



How reliable are crystalline silica dust concentration measurements?



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ABSTRACT

To determine how reliably commercial laboratories measure crystalline silica concentrations corresponding to OSHA's proposed limits, 105 filters were prepared with known masses of 20, 40, and 80 μg of respirable quartz corresponding to airborne silica concentrations of 25, 50, and 100 $\mu\text{g}/\text{m}^3$ and were submitted, in a blind test, to qualified commercial laboratories over a nine month period. Under these test conditions, the reported results indicated a lack of accuracy and precision needed to reliably inform regulatory compliance decisions. This was true even for filters containing only silica, without an interfering matrix. For 36 filters loaded with 20 or more micrograms of silica, the laboratories reported non-detected levels of silica. Inter-laboratory variability in this performance test program was so high that the reported results could not be used to reliably discriminate among filters prepared to reflect 8-h exposures to respirable quartz concentrations of 25, 50 and 100 $\mu\text{g}/\text{m}^3$. Moreover, even in intra-laboratory performance, there was so much variability in the reported results that 2-fold variations in exposure concentrations could not be reliably distinguished. Part of the variability and underreporting may result from the sample preparation process. The results of this study suggest that current laboratory methods and practices cannot necessarily be depended on, with high confidence, to support proposed regulatory standards with reliable data.

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1. Background

Silica is a very abundant mineral compound, found most often in crystalline form as quartz in sands, soils, rocks, dust, and air around the world and in many industry processes. Crystalline silica occurs when the oxygen and silicon molecules are arranged in a lattice. (WHO IARC, 2012) Workers in mining, construction, and manufacturing settings are exposed to silica dust (e.g., sand and dusts) and sufficiently prolonged inhalation exposure, to sufficiently high concentrations of crystalline silica dust, can cause adverse health effects including silicosis, a lung disease (NIOSH, 2004). Studies beginning in the 1980s also suggested that crystalline silica under some conditions might be carcinogenic (or co-carcinogenic), perhaps acting as a lung irritant and causing chronic inflammation of the lung (Borm et al., 2011) As a result of those findings, the Occupational Safety and Health Administration

(OSHA) regulates crystalline silica exposure as a health hazard (20 CFR 1910.1000, Table Z-3).

1.1. What is the regulatory history of silica?

In 1971, OSHA first promulgated a permissible exposure limit (PEL) for respirable crystalline silica (RCS) working under an authority to expedite PELs for air contaminants and based upon the recommendation of the American Conference of Governmental Industrial Hygienists (ACGIH) (NIOSH, 1978). The limit was not substantially changed when OSHA issued its Air Contaminants final rule for general industry in 1989, which sought to simplify exposure calculations. In 1992, the Air Contaminants final rule was vacated by the U.S. Court of Appeals for the Eleventh Circuit returning the PEL for RCS to its original form.

In 1994, OSHA formally recognized RCS regulation as a priority and in 1996 made further efforts to both enforce the PELs and to provide better education on the hazards of overexposure to crystalline silica. Finding it had made little progress in these areas, OSHA endeavored to adopt a comprehensive silica standard. After

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significant efforts and input from other agencies, on August 12, 2013, OSHA proposed a new occupational health standard for respirable crystalline silica (RCS), or respirable quartz, which proposes to reduce the PEL by half in general industry and even more in the construction industry (OSHA, 2013). The proposal would also require medical surveillance of employees, increase hazard training, establish new protection procedures, and revise exposure monitoring.

In addition to establishing PELs, OSHA also promulgated in 1983 the Hazard Communication Standard (HCS) which mandates recognition and awareness promotion of health hazards in the workplace. (OSHA, 1983) A substance is a hazard for purposes of HCS if there is significant evidence based on one or more appropriate scientific studies that exposed employees may suffer acute or chronic health effects as a result of the exposure. Silica sand, or crystalline silica, meets these conditions, as inhaling high concentrations for long periods can harm the lungs. Likewise, the HCS includes substances that are classified as hazardous by sources such as the International Agency for Research on Cancer (IARC), OSHA, ACGIH, the National Institute for Occupational Safety and Health (NIOSH), and the National Toxicology Program (NTP), often based on a consensus opinion of selected experts.

The IARC evaluates chemicals and cancer risks and publishes a list of substances tiered by judged carcinogenicity. IARC began evaluating substances in 1967 and in 1987 found crystalline silica to be a Group 2A – probably carcinogenic to humans, in the opinions of those involved – substance, distinguishing it from amorphous silica for which there was inadequate evidence of carcinogenicity. In 1996, IARC reclassified occupational exposure to crystalline silica in the form of quartz or cristobalite as a Group 1 carcinogen, meaning that the IARC found in the literature evidence that it considered sufficient to establish carcinogenicity to humans, although others have noted that the mechanisms of carcinogenicity probably involve inflammation-mediated damage that only occurs when exposures are relatively (perhaps unrealistically) high (Borm et al., 2011). Amorphous silica, however, remains in Group 3. In proposing to reduce the PEL and action level, OSHA relies on studies which suggest that there would be a significant health and economic benefit from doing so. Industry argues that current data do not support the conclusion that the proposed reduction will cause such benefits. Industry members have also raised the question of whether current methods are capable of effectively monitoring compliance and detecting violations at the proposed lower levels. This paper reports on a study designed to test the reliability of commercial laboratories in assessing compliance with the proposed exposure limits under real-world conditions.

The current PEL for RCS is equivalent to $100 \mu\text{g}/\text{m}^3$ averaged over an 8-h sampling period. OSHA's August 12, 2013 proposal (OSHA, 2013) would lower the PEL by a factor of 2, from 100 to $50 \mu\text{g}/\text{m}^3$ (consistent with recommendations from NIOSH) and possibly set an action level of $25 \mu\text{g}/\text{m}^3$ at which various ancillary requirements of the standard would be triggered. Commercial laboratories will analyze the majority of the RCS samples collected during exposure monitoring of silica-exposed workers.

Such samples typically are collected to assess workplace exposures with respect to a benchmark such as the PEL or an action level. It is of great practical interest, therefore, to assess the accuracy, precision, and reliability of analytical results that might be expected from commercial laboratories for filters with quartz dust loadings corresponding to RCS exposure concentrations of 100, 50 and $25 \mu\text{g}/\text{m}^3$. These determine the rates of false positive and false negative errors and ultimately the efficacy of the proposed standard as a tool to reduce risk.

To help with this assessment, the American Chemistry Council Crystalline Silica Panel (ACC) sponsored an RCS performance

testing program. Filters containing three different loadings of respirable quartz dust were sent over a period of several months, to five different commercial AIHA-accredited laboratories for analysis. The design of the program and the results of the analyses are described below, along with a statistical assessment of the findings.

2. Materials and methods

ACC contracted with RJ Lee Group (Monroeville, PA) to prepare polyvinyl chloride (PVC) filters containing different levels of respirable quartz dust loadings for analysis in a blinded testing program. The filters were sent to five AIHA-accredited commercial laboratories that perform analyses of RCS using x-ray powder diffraction (XRD) methodology. The program was blinded in the sense that the labs were not informed that they were participating in a performance testing program. The filters were submitted with standard chain-of-custody forms as if they were collected during ordinary workplace monitoring of crystalline silica exposures by commercial customers.

The testing program included three replicate rounds of testing over a period of months, so that precision and accuracy could be assessed on an intra-laboratory as well as an inter-laboratory basis (Hicks, 1993). For each round, three loading levels of respirable quartz (the "reference levels") were deposited onto new PVC filters by the RJ Lee Group. These loadings were the masses of respirable quartz that would be collected during 8-h monitoring at a sampling rate of 1.7 lpm when concentrations of respirable quartz dust in air were 25, 50, and $100 \mu\text{g}/\text{m}^3$. The resulting reference levels (masses) of quartz dust on the filters were 20, 40 and $80 \mu\text{g}$ of quartz, respectively.

To assess the impact of other mineral interferences on reported lab results, filters for each reference level of RCS were to be prepared with three different matrices: (1) silica only (Min-U-Sil 5 (U.S. Silica Corp., Frederick, MD); (2) silica mixed with respirable kaolin; and (3) silica mixed with respirable soda-feldspar (SRM 99a; NIST). In addition, a blank filter was submitted to each lab with each round. Thus, in each replicate round, each of the five labs received 10 filters: 3 pure silica samples, 3 silica/feldspar samples, 3 silica/kaolin samples, and 1 blank filter – for a total of 150 samples (10 filters \times 5 labs \times 3 rounds).

2.1. Sample generation

The filters were prepared by weighing the minerals, suspending them, and then filtering the suspension onto new filters. To ensure that the mineral samples used were the respirable fraction, the oversize material in each sample was removed using sedimentation. A portion of the mineral was suspended in pH neutral, distilled water, agitated, and poured into a volumetric cylinder. The suspension was allowed to settle over a distance of 10 cm for 75 min before the remaining supernatant was siphoned and filtered. Each material was dried in a low-temperature oven overnight before being used to prepare the test filters.

To prepare the test samples, PVC filters (0.8 μm pore) were pre-conditioned in an oven at approximately 30°C . Each filter was assigned a three digit tracking number and pre-weighed on a Mettler Toledo MX5 Microbalance (readability down to $1 \mu\text{g}$). The test material was then tapped into a small, clean pan tared on the micro-balance. The contents of the pan were then carefully transferred to a beaker and the pan was rinsed well with isopropyl alcohol. The pre-weighed PVC filter was placed on the vacuum filtration system and topped with a funnel. The pre-made solution was poured onto the filter, the filter was allowed to air dry, and was then removed from the filtration set up. Filters were stored in a desiccator so they did not pick up moisture from the air until post-

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