February 9, 2014

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

AB36-COMM-50-3

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

Dear Sir or Madam:

The International Diatomite Producers Association (IDPA) presents these comments on OSHA's proposed rule regarding occupational exposure to crystalline silica.[1] IDPA represents the major manufacturers of diatomaceous earth products worldwide. The crystalline silica rulemaking is as significant as any initiative that OSHA has launched during this Administration, and IDPA is pleased to offer its comments on the subject.

IDPA belongs to the American Chemistry Council's Crystalline Silica Panel (the Panel).[2] The Panel has filed comments separately in this docket that focus on the appropriateness of OSHA's proposed permissible exposure level (PEL). Those comments address issues of significant risk and issues of economic and technological feasibility (including feasibility of measurement). In brief, they show that OSHA has not established that a significant risk of material health impairment from crystalline silica exists at the current permissible exposure limit (PEL) of 100 μg/m^3, or that any such risk would be substantially reduced by a PEL of 50 μg/m^3. The Panel's comments also demonstrate that the proposed standard, with a PEL 50 μg/m^3, is not technologically or economically feasible. IDPA supports and hereby adopts those comments.

IDPA and the National Industrial Sand Association (NISA) are both members of the International Minerals Association - North America (IMA-NA) – IDPA is the sole member of the diatomite section of IMA-NA, and NISA is the sole member of the industrial sand section of IMA-NA.[3] NISA has also filed comments separately in this docket that focus primarily on OSHA's proposed action level and ancillary provisions and their integration with the PEL. In sum, NISA advances the "NISA Solution": a comprehensive standard, in the form of a variant of OSHA's Alternative #1: the current PEL of 100 μg/m^3 and action level of 50 μg/m^3, with exposure monitoring and medical surveillance triggered by exposures *above the action level* (not

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[1] 78 Fed. Reg. 56274 (Sept. 12, 2013).
[2] Information about the Panel is available at http://www.americanchemistry.com/ProductsTechnology/Crystalline-Silica.
[3] Additional information regarding IMA-NA is available at http://www.ima-na.org/.

the PEL). As NISA's comments demonstrate, this alternative substantially reduces any risks of material health impairment from workplace exposure to crystalline silica arising from the persistently high level of noncompliance with the current PEL, and is economically and technologically feasible. IDPA supports and hereby adopts those comments as well.

This document goes beyond the scope of the Panel's and NISA's comments and focuses on the appropriate PEL and action level for cristobalite, the predominant polymorph of crystalline silica found in calcined (as opposed to natural) diatomaceous earth products. The comments commend OSHA for proposing to treat quartz and cristobalite alike for purposes of this rulemaking and, in particular, for setting the same PEL and action level for both quartz and cristobalite. As OSHA explains in the preamble to the proposal, and as further substantiated below and in the attached comments of Kenneth A. Mundt, PhD[4] and a recent article by Brooke T. Mossman and Robert E. Glenn,[5] there is no basis in experimental toxicology or epidemiology to believe that the two polymorphs pose materially different health risks in the workplace or warrant differential treatment. To the contrary, all available evidence militates in favor of treating them alike – as OSHA has correctly proposed to do.

These comments begin by providing more information about IDPA and the manufacture of diatomaceous earth products. This portion of the comments also explains IDPA's stake in this rulemaking. With that essential background, the comments then respond to Issues ##10 and 39 in OSHA's list of issues. That is, they:

- Describe work environments or processes that may expose workers to cristobalite; and
- Provide justification for why:
    - Quartz and cristobalite should be subject to the same PEL and action level; and
    - Those values should be 100 $\mu g/m^3$ and 50 $\mu g/m^3$, respectively.

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

I. IDPA and the Manufacture of Diatomaceous Earth Products

IDPA is a nonprofit 501(c)(6) trade association representing the major manufacturers of diatomaceous earth products worldwide. Founded in 1987, IDPA is committed to the safe use of diatomaceous earth products and to advancing research and maintaining a dialogue with industry, legislators, regulatory agencies and the scientific community in support of the safety of our employees, our customers, and the communities we serve. IDPA currently has five member

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[4] Kenneth A. Mundt, PhD, "Review of the Epidemiology of Occupational Exposure to Cristobalite" (Jan. 24, 2014) (attached).

[5] Brooke T. Mossman and Robert E. Glenn, "Bioreactivity of the crystalline silica polymorphs, quartz and cristobalite, and implications for occupational exposure limits (OELs)," 43 CRIT. REV. TOXICOL. 632 (Sept. 2013), available at http://informahealthcare.com/doi/abs/10.3109/10408444.2013.818617.

companies that collectively account for the majority of the production of diatomaceous earth products worldwide.[6]

Diatomaceous earth – also known as diatomite – is a naturally occurring, non-metallic mineral composed of the fossilized remains of microscopic single-celled aquatic algae called diatoms. In rare cases, these diatomite deposits are found in sufficient thickness and purity to be mined for many beneficial uses. Diatomite is usually mined in open-pit, surface mines. A considerable thickness of earth, known as overburden, may have to be removed. Once this layer is removed and the purest of the diatomite strata is exposed, it is then cut from the bed with powerful scrapers and stockpiled. The stockpiled material is then hauled to the processing plant for crushing, drying at relatively low temperatures, and milling.

Diatomaceous earth as it naturally occurs is predominantly composed of amorphous silica - that is, non-crystalline silicon dioxide. It may also contain small amounts (typically less than 3%) of naturally occurring crystalline silica, normally in the form of quartz. The "natural grade" of diatomite that results from crushing, drying and milling retains this composition.

For most applications, however, the ore is then either calcined or flux calcined in a large rotary kiln to remove the moisture and organics remaining in the ore, agglomerate the diatom frustules and produce the desired grade. Calcined grade products are produced by calcining, or sintering, at higher temperatures, typically around 1800°F (1000°C), and then classified to produce a variety of particle-sized products. During calcination, some of the amorphous silica may undergo a physical mineralogical transformation to form crystalline silica, predominantly as cristobalite. As a result, calcined diatomite may contain from 0 to 40% cristobalite.

Flux-calcined products are also produced by calcining at high temperatures, but in the presence of a fluxing agent such as soda ash (sodium carbonate), and then classified to produce a variety of particle-sized products. During flux calcination, the fluxing agent helps to fuse the diatoms together, which considerably increases the particle size of the product. As with calcined grades, a portion of the amorphous silica undergoes a transformation to crystalline silica in the process. Flux-calcined grades may contain up to 70% cristobalite.

As predominantly mining and processing operations, IDPA members' workplaces are typically regulated by MSHA, not OSHA, for purposes of occupational safety & health. IDPA has a substantial stake in the outcome of the OSHA crystalline silica rulemaking, however, for several reasons:

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

2. IDPA member companies have a substantial business interest in the financial well-being of our customers, who are OSHA regulated. A standard that is more costly than is

[6] The members of IDPA are CECA S.A., Damolin, EP Minerals, LLC, Imerys, and Showa Chemical Industry Co., Ltd. *See* www.diatomite.org/Our-Companies.

necessary to reduce significant risks, or that is infeasible, could subject our customers to significant economic hardship, some proportion of which would likely translate into reduced revenues for IDPA members.

3. IDPA members are also committed to the safe use of diatomaceous earth products. In 2009, IDPA published "A Guide to the Safe Handling of Diatomaceous Earth Products-North American Version," which provides very general guidance to diatomite distributors and users regarding the benefits of engineered ventilation controls, safe work practices and respiratory protection programs.[7] On its website, IDPA also provides a link to NISA's "Occupational Health Program for Exposure to Crystalline Silica."[8] Along these same lines, IDPA believes that the exposure monitoring and medical surveillance provisions that OSHA has proposed would provide valuable additional workplace protections at OSHA-regulated workplaces where cristobalite exposure may occur.

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

II. Response to Issue #10: Workplace Environments or Processes that Might Expose Workers to Cristobalite

Diatomite is used in the manufacture of thousands of products. Diatomite improves crops, stabilizes explosives, absorbs hazardous materials, serves as a filler, adds strength to construction materials, filters impurities, lends abrasion to cleaning and polishing products, and serves as a carrier for active ingredients in products. Calcined grades are most commonly used for fine (high clarity) filtration applications. Flux-calcined grades are used for a wide variety of filtration, filler, and functional additive applications. Examples of filtration applications are swimming pool filtration, beer and pharmaceutical manufacture, and motor oil processing. Functional additive applications include paint and plastic manufacture, pesticides and animal feed. Diatomite products may be shipped in a variety of containers, including paper or plastic bags, semi-bulk bags and cardboard containers, as well as in bulk by rail hopper cars and tank trucks. All of the foregoing uses of diatomite raise the potential for workplace exposure to cristobalite. As OSHA notes, cristobalite may also be created in high-temperature refractory furnaces.

III. Response to Issue #39: OSHA Should Set a Single PEL of 100 $\mu g/m^3$, and a Single Action Level of 50 $\mu g/m^3$, for both Quartz and Cristobalite

A. OSHA Should Set the Same PEL, and the Same Action Level, for Both Quartz and Cristobalite

[7] The Guide is available at http://www.diatomite.org/idpa/files/ccLibraryFiles/Filename/000000000046/IDPA%20Guide%20to%20Safe%20Handling.pdf.
[8] *See* http://www.diatomite.org/Health-Safety.

OSHA's proposed standard for general industry defines "respirable crystalline silica" to include both quartz and cristobalite particles.[9] That phrase is in turn referenced in the subsection establishing the PEL[10] and in the definition of "action level."[11] Thus, the proposed standard sets a single PEL and a single action level for both quartz and cristobalite. IDPA supports OSHA's express conclusion that it should set the same PEL for both polymorphs, and urges it also to expressly state that it should set a single *action level* for both polymorphs. As explained below:

- The preamble to the proposed rule provides ample basis for these conclusions;
- They are also justified based on the surveys of the literature summarized in the attached comments of Dr. Mundt and in a recent article by Mossman and Glenn; and
- A single PEL for both quartz and cristobalite would bring OSHA into alignment with most other expert bodies that have addressed the issue in recent decades.

1. OSHA's Preamble Adequately Justifies Setting a Single PEL

In its proposed rule, OSHA declares its "belie[f] that it is appropriate to establish a single PEL that applies to respirable quartz, cristobalite, and tridymite."[12] As the preamble explains:

> OSHA has examined evidence on the comparative toxicity of the silica polymorphs (quartz, cristobalite, and tridymite). A number of animal studies appear to suggest that cristobalite and tridymite are more toxic to the lung than quartz and more tumorigenic (e.g., King et al., 1953; Wagner et al., 1980). However, in contrast to these findings, several authors have reviewed the studies done in this area and concluded that cristobalite and tridymite are not more toxic than quartz (e.g., Bolsaitis and Wallace, 1996; Guthrie and Heaney, 1995). Furthermore, a difference in toxicity between cristobalite and quartz has not been observed in epidemiologic studies (tridymite has not been studied) (NIOSH, 2002). In an analysis of exposure-response for lung cancer, Steenland et al. (2001a) found similar exposure-response trends between cristobalite-exposed workers and other cohorts exposed to quartz.[13]

OSHA documents this conclusion most thoroughly in the context of lung cancer:

> OSHA's current PELs for respirable crystalline silica reflect[] a once-held belief that cristobalite is more toxic than quartz (i.e., the existing general industry PEL for cristobalite is one-half the general industry PEL for quartz). Available evidence indicates that this does not appear to be the case with respect to the carcinogenicity of crystalline silica. A comparison between cohorts having principally been exposed to cristobalite . . . with other well conducted studies of quartz-exposed cohorts suggests no difference in the toxicity of cristobalite versus quartz.

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[9] *See* 78 Fed. Reg. 56487 (proposed 29 C.F.R. § 1900.1053(b), definition of "respirable crystalline silica"). IDPA does not express any opinion in these comments regarding either (i) the appropriate levels for regulating exposure to tridymite or (ii) the proposed construction standard.
[10] *Id.* (proposed 29 C.F.R. § 1900.1053(c)).
[11] *Id.* (proposed 29 C.F.R. § 1900.1053(b), definition of "action level").
[12] *Id*. at 56446.
[13] *Id*. at 56310.

> . . .
>
> OSHA believes that the current epidemiological literature provides little, if any, support for treating cristobalite as presenting a greater lung cancer risk than comparable exposure to respirable quartz. Furthermore, the weight of the available toxicological literature no longer supports the hypothesis that cristobalite has a higher toxicity than quartz, and quantitative estimates of lung cancer risk do not suggest that cristobalite is more carcinogenic than quartz. . . . OSHA preliminary concludes that respirable cristobalite and quartz dust have similar potencies for increasing lung cancer risk.[14]

OSHA also notes the concordance of authoritative bodies on the appropriateness of a single OEL for all crystalline silica polymorphs:

> OSHA's preliminary conclusion that quartz, cristobalite, and tridymite should be addressed under a single standard and subject to the same PEL is consistent with the recommendation of the National Institute for Occupational Safety and Health (NIOSH), which has a single Recommended Exposure Limit (REL) covering all forms of respirable crystalline silica. In addition, the American Conference of Governmental Industrial Hygienists (ACGIH) has issued a single Threshold Limit Value (TLV) for quartz and cristobalite.[15]

OSHA's conclusions are supported by Dr. Mundt's comments and the Mossman and Glenn article and would bring OSHA into alignment with other authoritative bodies, as explained below.

2. Recent Surveys of the Scientific Literature Support Use of a Single PEL (and Action Level) for Both Quartz and Cristobalite

Two recent documents have surveyed the scientific literature regarding the toxicity of cristobalite. Both also address (to varying degrees) the relative toxicity of cristobalite and quartz, concluding in each case that there is no reason to think one is more toxic than the other.

a. Mundt Report

IDPA retained Kenneth A. Mundt, PhD, Director of Applied Epidemiology at Environ, to comprehensively review the epidemiological literature regarding cristobalite.[16] The Mundt report discusses the three major cohorts in which occupational exposure to cristobalite has been investigated: California diatomaceous earth workers, refractory workers in China, Italy and the

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[14] *Id*. at 56304-05.
[15] *Id*. at 56442.
[16] As Dr. Mundt's report states on the cover page, IDPA underwrote the development of the report. IDPA reviewed drafts of Dr. Mundt's report but did not seek to alter any of his conclusions.

UK, and UK pottery workers. Following the recommendations of the National Research Council,[17] Mundt:

- conducted a literature search using specified terms;
- selected roughly a dozen studies that presented the results of primary research and contained data or estimates of individual exposure;
- prepared evidence tables that present key information about each study, supplemented by textual discussion;
- summarized the findings of the studies by disease category, again presented in evidence tables supplemented by discussion; and
- provided a discussion, synthesis and conclusions.

In that latter section of his report, Mundt states:

> [T]oo few studies of high quality exist on which to assess risks associated with cristobalite exposure (as compared to quartz exposure). Even among the studies of higher relative quality among those reviewed for this report, concomitant exposure to quartz was possible among those exposed predominantly to cristobalite. Many other studies of lower relative quality (i.e. tier two and three) among those reviewed for this report included cohort members with mixed exposures to cristobalite and quartz or predominantly quartz.
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> Thus, regardless of outcome studied, there is insufficient epidemiological evidence to support a lower PEL for cristobalite versus quartz. For lung cancer, the relative risk estimates among workers exposed predominantly to cristobalite (SMR=1.3, 95% CI 1.0 – 1.6 for DE workers) do not differ consistently or substantively from study cohorts in which the workers were exposed to crystalline silica from quartz (SMR=1.4, 95% CI 1.0 – 2.0 for Finnish granite workers; SMR=1.2, 95% CI 1.0 – 1.3 for US granite workers; SMR=1.6, 95% CI 1.2 – 1.9 for US industrial sand workers; SMR=1.1, 95% CI 0.84 – 1.4 for China pottery workers; SMR=2.1, 95% CI 1.7 – 2.6 for China tin workers; SMR=1.2, 95% CI 1.0 – 1.4 for US gold miners; and SMR=1.8, 95% CI 1.5 – 2.1 for Australian gold miners) (as summarized by Steenland et al. 2001 (Steenland, Mannetje, et al. 2001)).
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> Additionally, the small number, modest size, and overall absence of a quantitative exposure assessment in most of the studies reviewed limit the ability to determine the specific level of exposure to cristobalite that is associated with an increased risk of each of the diseases related to crystalline silica exposure.
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> For the evaluation of lung cancer – for which there is the greatest number of published studies – questions of confounding by smoking and occupational asbestos exposure remain. Nevertheless, most studies demonstrate increased risks of lung cancer with higher categories of crystalline silica exposure, with no remarkable differences seen among cohorts more likely exposed to cristobalite than to quartz (see Steenland et al.

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[17] NRC, REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE (2011), at 158.

> 2001 (Steenland, Mannetje, et al. 2001) for a summary of lung cancer risk estimates in cohorts exposed to quartz).[18]

Mundt also notes that, as with studies assessing the potential for quartz exposure to cause lung cancer, it is unclear whether cristobalite is a lung carcinogen in the absence of silicosis:

> While the OSHA proposed rule emphasized increased risk of lung cancer mortality with occupational exposure to respirable cristobalite, several studies suggest that the increase in lung cancer risk is driven by a positive diagnosis of radiographic silicosis resulting from exposures at historically higher levels than the current PEL.
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> …
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> Overall, the evidence for an association between occupational exposure to respirable crystalline silica (mainly cristobalite) and lung cancer among non-silicotics is weak, or lacking. While there is stronger evidence of an association between occupational exposure to silica and lung cancer among silicotics, it remains unclear whether this increased risk for both diseases resulted from much higher exposures to crystalline silica decades prior to the epidemiological studies reporting increased risks.[19]

b. Mossman and Glenn

Mossman and Glenn conducted a broader review of the relative toxicity of cristobalite and quartz, again summarizing the studies they reviewed in standardized evidence tables.[20] As can be seen, this review both concurs with Mundt regarding epidemiology studies and offers additional explanation for the similarity observed in those studies regarding the toxicity of quartz and cristobalite.

Mossman and Glenn begin with mechanistic *in vitro* research involving cell cultures, concluding that, compared with in vitro studies of quartz, in vitro "studies [of cristobalite] point to similar mechanisms of action of cristobalite on inflammasome activation, increases in capase-1 enzyme activity, release of mature IL-1b and basic fibroblast growth factor (bFGF) and fibroblast proliferation (Peeters et al., 2013)."[21]

The authors then turn to inhalation studies involving rodents, which they say "reveal in vivo mechanisms of action of CS that validate mechanistic data in vitro . . . . Moreover, data point to commonalities in lung injury, inflammation and fibrogenic responses to quartz and

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[18] Mundt report, *supra* note 4, at 30.
[19] *Id*. at 31-32.
[20] *See* note 5 *supra*. As disclosed at 43 CRIT. REV. TOXICOL 656, the Mossman and Glenn report was funded, in part, by IDPA, although research on silica in Dr. Mossman's laboratory is funded by an unrestricted grant from the Weijerhorst Foundation in collaboration with investigators at the University of Maastricht. IDPA reviewed drafts of the Mossman and Glenn manuscript but did not seek to alter any of their conclusions.
[21] *Id*. at 638.

cristobalite."[22] They note in addition that "[i]nhalation studies using α-cristobalite . . . have demonstrated virtually identical patterns of histopathology and immunological responses when compared to studies with [quartz]."[23]

Turning to epidemiology and the Hughes (1998) study of California diatomaceous earth workers, the authors note that "it appears the fibrogenicity of the one quantitative exposure-relationship for cristobalite is comparable to a similar study of quartz and demonstrates a much lower risk than yet another study of quartz-exposed miners. Hughes et al. conclude that their study results do not support the view that cristobalite is more fibrogenic than quartz at comparable crystalline silica exposures."[24]

Finally, discussing the Cherry (1998) study of UK pottery workers, Mossman and Glenn report that "[t]he researchers noted that they failed to find a difference in the probability of radiographic opacities in workers in jobs prior to kiln firing [where crystalline silica exposure was primarily to quartz] and jobs at the kiln or post-firing jobs [where crystalline silica exposure was primarily to cristobalite]. They concluded that there was no evidence for any increased risk with exposure to cristobalite compared to quartz. . . . This study does not provide support for variable potency of an increased exposure to cristobalite compared to quartz."[25]

Mossman and Glenn thus reach the same conclusion as Mundt: the epidemiological literature uniformly supports the conclusion that cristobalite is no more toxic than quartz, whether in terms of silicosis, lung cancer or other adverse health effects.

3. Use of a Single PEL (and Action Level) for Quartz and Cristobalite Will Align OSHA with Most Other Agencies and Authoritative Bodies

OSHA's use of different PELs for quartz and cristobalite is an artifact of the time that it was adopted, and has become increasingly anachronistic over the past forty years. Use of a single PEL (and action level) would bring OSHA into the modern world.

OSHA adopted the current PEL in 1971, based on a 1968 ACGIH proposal to set the TLV for cristobalite at one-half the TLV for quartz.[26] ACGIH adopted that proposal in 1972. MSHA in 1973 then also adopted the ACGIH values. By 1999, however, ACGIH had reconsidered, and at that time set the same TLV for both polymorphs. Meanwhile, when NIOSH first considered the issue, in 1974 – just three years after OSHA set the PEL, NIOSH found no basis to distinguish between quartz and cristobalite and recommended use of a single PEL for both. NIOSH reaffirmed this conclusion in 1977, 1980, and 2002. The German MAK in 1999 concluded that the information available to date was insufficient for a differential assessment of individual types of CS. Finally, the UK's Health & Safety Executive (HSE) in 2002 constructed

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[22] *Id.*
[23] *Id.* at 641.
[24] *Id*. at 647.
[25] *Id*. at 648.
[26] 78 Fed. Reg. 56292; 43 CRIT. REV. TOXICOL at 654. The balance of this paragraph is drawn from *id*. at 654-55.

a "Potency Matrix" under which cristobalite was ranked as of equivalent potency to quartz at equivalent conditions of exposure. A year later, the HSE reaffirmed this conclusion, emphasizing that there was limited information from experimental studies on the carcinogenic potential of quartz and cristobalite, and no reason to indicate that they would differ from one another. Thus, outside of OSHA and MSHA, no authoritative body besides ACGIH has adopted the notion that cristobalite is more toxic than quartz, and even ACGIH abandoned that view fifteen years ago. Unfortunately, OSHA's outdated values have been locked in place by the ponderous process required to change them.

As OSHA notes, the idea that cristobalite is more toxic than quartz derives primarily from a single study – King et al. (1953) – which involved intratracheal instillation of crystalline silica in rats. As explained by Mossman & Glenn, this study "would be considered nonphysiologic by modern laboratory standards," had no controls, and involved only a single, very high dose (50 mg) "that would be considered excessively high by current techniques, and [at which] it is likely that . . . the animals experienced lung overload."[27] They continue:

> High mortality in all groups treated was experienced in the first 120 days which resulted in comparisons of unequal numbers of rats for each treatment group. For example, only one quartz-treated rat compared to 14 cristobalite-treated were necropsied for the 61–90 day sacrifice. King et al. (1953) concluded that the polymorphs of quartz and cristobalite were similar in severity of pulmonary responses; however, cristobalite induced slightly faster responses than quartz.[28]

Glenn & Mossman identify only one publication involving inhalation studies conducted at the same institution that purports to find that cristobalite produces faster and more severe inflammatory responses than quartz, but that study also found that amorphous silica does as well, which is contrary to the great weight of evidence.[29]

There is no reason for OSHA's values to continue to be driven by this 60-year-old study. Rather, OSHA should bring its values into alignment with the rest of the world. (Hopefully MSHA will shortly afterward follow suit.) OSHA has proposed to do so, and IDPA endorses that proposal.

B. The PEL for Both Quartz and Cristobalite Should Be 100 $\mu g/m^3$, and the Action Level for Both Quartz and Cristobalite Should Be 50 $\mu g/m^3$

As noted at the outset of these comments, IDPA adopts the comments of the ACC Crystalline Silica Panel filed in this docket. Part II of those comments, supported by reports submitted by Dr. Anthony Cox and Dr. Peter Morfeld, explains in exhaustive detail how OSHA has not shown that exposure to crystalline silica at the current PEL presents a significant risk of material health impairment, or that any such risk would be substantially reduced at a PEL of 50

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[27] 43 CRIT. REV. TOXICOL. at 655-56.
[28] *Id*. at 656.
[29] *Id*., discussing D.R. Hemenway et al., "Comparative clearance of quartz and cristobalite from the lung," 51 AM. IND. HYG. ASSOC. 363–9 (1990).

$\mu g/m^3$. Based on these comments, IDPA urges OSHA to set a PEL of 100 $\mu g/m^3$ for both quartz and cristobalite.

IDPA also adopts the comments in this docket filed by NISA, which urges OSHA to set an action level at 50 $\mu g/m^3$ that would trigger exposure monitoring, medical surveillance, hazard communication and training. In particular, exposure monitoring will produce greater compliance with the PEL and greater health protection than occurs now, when most employers have no basis to know whether they are exceeding the PEL. Noted epidemiologist Noah Seixas makes the same point in a recent editorial on crystalline silica:

> Analyses of the results of this program presented at this year's Inhaled Particles symposium showed that overall there had been a 2- to 3-fold reduction of exposure concentrations since the start of [an Industrial Minerals Association - Europe] project (Kromhout et al., 2013), providing support for the concept that exposure monitoring with feedback to the affected worksites helps to support control measures.[30]

OSHA seems to agree: "OSHA anticipates that the ancillary provisions in the proposed standard, including requirements for regulated areas and medical surveillance, will further reduce the risk beyond the reduction that would be achieved by the proposed PEL alone."[31] IDPA therefore urges OSHA to set an action level of 50 $\mu g/m^3$ for both quartz and cristobalite.

IV. Conclusion

As explained above, there is no basis in experimental toxicology or epidemiology to believe that quartz and cristobalite pose materially different health risks in the workplace or warrant differential treatment. To the contrary, all available evidence militates in favor of treating them alike – as OSHA has correctly proposed to do. IDPA urges OSHA to set a PEL of 100 $\mu g/m^3$, and an action level of 50 $\mu g/m^3$, for both quartz and cristobalite.

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

Sincerely,

Mark G. Ellis
Executive Director

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