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on behalf of the

National Industrial Sand Association

before the

Occupational Safety & Health Administration

regarding

OSHA's Proposed Rule Regarding Occupational Exposure to Respirable Crystalline Silica
Docket No. OSHA–2010–0034

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Good morning. My name is Andrew O'Brien, and I am the Vice President of Safety & Health for Unimin Corporation. I am pleased to testify before you this morning on behalf of NISA concerning OSHA's proposed rule regarding crystalline silica. As Mark just noted, NISA, and its member companies, strongly support the promulgation of a crystalline silica rule that requires exposure monitoring and medical surveillance at an Action Level (AL) of 50 μg/m3, while retaining the current Permissible Exposure Limit (PEL) of 100 μg/m3. The focus of my testimony this morning will be two-fold:

- First, I will testify regarding NISA's groundbreaking Silicosis Prevention Program (or SPP) and the profound effect the SPP has had in eliminating the occurrence of new cases of silicosis in NISA member company workplaces. The SPP includes both exposure monitoring and medical surveillance, and the results of the SPP – as shown by annual company reporting within the association – provide clear support for including both of these practices as ancillary provisions in a comprehensive OSHA crystalline silica standard. I'll also comment briefly on the economic feasibility of exposure monitoring and medical surveillance.
- Second, I will testify regarding a major epidemiological study that NISA has commissioned, and that is ongoing as we speak. We expect that this study will make a substantial contribution to the existing body of science that exists to date regarding the shape of the dose-response curve for silicosis, in large part because of the extensive data available for this study, as I will discuss. We urge OSHA to incorporate the results of this study in its decision-making process for the final rule.

But first, let me provide some background on myself and Unimin.

I am a Certified Industrial Hygienist and Certified Safety Professional with a Master of Science Degree in Industrial Hygiene and a B.S. degree in Safety Engineering.

I am currently the Vice President of Safety & Health for Unimin Corporation. Founded in 1970, Unimin has grown from a small, local sand mining company to become a leading producer of non-metallic industrial minerals in the Worldwide Sibelco Group. We are the largest producer of

industrial sand in each of the United States, Canada and Mexico, and, along with our affiliates in other countries, we are the largest producer in the world. Our products are the fundamental building blocks of nearly every manufacturing and industrial process. We're a worldwide supplier to the glass, ceramic and lighting industries, to oil and natural gas service companies, and to paint, plastic, rubber and composite manufacturers. Our high purity quartz products are the starting point for the world's semiconductor and solar photovoltaic cell production. We're also an integral supplier to the metallurgical and foundry industries, and we participate in a wide range of civil, industrial, environmental and building-related applications. Our products touch the lives of millions of people daily.

In my current capacity at Unimin, I am responsible for the safety and health of Unimin's employees throughout North America, with a current census of approximately 2,400. Within this capacity lies Unimin's occupational health program, which has a significant emphasis on the prevention of new cases of silicosis. Routinely quantifying employee exposure to respirable crystalline silica and regularly conducting medical surveillance programs are the backbone of Unimin's efforts to prevent new cases of silicosis.

Unimin has been a proud member of NISA since 1970. Unimin has always believed strongly in NISA's mission, and Unimin employees have historically had leadership positions within NISA. Three of NISA's past chairmen have been Unimin executives, and a fourth is currently on NISA's Executive Committee. And, as Mark noted, I am the Chair of NISA's Silica Health Effects Committee, and Chair of the Safety & Health Committee for NISA's umbrella organization, the Industrial Minerals Association – North America.

The NISA Silica Health Effects Committee is responsible for continuing to steward the NISA Silicosis Prevention Program, and for facilitating the conduct of our ongoing epidemiology study, in collaboration with NISA's Epidemiology Research Task Force. Coordinating efforts among government and industry representatives, the NISA Silica Health Effects Committee was also largely responsible in facilitating development and publication of NIOSH's RI 9689, entitled "Dust Control Handbook for Industrial Minerals Mining and

Processing." I am happy to be able to testify today about both the NISA Silicosis Prevention Program and our epidemiology study and their potential implications for this rulemaking.

The Silicosis Prevention Program

As Mark Ellis explained, industrial sand companies produce essentially 100% pure crystalline silica. As a result, NISA members have generally had longer histories of working with silica, more direct contact with silica, and greater challenges due to the 100% silica content of our products, than anyone else in industry. It is also why, beginning in the late 1970s, NISA and its member companies reached out to occupational health experts to establish a voluntary program of employee exposure assessment and medical surveillance. The Program, referred to as the "Occupational Health Program for Exposure to Crystalline Silica in the Industrial Sand Industry" (or OHP), is the basis for the SPP.

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. 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 before that date, whether at NISA member companies or elsewhere; or after that date, but before employment at a NISA member company.

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 (or SPP). I'll discuss these two programs in reverse order below.

The scope and elements of the SPP are set out in this guide, entitled *National Industrial Sand Association Silicosis Prevention Program*, which NISA included as an appendix to its comments. The SPP declares "NISA['s] expect[ation that] all member companies [will]

implement and manage a comprehensive Silicosis Prevention Program at all worksites sufficient to eliminate silicosis among its employees."

The SPP currently comprises seven steps:

First, *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. I'll turn to that data sharing process in a moment.

Second, *implementation of the OHP*. The OHP prescribes in great detail how respirable crystalline silica exposure monitoring and medical surveillance are to be conducted by NISA members.

Third, *periodic assessments to quantify worker exposure to respirable crystalline silica dust*. As the SPP states:

> It is crucial that NISA member companies implement and manage a silica exposure program to collect personal breathing zone samples from all employees exposed to industrial sand so that periodic measurements of silica exposure and cumulative exposure assessments can be made. After all, if you're not quantifying employee exposure, how do you know whether or not you are adequately controlling employee exposure?

Fourth, *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:

- It establishes a baseline for future measurements (so that each employee serves as his or her own control);

- It allows detection of 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;
- It prevents the development of silicosis that could produce pulmonary impairment in the worker;
- It prevents the development of other occupational conditions that might be associated with exposure to silica;
- It enables disclosure to the worker of occupationally and non-occupationally related abnormalities, for appropriate medical follow-up; and
- It leads to the development of a database on which epidemiological studies of crystalline silica exposure can be based.

The fifth element of the SPP is *implementation of dust control equipment or processes.* The SPP encourages NISA member 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:

> The 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.

The sixth element is *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." It describes steps for promoting employee engagement and provides example actions management can take.

The seventh element is *smoking cessation programs*. The principal goal of such programs is to reduce the added impact of smoking on silica-related health effects. A related

goal is to diminish the serious adverse health effects that are directly caused by smoking and exposure to second-hand smoke.

Occupational Health Program

Of the seven elements of the SPP, the two that are most relevant to this rulemaking are also the historic core of the SPP: regular personal sampling of employees' exposure to respirable crystalline silica and periodic medical surveillance. The details of these two elements are spelled out in the current NISA Occupational Health Program, on which the SPP is based, which we also included as an appendix to our comments. The OHP 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:

- With respect to *dust sampling,* the OHP's goal 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." *Importantly for this rulemaking, what the OHP – and our experience – show is that companies don't need to hire outside contractors to competently conduct exposure monitoring. Company staff can be trained to do it, and do it competently. I'll come back to this point in a moment.*
- On the subject of *medical surveillance*, the OHP 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 of the elements of the medical surveillance program.

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. NISA is proud of these references and appreciates being able to provide a model for such an important element of silica workplace health.

Member Company Annual Reporting

Now that I've described what the SPP is, I'd like to turn to what it has accomplished. As I mentioned a moment ago, part of the management commitment that is Step 1 of the SPP is a commitment to sharing data on both exposure measurements and chest X-ray results with other NISA member companies at annual benchmarking sessions. These annual sessions have occurred every year since 1994. Each year, SPP participating members report employee personal dust sampling and chest X-ray data for the previous year to NISA staff. That information is compiled by NISA staff, under my committee's direction. I then present the information, on a blinded basis, to the membership at a special session of the Annual Meeting.

In these annual reports, respirable crystalline silica exposure data are presented for the SPP participants as a whole, as well as for individual company participants. Information such as the number of measurements, average percent quartz and average percent exposure (as a percentage of the PEL) for ten different processes (for example, mining, bagging, and screening) are included in this reporting.

Chest X-ray data are presented within the Annual Report as the number of individuals per company with chest X-rays classified as having a profusion rating of ≥1/1 on the ILO scale. Those X-rays are generally read by more than one certified B-reader in accordance with the OHPs consensus reading process.

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

They also allow NISA to assess the effectiveness of the SPP. A total of eleven companies have reported chest X-ray data since 1994. Over this 19-year period, medical surveillance at these companies has yielded a total of 8 cases with radiographic evidence of silicosis – again, that means ≥1/1 on the ILO scale. Those 8 cases have occurred at a total of 3 companies. Those 3 companies advise NISA that they do not regard these as "new" cases – meaning that, in each case, the company determined that the silicosis was attributable to exposures occurring either before 1994, either at that company or elsewhere; or after that date, but before employment at the company. I should note that several NISA members have grown substantially by acquisition in the past two decades. The acquired companies typically had not implemented exposure monitoring, medical surveillance, or the other elements of the SPP – although that certainly changes once they get folded into the acquiring company. It is not surprising, therefore, that along with those new acquisitions, NISA members have inherited cases of detectable or incipient silicosis.

But let me pause now to repeat our findings: a total of eleven NISA members, over a period of nineteen years, have found eight cases of silicosis, none of which were new. In other words, implementation of the SPP by participating companies has eliminated the creation of new silicosis cases among those companies' employees, even as those companies were subject to the current PEL of 100 $\mu g/m^3$.

We recognize that silicosis, while dramatically reduced, is still being diagnosed elsewhere around the country. NISA believes that this disease is caused by the persistently high rates of noncompliance with the current PEL that OSHA continues to witness, despite years of focused enforcement. We further believe that the absence of an exposure assessment requirement from the current crystalline silica PEL is the principal reason for this widespread and often severe noncompliance. This conclusion is supported, by the way, by a study of an Industrial Minerals Association – Europe initiative, described in our comments, which that found that exposure monitoring with feedback to the affected worksites produced a two- to three-fold reduction in exposure concentrations. Quantification of exposure via personal dust sampling of

employees is thus key to ensuring compliance with any PEL for crystalline silica. NISA therefore supports OSHA's proposed inclusion of exposure monitoring, as well as medical surveillance, as part of a comprehensive crystalline silica standard. We believe that the NISA Solution – the current PEL, supplemented by exposure assessment and medical surveillance triggered at a 50 $\mu g/m^3$ action level – should reduce significant risk of material health impairment from silicosis sufficient to meet the requirements of Section 6(b) of the OSH Act.

Costs of Exposure Monitoring and Medical Surveillance

Unimin has found that the costs of conducting exposure monitoring and medical surveillance to be quite minimal. These costs, in fact, are considered insignificant within our company. We included actual cost data for five NISA member companies in our comments, on page 24. The real cost impact of the proposed rule will be driven by the engineering controls required to achieve the lower PEL, where that can be done.

But I do want to highlight one way in which OSHA has overstated the costs of exposure monitoring, in our view. In its cost analysis, OSHA assumes that employers will use outside contractors to conduct initial and periodic exposure assessments. As I mentioned earlier, NISA's member companies conduct exposure assessments using in-house personnel. Obviously, no one can say for certain what the broad variety of industries covered by OSHA's proposed standard for general industry would do in response to an exposure monitoring mandate. 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 it cost-effectively.

Nonetheless, we believe that some percentage of OSHA-regulated establishments can and 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, than it is to hire consultants. As I explained earlier, our OHP document provides 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." We post the OHP on our website, and so that learning is available now for companies to review.

Given our experience, we urge OSHA to analyze scenarios in which some percentage of regulated establishments do their own exposure assessments. We also urge OSHA to use the data NISA supplied. Three of the five companies included in our sample are among the largest NISA members (on a revenue basis), but another meets the SBA's size standard for a small business.

Ongoing NISA Silica/Silicosis Dose/Response Study

The last topic I'd like to address today is NISA's ongoing Silica/Silicosis Dose/Response Study. While the association between silicosis and exposure to respirable crystalline silica is indisputable, there is still considerable uncertainty regarding the dose/response relationship of this association, particularly in the case of chronic simple silicosis, which is the most common form of silicosis. 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 the vast majority of published studies of silicosis risk is their reliance on poor-quality or uncertain exposure measurements. This undermines the reliability of any quantitative risk estimates based on those studies, including OSHA's. Many silicosis studies 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. Others lack data for early exposure years, and so early exposures are based on inferred or extrapolated concentrations. Others are based on area sampling rather than personal sampling. 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. This latter defect is a serious limitation, because it has become increasingly clear that there is no single, defensible conversion factor from particle count measurements to gravimetric measurements. No published study involves so much exposure data, collected rigorously and consistently via personal samplers, and evaluated gravimetrically, with percentage quartz assessed with X-ray diffraction.

On the other hand, NISA's two largest member companies, Unimin and U.S. Silica, 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. These exposure samples encompass a large number of job positions 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 X-ray diffraction. 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 individuals, the database includes more than 10 chest X-rays.

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, using this database. The study will compare the silica exposures of an exposed cohort of employees that have radiographic evidence of silicosis (as identified by a panel of three radiologists) to the silica exposures of three matched controls without radiographic evidence of silicosis. Roughly 1,670 employees and former employees from 14 plants in 10 states fit the criteria for inclusion in the study (which are at least 10 years of employment, with a chest X-ray taken at least 10 years after commencement of employment). We thus have a robust study population. The study will assess three main questions:

1. The relative risk of radiographic silicosis at cumulative and average exposures, and duration of exposure;
2. The absolute risk of radiographic silicosis at average exposures of 50, 100 and 200 $\mu g/m^3$ over a working lifetime; and
3. In cases in which chest X-ray changes have occurred, what factors are associated with the progression of radiographic silicosis.

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. We included their biosketches as appendices to our comments. Their study employs a common, well-respected epidemiological study design – and we also attached the study protocol as an appendix to the comments. To help ensure that the study is viewed as objective and reliable, 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, and NIOSH provided extensive comments to the draft protocol, which were considered and addressed by the research team.

NISA is paying for this study – we're making no secret of that. But we fully intend 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." We believe we have thus voluntarily and adequately addressed concerns that might be raised about NISA's influence on the investigator's scientific and editorial freedom.

The agreements with the research team require them to submit, for publication in the peer-reviewed medical literature, an article based upon their report. NISA anticipates that the research team will issue their final report sometime during the second quarter of 2015, and have a manuscript completed to submit for publication shortly thereafter. While the record for this rulemaking will most likely have closed by that time, NISA intends to submit the manuscript, after it is accepted for publication, to the docket, and will request that OSHA publish a Federal Register notice reopening the record for some short period of time, say 30 days, and request comment on the manuscript. 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. NISA does not know what the conclusion of this study will be, but we believe that, upon release, it has the potential to contribute in a meaningful way to the existing body of science regarding the silica/silicosis dose-response relationship. We strongly urge OSHA to re-open the rulemaking record when this study is complete.

This concludes my testimony today. I thank you for the opportunity to testify, and I'd be happy to respond to questions.