, such an approach would likely be both technically and economically infeasible for employers and infeasible for OSHA to enforce. To demonstrate results meeting the 95 percent confidence limit, we believe it would be necessary to take 20 or more samples under substantially identical conditions. It is infeasible to place more than two samplers on a single worker at the same time – one on each collar, because the samples will not be duplicating the exposure measurements. Even with two, the sample results can differ depending on the activities of the employee. To obtain 20 samples, it would be necessary to place two samplers (one on each collar) on the same employee every day for two (5-day) work weeks. Under this approach, the demand for sampling devices would be 20 times the OSHA estimate, the cost of the lab analyses would be 20 times OSHA's estimate, and the fees of the highly compensated industrial hygienists (who would be performing sample collection at the site 10 times instead of once and analyzing the results of those additional test results) would be 10 times OSHA's estimate (if there were enough industrial hygienists in the US to meet this demand). For infrequently performed maintenance or construction tasks, it would be impossible to obtain the number of samples necessary for the employer to establish a statistical average.

OSHA well knows that occupational exposures are not distributed on a normal bell curve. Leidel and Busch more than 35 years ago showed that the higher the variability of the combined

sampling and analytical method, the greater the difference between the measured exposure that the standard that has to exist to be confident that OSHA's measurements will agree.[21] In those early days, the action level was set at 50 percent of the PEL, in part because of these measurement difficulties. Because employers could not be sure that exposure measurements above those levels were not simply statistical anomalies when the true exposure is about the PEL, OSHA established the action level concept and required employers to begin with the ancillary provisions at the action level. The idea that a residual risk exists below the PEL that warrants the imposition of the ancillary provisions was unproven then, and we believe remains so now. Simply stating that a risk exists below the PEL that OSHA considers it significant, and that OSHA believes the ancillary provisions will significantly reduce that risk does not meet the Supreme Court standard set in the Benzene decision.

Even if it was technically and economically feasible for an employer to obtain the measurements required to establish this average exposure level, it would be impossible for OSHA to duplicate that effort in the course of its enforcement investigations. Furthermore, this incredibly burdensome monitoring procedure would not be required solely for the initial assessment, but for each quarterly or semiannual periodic monitoring measurement. Finally, given the burdens imposed by all of the other ancillary requirements that would be triggered by an exposure level in excess of the PEL, it would be unreasonable to have those requirements triggered by a technically and economically infeasible testing regime. In other words, OSHA has demonstrated that measurement of exposures at the proposed PEL and AL cannot be reliably performed to demonstrate compliance with the proposed PEL and AL, and that compliance with the proposed PEL is technically and economically infeasible. OSHA has not discussed the other methods NIOSH has reviewed and for which NIOSH provided statistical analyses of their performance. OSHA needs to demonstrate that these methods are inferior to the proposed method before requiring laboratories and the regulated community to substitute what appears to be an inadequate technique.

[21] Occupational Expo Sure Sampling Strategy Manual, Leidel, N.A., Busch, K.A., and Lynch, J.R.; U.S. Department Of Health, Education, And Welfare, Public Health Service, Center for Disease Control , National Institute for Occupational Safety and Health, Cincinnati, Ohio 45226, Pub. No. 77-173.

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Finally, OSHA ignores the intellectual inconsistency of relying on reported data with sampling results well below what OSHA acknowledges is the limit of detection for the method used. If the limit of detection is, as we believe is shown by well-known data, approximately 50 $\mu g/m^3$, then how can OSHA rely on data purporting to show that exposures are below 30? OSHA's technical feasibility analyses are replete with references to measurements below the detection limit, which OSHA argues show that compliance is feasible. If the results on which OSHA relies are unreliable, how can they be used to support OSHA's position?

If and when technical advances reduce the overall analytical error of the testing methods to a nominal level, and OSHA is able to demonstrate the need for a reduced PEL, we believe it would be essential for OSHA to establish a flexible compliance and enforcement procedure that accommodates the potential for some day-to-day variability in actual exposures. For example, if OSHA's measurements vary from the employer's consistently obtained results, the proper approach would be for OSHA to statistically analyze the available data and determine whether the employer's data represent a more accurate assessment of the exposures. If the employer has correctly monitored the exposure, then OSHA should rely upon the employer's measurements on the basis that the employer's multiple readings more accurately represent the exposures than a single day's assessment that is typical of an OSHA inspection.

C. OSHA's Analysis Neglects The Costs And Delays Likely To Be Encountered By Employers Who Are Required To Adopt Increased Ventilation As A Control Measure Due To Environmental Air Quality Permitting Requirements

OSHA's primary reliance on engineering controls means employers will necessarily rely on increasing the amount of ventilation and air movement to reduce the amount of RCS in the workplace. OSHA's analysis suggests that simply increasing ventilation rates will control exposures, but the law of diminishing returns means that the increase in the quantities of air to be moved, cleaned, and replaced will increase exponentially. Those changes in volume and the increased number of vents that exhaust respirable crystalline silica particulates into the outdoor environment will likely require employers to update federal, state or local environmental air emission permits. In addition, they will result in greatly increased energy costs for the heating and cooling of these huge volumes of additional air.

Air quality permits take considerable time and monetary resources to obtain and modify. Because of the requirements for public input on Clean Air Act permits, we can anticipate that OSHA's implementation time frame is too short, possibly by three to five years or more. Simply obtaining the necessary installation and operating permits on an expedited basis can take six months or more. For example, Ohio has an Air Permit-to-Install and Operate Program that has a statutory time frame for issuing the permit of 180 days.[22] The agency review period does not include the time to (1) determine what if any changes are necessary that will require modifications to the air and operating permits of a facility, (2) design the changes, (3) prepare the appropriate documents, and (4) submit the application. The NAM has not found an analysis in OSHA's PEA in which OSHA accounts for these requirements. Nor does OSHA account for the need and cost to participate in the public review process or for possible extensions if there is significant public opposition or comment. OSHA should (1) modify its PEA to account for these costs (they can be substantial and thus significant) and (2) modify the implementation period to account for these kinds of requirements. Otherwise, OSHA may find itself inundated with requests for temporary variances authorized under Section 6(b)6(A) of the OSH Act and the requirements in 29 CFR 1905.10 to cover contingencies over which neither OSHA nor the employer will have control.

D. The Proposed Requirement To Use Engineering and Work Practice Controls Even When They Will Not Reduce Exposure To Or Below The PEL Should Be Eliminated

1. Overview

In developing the proposed rule, OSHA has established a hierarchy of controls familiar to other OSHA standards involving airborne health hazards. Specifically, OSHA requires that an employer bring exposure levels below the PEL through a range of complex and intensively expensive engineering controls such as the use of wet assisted dust suppression equipment, vacuum assisted equipment, and ventilation systems.[23] As discussed below, manufacturers can spend millions of dollars on ventilation systems, often only to discover afterwards that these

[22] Ohio EPA, Division of Air Pollution Control, Air Permit-to-Install and Operate Program Fact Sheet, May, 2013. http://www.epa.ohio.gov/portals/27/permits/PTIOfactsheet.pdf

[23] Proposed §1910.1053(f) at 78 Fed. Reg. 56489; see also proposed Table 1 at 78 Fed. Reg. 56496.

costly infrastructure expenses resulted in little or no appreciable gains in controlling silica exposures.

OSHA proposes that: a) wherever feasible, the employer should use engineering and work practice controls; and b) where engineering and work practice controls do not reduce exposures to or below the PEL, the employer shall use them to reduce exposures to the extent feasible and supplement those measures with respiratory protection. [24] This provision is based on a policy adopted as a good industrial hygiene practice before OSHA was created, and while OSHA attempts to justify its continued inclusion in every substance-specific health standard, OSHA's analysis fails for several reasons, which are explained in the next section of these comments.

In addition to engineering controls, OSHA permits work practice controls; however it prohibits the use of job rotation that is implemented strictly for the purposes of reducing exposure to RCS. This is without justification and ignores the wide body of evidence that reducing the cumulative exposure in this manner will concomitantly reduce incidences of silicosis and other silica related diseases.

Finally, OSHA would prohibit reliance on respiratory protection as the primary method of controlling exposure to RCS even when feasible engineering controls and work practices would not achieve compliance with the PEL. OSHA would allow reliance on respiratory protection only in four types of situations: when engineering controls are not feasible, while the employer is developing and installing engineering controls, when engineering or work practice controls are implemented but not sufficient by themselves to achieve an exposure level below the PEL, when the employee is in a regulated area or in an area where respirator use is required under an access control plan.[25]

2. The Proposed Rule Improperly Dismisses Respirator Use As A Suitable And Most Cost-Effective Approach To Managing Exposure

The basis for OSHA's antagonism to respirator use as a primary method of exposure management is outdated and premised upon outdated respirator designs that are no longer in use.

[24] Proposed § 1910.1053(g) at 78 Fed. Reg. 56489.

[25] Proposed standard at § 1926.1053(g), 78 Fed. Reg. 56499-500.

OSHA believes that respirators are not foolproof because they require that employees properly select and continuously use respirators, and that employees properly maintain respirators and timely replace respirator filters. [26]

OSHA asserts, without submitting or relying upon any evidence, that respirators, in order to be effective, must be individually selected, fitted, and periodically refitted, conscientiously and properly worn, and regularly maintained and replaced as necessary.[27] OSHA also opines that in "some difficult or dangerous jobs," respirators "limit vision and communication."

However, these are the same concerns that attend engineering controls and work practice controls. The proper use of ventilation systems requires ongoing, expensive inspection and maintenance in order to be effective. HEPA filtration on ventilation systems or on vacuum assisted tools must be regularly maintained and replaced. Wet- and vacuum-assisted devices must be used conscientiously and properly in order to be effective; they also have to be maintained to achieve optimal performance. Engineering controls also contribute background noise to the work environment, potentially increasing the noise levels in the affected workplace. To prevent these potential noise sources from creating significant hazards, employers would have to purchase and possibly design more expensive systems that would avoid or control that noise. OSHA does not appear to have taken this potential cost into account in its economic analysis.

However, respirators alone enjoy the distinction of being portable, readily available, capable of immediate implementation and a highly cost-effective solution to RCS exposure. While OSHA facially asserts that it "does not believe that respirators provide employees with a level of protection that is equivalent to engineering controls,"[28] the reality is that respirators offer superior protection when ambient concentrations of a contaminant are within expected ranges because they will reduce exposures below the PEL.

[26] See, e.g. 78 Fed. Reg. at 56467, col. 1, "They reflect the Agency's determination…that respirators are inherently less reliable than engineering and work practice controls in reducing employee exposure to respirable crystalline silica."

[27] 78 Fed. Reg. at 56542-543.

[28] 78 Fed. Reg. 56543 col. 1.

Astoundingly, OSHA has neglected one of the most cost effective methods for managing RCS exposure. This is unfortunate since, intuitively, the manufacturing community will most broadly adopt the compliance method that is the quickest to implement, easiest to manage and monitor and most cost effective among equally effective alternatives.

NAM notes that the quality and efficacy of respirators has improved dramatically over the last 40 years. Respirator manufacturers are consistently improving the technology to assure better fitting and more reliable devices. OSHA has not taken these improvements into account.

An example is the development of the powered air-purifying respirators attached to helmets that provide clean air effectively and with less potential for inadequate fit or efficacy. OSHA has not considered information that is publicly available about these air helmet devices, among others, and the effective and less costly alternative that they provide.

Further, the requirement to incorporate "all" feasible engineering and administrative controls is an unbounded requirement that OSHA needs to revise, because employers will never know when they are in compliance. This creates unnecessary confusion and uncertainty and represents poor public policy. OSHA should endeavor to make its requirements clear and base them on objective criteria so that employers know exactly what is required. Moreover, because the proposed requirements become increasingly expensive and provide reduced benefit as controls are added to the regime, they will become economically infeasible[29] and will exceed the bounds of what is reasonable for each affected industrial sector.[30]

In adopting the PELs for chromium and cadmium, OSHA determined that it would be infeasible to for employers engaged in certain activities to comply with the PEL solely with engineering controls and work practices. OSHA determined the lowest exposure levels that could be achieved with engineering controls and work practices, established a Separate Engineering Control Air Limit (SECAL) at those levels for those activities, and allowed the employers to rely

[29] *Id.*

[30] American Federation of Labor and Congress of Industrial Organizations v. OSHA, 965 F.2d 962 (11th Cir. 1992) (PELs), ADA v. Secretary of Labor, 61 USLW 2459, 15 O.S.H. cas. (BNA) 2097, 61 USCW 2459 (7th Cir. 1992) (Bloodborne Pathogens) 965 F.2d 962 (1992)

on respirators to reduce exposures from the SECAL to the PEL. Thus, respirators are routinely being used to reduce exposures to hazardous chemicals.

OSHA's approach in this regard lacks common sense. Use of respirators can be as effective as engineering controls because engineering controls are subject to the same limitations as respirators. They require that employees use them properly and they require maintenance to maintain efficiency and efficacy at acceptable levels. They have limited ability to reduce exposures well below the PEL. Allowing respirators to be used up when the ambient concentrations are below a specified level can result in greater protection, because the resulting exposure will be below the PEL by some greater margin.

OSHA could allow the use of respirators as an alternative when engineering controls reduce exposures to, for example, the general respirable dust PEL of 5 mg/m^3, which is consistent with OSHA's current PEL for general respirable dust exposure. This would mean that a person would be able to use respirators that provided a protection factor of 100 to achieve compliance. If respirable dust exposures were below 5 mg/m^3 or the protection factor of the respirator was above 100, employees would receive additional protection. In addition, the benefit of respirator use would be significant and employee acceptance of overall practices and procedures for compliance would be improved, because the required use of the respirator would reinforce the potential risks and emphasize the need for employees to follow all related procedures.

OSHA should adopt language such as the following to allow respirators to be used when exposures are below a specified level:

> Where airborne exposures to RCS on a time-weighted-average basis are below XX milligrams per cubic meter, employers may require the use of respirators in accordance with the requirements of 1910.134. Where exposures exceed this level, employers are required to adopt engineering and administrative controls to reduce exposures.

OSHA could establish a maximum number of days per year when respirators can be used in place of engineering controls. If OSHA decides to adopt this approach on a frequency- and

duration-limited basis, the NAM recommends that OSHA allow this approach when exposures of less than a specified number of hours per day occurs on less than a specified percentage of assigned work days. For a typical 8-hour, 5-day, 40-hour work week, respirators would be allowed as the primary means of protection if the number days of exposure in a year exceeded the specified number of working days per year, and would lower the cost of compliance.

E. OSHA Should Adopt The Most Cost-Effective Approach For Monitoring

In making these comments on the ancillary provisions, the NAM wishes to be clear that it does not believe OSHA has demonstrated the need for a reduced PEL or that the proposed PEL is technically or economically feasible. Accordingly, the NAM does not believe the following comments should apply except in two scenarios: (1) if and when technical advances reduce the overall analytical error of the testing methods to a nominal level, and OSHA is able to demonstrate the need for a reduced PEL, or (2) if OSHA elects to adopt the proposed auxiliary provisions and tie their application to exposures above the current PEL. Nevertheless, these comments apply to any consideration given by OSHA to adopting any of the proposed ancillary provisions.

1. OSHA's Standard Should Permit Reliance On Any Reliable And Representative Sampling Data To Establish Initial And Continuing Exposure Levels

OSHA proposes that exposure assessments be based on recent monitoring data at the site or "objective data." OSHA proposes to define "objective data" as information such as either air monitoring data from industry-wide surveys or calculations establishing a maximum employee exposure based on the composition and chemical and/or physical properties of the subject chemical. This requirement is apparently designed to provide employers with some flexibility in relying on existing information to make initial exposure assessments rather than performing exposure monitoring to make every initial exposure assessment. While we support the underlying concept of providing flexibility, we believe the options offered by the draft proposal are unnecessarily limited.

We believe that a more flexible approach, which permits the use of any existing or historical data that provides a reasonably accurate estimate of ambient exposures, will achieve the same result in a far more cost-effective manner. Exposure data does not need to derive from

"industry-wide surveys" in order to be reliable. Rather, any data that was developed in a manner that shows it is reliable, regardless of the age of the data, should be sufficient provided that it is adequately representative of the particular environmental conditions, product, process, operation or activity for which it is being used. In short, the reliability and relevance of the data is the critical feature of being "objective data," and "industry-wide surveys or calculations" serve as an unduly burdensome proxy for reliability or relevance to the workplace conditions to which the data is applied. For the same reasons, as discussed below, there is no justification for limiting the use of an employer's survey data or any other data on which it wishes to rely, to that which has been collected within the last year.

OSHA should explicitly acknowledge that there are many reliable sources of objective data. Among them are: published scientific reports in the open scientific literature; NIOSH Health Hazard Evaluations; insurance carriers' loss prevention reports; information that the silica in a process cannot be released because it is bound in a matrix preventing formation of respirable particles; and others. Data collected and collated in a reproducible manner, from identified sources, using methods that are clearly explained should be allowed. The only question is whether the data can reliably predict employee exposures and whether they "reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations." If the employer can show the reliability of the data on which he or she relies and the relationship to the predicted exposures, that should be sufficient. The NAM urges OSHA to modify the language in this provision to establish criteria for reliability by adding the following to the paragraph defining objective data:

> "means information . . . demonstrating employee exposure or other such data as the employer may show reliably predicts employee exposure to RCS . . . ."

2. An Initial Exposure Assessment Need Only Be Reliable And Relevant, And OSHA Should Eliminate Language That Suggests Multiple Employees Must Be Monitored.

OSHA proposes that, in conducting exposure assessment, where several employees perform the same job tasks on the same shift and in the same work area, the employer may sample a "representative fraction" of these employees in order to meet this requirement, but that

representative sampling shall involve employees who are expected to have the highest exposure to respirable crystalline silica.[31] This proposed provision takes an unnecessarily narrow and burdensome approach to representative sampling. The only question is whether the data "reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations."

There is no justification for limiting representative sampling to sampling of the same shift and area. For maintenance and construction tasks performed in varying locations, that approach is infeasible and would inappropriately appear to preclude representative sampling. For repetitive tasks performed in a constant manufacturing environment, there would rarely be a reason to sample multiple areas and shifts. Rather than this specification approach to the issue, employers should be required to use professional judgment and be prepared to justify the path they have taken under a performance-based approach.

Furthermore, by referring to a "representative fraction," OSHA introduces unnecessary ambiguity and complexity into what should be stated in a clear and unambiguous manner, and provides for the most cost-effective approach. If multiple employees perform substantially the same job tasks under substantially the same conditions, regardless of whether they are performed on the same shift and in the same work area, it can therefore reasonably be concluded that their exposures are substantially the same, and the employer should be permitted to rely upon data derived from sampling one representative employee in that cohort. If one employee performs the task for eight hours and all of the others perform the task for six hours, the employer could choose to rely on the sampling results of the employee performing the task for eight hours as representative for all. Alternatively, the employer could elect to sample the employee performing the task for eight hours and one of the employees performing the task for six hours and treat the eight-hour result as representative of the exposures for the employees performing the task for six hours.

There is absolutely no reason to require that the employer sample a "representative fraction" of similarly exposed employees. The term "representative fraction" is impermissibly vague and completely unnecessary, and has no precedent in prior OSHA standards. An employer

[31] 78 Fed. Reg. 56487 col. 2, proposed standard § 1910.1053(d)(iii).

could not possibly know how many employees out of a group would need to be sampled in order to satisfy a future OSHA compliance officer as to what would be considered a representative fraction. Furthermore, we doubt OSHA's estimate of the impact of this provision on the cost of compliance would be anything more than gross speculation.

Consistent with the foregoing, the NAM recommends that OSHA change the language in the provision to read as follows:

> The employer shall determine the eight-hour TWA exposures on the basis of one or more samples that reflect the exposures of employees on each shift, for each job classification, in each work area. Where several employees perform substantially the same job tasks under substantially similar conditions, the employer may perform representative sampling instead of sampling all employees in order to meet this requirement. Where conditions are substantially similar on different shifts or in different areas, the employer may perform representative sampling that covers multiple shifts and areas. Representative sampling shall allow the exposures to be assessed of the employee(s) expected to have the highest exposures to respirable crystalline silica.

3. An Initial Exposure Assessment Need Not Be Based Upon Employee Monitoring Within One Year After the Effective Date Of the Final Rule In Order to Be Reliable and Relevant.

OSHA proposes that an employer conducting an initial exposure assessment may rely on existing data to satisfy the proposed standard's initial monitoring requirement only if the employer has monitored employee exposures in the twelve months prior to the effective date of the final rule.[32] It is not clear why OSHA believes that data more than 12 months old are somehow invalid. Absent changes in process or operations, an employee, or group of employees, who have performed substantially the same task in substantially the same operations and in substantially the same environment for years will predictably have similar exposures over the time period since the previous changes. OSHA in fact relies on such predictability in the epidemiological studies in its risk assessment. OSHA has offered no explanation why it believes data that are more than a year old are somehow unreliable in assessing exposure.

[32] 78 Fed. Reg. 56487 col. 2, proposed standard at §1053(d)(2)(ii).

Any exposure monitoring that has been performed under the same conditions in years past should be sufficient for the purposes of making an initial exposure assessment. OSHA's insistence upon new exposure monitoring following the effective date of the new rule is arbitrary and inconsistent given that OSHA permits an employer to rely upon industry wide surveys, which it includes within its definition of "objective data."[33] A requirement to perform new exposure monitoring simply because the previous monitoring was performed more than 12 months earlier increases compliance costs and the regulatory burden without benefit.

To permit the most cost-effective approach to compliance, OSHA should instead permit an employer to rely upon any monitoring data collected under conditions that closely resemble those currently prevailing, without regard to the date of the data, since the requirement that the conditions "closely resemble" currently prevailing conditions is in fact the best indicia of reliability.

In contrast to imposing this unnecessary requirement on employers, OSHA is relying on data that is sometimes decades old to establish its risk assessment. If such an assumption is appropriate for determining risk, it certainly makes sense the data would be sufficiently reliable to allow predictions of compliance today. OSHA should remove the time limit on data and require only that the employer be able to demonstrate that the data are reliable and representative in predicting employee exposure levels.

4. OSHA's Proposed Requirement That An Employer Conduct New Monitoring Every Three Months When Exposures Are Above The Proposed PEL Is Unduly Burdensome and Unnecessary

Where employers rely on ventilation or other engineering controls to maintain exposure levels below the PEL, exposure monitoring is not necessarily the most cost effective technique for monitoring performance of those systems. For example, current OSHA standards acknowledge that monitoring pressure drop or air velocities in spray booths can be used to determine if that system is operating within normal limits. Employers should have the flexibility to develop methods to assure that control systems are functioning properly, without the expense of air monitoring where it is not necessary. Furthermore, even if air monitoring is an appropriate

[33] 78 Fed. Reg. 56487 col. 1, at §1053(b).

check on the effectiveness of a control measure, it would not be necessary to perform monitoring on each shift or in each area to check control measures common to multiple shifts and areas.

OSHA has acknowledged that there will be a number of circumstances where it will not be feasible to achieve an exposure level at or below the proposed PEL.[34] For example, in settling a number of citations alleging violations of the PEL for RCS, OSHA has conceded that compliance with the current PEL is infeasible and permitted the employer to rely on respiratory protection in order to manage worker exposures.

OSHA nevertheless proposes that in these types of situations, where compliance with the current PEL is infeasible, the employer will be required to conduct periodic exposure monitoring at least every three months, which will simply confirm what is already known. The mere act of conducting monitoring does not reduce exposure and where environmental factors, practices and process, and operations have not changed; a periodic monitoring requirement would simply increase compliance costs for no apparent benefit. We propose that OSHA adopt a more reasonable and more flexible approach. Where the initial or subsequent exposure monitoring reveals that employee exposures exceed the PEL, an employer should be required to conduct repeat monitoring reasonably soon after an employer has implemented substantial changes in its operations, its engineering or work practice controls, or in its environmental conditions. If, after all feasible measures have been implemented, the exposure levels remain consistent and above the PEL for a year, periodic exposure measurements should no longer be required absent a change in circumstances. In the absence of any changes to any relevant circumstances, where it is infeasible to achieve the PEL, the repeated monitoring requirement would be nothing more than an unnecessary expense imposed on employers with workplace exposures above the PEL.

5. OSHA's Requirement That The Employer Use Laboratories That Are Accredited Under The ANS/ISO/IEC Standard 17025:2005 Is Not Reasonably Necessary Or Appropriate

OSHA proposes that an employer "ensure" that all samples are evaluated using one of six referenced procedures (apparently the most current version) and that its samples are sent to a laboratory that is accredited to ANS/ISO/IEC Standard 17025:2005 and compliant to ISO/IEC

[34] See, e.g. 78 Fed. Reg. 56286 col. 2, stating "OSHA has made a preliminary determination that compliance with the proposed PEL can be achieved *most* of the time through the use of engineering and work practice controls."

Standard 17011:2004.[35] It further proposes that the employer must use a laboratory that uses the most current National Institute of Standards and Technology (NIST) standards, implements an internal quality control program, and uses specific analytic methods.[36]

In proposed Section 1910.1053(d)(5)(ii), OSHA identified the specific ANSI and ISO laboratory accreditation standards that it would incorporate by reference into the proposed rule with their publication dates. Under the principles of due process established by the US Constitution, OSHA must similarly identify, preserve and make readily available in the identified form, the six analytical methods inadequately identified in proposed Section 1910.1053(d)(5)(i) and the applicable NIST standards. It is impermissible for OSHA to require compliance with the "most current" version of standards adopted by other entities and incorporated by reference. This is a well–established constitutional principle and it is disconcerting that we still need to remind OSHA of its obligation to follow it.

A proposed requirement on employers to *ensure* that samples are analyzed in accordance with a certain procedure and that labs meet these standards ignores the technical and economic realities of the relationship between the tens of thousands of establishments that work with a handful of laboratories. Most employers do not have the means to enforce compliance with these terms; at best, they can incorporate this requirement into their contracts with the labs. If these requirements are retained, the proposed language should be revised to read as follows: "(ii) The employer shall ensure that samples are analyzed by a laboratory that represents that: …."

While ANSI/ISO standards are certainly useful, they should not be substituted for clear, basic requirements. Such an approach almost assures that no alternative approaches will be developed and is likely to inhibit innovation and technological development. As a matter of policy, OSHA should reference such standards as one means (a "safe harbor") of accomplishing its objective, but should leave open the opportunity for others to demonstrate the required capability.

[35] 78 Fed. Reg. 56487.

[36] Id.

6. The Employee Notification Requirement Must Be Clarified To Set A Flexible Standard As To When The Analysis Is Complete And Ready For Delivery To Employees

The proposed standard requires employers to notify employees of the results of an exposure assessment, either individually or by posting, within five days of completion.[37] The standard needs to provide sufficient flexibility as to when an assessment is deemed to be complete so that employers have time to perform and get the results of comprehensive surveys, perform appropriate quality assurance of those results, and meet with employees as appropriate to discuss the results rather than being obligated to communicate each individual result within five days of the issuance of a laboratory result.

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

Further, the proposed standard requires that an employer must notify the employees of the corrective actions being taken to reduce employee exposures to or below the PEL in instances where the exposure assessment is above the PEL.[38] That language does not make sense where it is infeasible to bring the exposure level down to the current or proposed PEL.

F. The Proposed Requirements Relating To A Regulated Area Are Ambiguous And Not Operationally Feasible

The proposed standard requires that the employer establish a regulated area beyond which access is limited and the controls for entry are set forth by regulatory requirement.[39] The definition of "regulated area" is currently proposed to be "an area, demarcated by the employer,

[37] 78 Fed. Reg. 56488 col. 1., proposed standard § 1053(d)(7)

[38] Id.

[39] Proposed standard at § 1053(e)(2)(iii).

where an employee's exposure to airborne concentrations of RCS exceeds, or can reasonably be expected to exceed, the PEL."[40] The PEL, by definition, is a function of exposure levels over a time-weighted-average of eight hours. OSHA's requirements for protective clothing and respirators, without regard to the length of time an employee spends in a regulated area, is operationally cumbersome, creates administrative issues, goes beyond the level of protection required to significantly reduce risk, and is not tied to actual risk. Such a requirement can be based only on the assumption that a significant risk exists when there is *any* exposure to RCS. OSHA admits that this not true. Furthermore, the requirement to have regulated areas in a manner similar to other standards is not practical.

The NAM takes the intent of the provision to limit the number of employees exposed to RCS. There are more cost effective means to do this For example, section (e)(2)(iii)(A) could instead state:

> the employer shall limit access to regulated areas to persons authorized by the employer and required by work duties to be present in the regulated area when such persons' entry into the regulated area will be of such frequency and duration as to constitute a hazard. Exposure at the PEL for more than __ hours on more than __ days per year is presumed to constitute a hazard.

IV. Summary and Conclusions

The NAM and its members understand that employees are the key resources in our facilities and that all employees deserve a safe and healthful workplace. We support OSHA's efforts to reduce significant risks of adverse health effects from workplace exposure to hazardous substances such as RCS. We are also mindful of the competing demands for what are always limited resources. In adopting the OSH Act, Congress recognized the need to take a balanced approach to the regulation of workplace exposures. This means, in significant part, limiting the scope of OSHA standards to those activities and employers whose employees are truly at risk and adopting requirements that materially and directly reduce the risk in the most cost-effective manner so as to provide a safe workplace while minimizing the negative impacts on productivity

[40] Proposed standard at § 1053(b)

and manufacturers' competitiveness. Unfortunately, the proposed rule does not meet these criteria.

OSHA has not employed the best available evidence to determine whether there is a significant risk of harm to employees exposed to RCS at the present PEL and, therefore, has not established whether there is a significant risk of harm to employees exposed to RCS at the present PEL. Furthermore, OSHA has, in effect, acknowledged that the proposed PEL is not technically feasible. Given the wide margins of error associated with the official OSHA sampling and sample analysis, it would be infeasible for an employer to demonstrate compliance with the PEL, much less that it was below the action level, with a single sample unless it operated to achieve an effective PEL of 37 ug/m^3, which OSHA has acknowledged is infeasible. The alternative, assuming it was accepted by OSHA, would be to determine a statistically reliable average exposure limit below the PEL through an adequate number of samples. The cost of that approach could result in a 20-fold increase in exposure monitoring costs, which would be economically infeasible, and that approach would be technically infeasible for infrequently performed tasks.

Accordingly, the NAM submits that the only appropriate recourse is for OSHA to withdraw its proposed rule on occupational exposure to respirable crystalline silica until the Agency can properly address these issues using the best available evidence.

If OSHA chooses to nevertheless proceed in this rulemaking, then the NAM submits that OSHA should substantially revise its proposal to conform to the comments enclosed herein. Specifically, any requirements that OSHA proposes must address an existing significant risk not addressed under the current standard; must be reasonably calculated to significantly reduce that risk; must be both economically and technically feasible; must be premised upon the best available evidence; and must permit the employer to utilize the most cost-effective method for addressing a hazard.

Thank you for your consideration.

Respectfully submitted,

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