Before the Occupational Safety and Health Administration
United States Department of Labor

Comments of URS Corporation on the Analytical Methods Discussion in OSHA's Notice of Proposed Rulemaking for a Crystalline Silica Standard and in the Associated Preliminary Economic Analysis (PEA) Document

Docket No. OSHA-2010-0034, 78 Fed. Reg. 56274 (September 12, 2013)

February 7, 2014

Executive Summary

These Comments address the question whether the sampling and analytical methods for crystalline silica are adequate to reliably measure respirable crystalline silica ("RCS") with acceptable accuracy and precision at the Permissible Exposure Limit (PEL) of 50 μg/m^3 and the Action Level (AL) of 25 μg/ m^3 that the Occupational Safety and Health Administration (OSHA) has proposed in a Notice of Proposed Rulemaking (NPRM) dated September 12, 2013. 78 Fed. Reg. 56,274 (Sept. 12, 2013). These Comments were prepared by URS Corporation at the request of the American Chemistry Council Crystalline Silica Panel, which has supported the work financially. Here is a brief summary of our findings:

First, OSHA relies principally on a March 2013 study conducted at its Salt Lake Technical Center ("2013 SLTC study") to support its contention that RCS exposures of 50 μg/m^3 can be measured reliably with acceptable precision. But that study has important shortcomings and cannot support the feasibility of measuring RCS concentrations at or below 50 μg/m^3. In the 2013 SLTC study, OSHA claimed a 95% confidence limit for precision of 14 to 17% on low level replicate "samples" of 20 and 40 micrograms of silica. However, this study was performed in a controlled laboratory setting using only pure silica reference material that was directly deposited onto a sample filter. No matrix interferences were added, and none of the analytical procedures used to remove them were applied to any sample. And, since it was a single laboratory study, it could not account for inter-laboratory variability. In addition, OSHA inappropriately used a one-sided 95% confidence interval, making the precision appear better than it actually was. Further, a larger, earlier 2010 study *by the same SLTC laboratory* reported much higher variability at both the 20 μg and 40 μg silica loading levels, even though that study also involved the analysis of pure silica reference material with no interferences added. Longer term tests of precision at the SLTC laboratory also showed much higher variability values than the March 2013 SLTC study. And the SLTC's precision values in the IHPAT program, where simulated interfering matrices are included, were dramatically worse.

Second, OSHA erroneously suggests that low-level silica concentrations can be measured as accurately as higher concentrations. This is not supported by the data in the record. OSHA's assertion is based on a subset of data from the Industrial Hygiene Proficiency Analytical Testing ("PAT") program, all of which corresponds to silica concentrations that are significantly higher than the proposed PEL. Furthermore, due to an incorrect calculation, OSHA asserts that the results for lower silica loading samples (49-70 μg), representing exposure concentrations from 60-86 μg/m^3, are as precise as those for higher silica loading samples, representing higher exposure concentrations. In fact, when OSHA's calculation error is corrected, the "low-concentration" IHPAT samples show appreciably *increased* variability when compared to higher-concentrations samples. The reduced precision observed at lower concentrations is likely to be exacerbated as concentrations approach the PEL.

Third, OSHA unreasonably dismisses more representative data from the IHPAT program, which is the only recognized accreditation program for industrial hygiene silica analysis in the United States. These data show much greater variability (and much poorer precision) than the SLTC study that OSHA touts as demonstrating that exposures of 50 μg/m^3 and below can be measured reliably, accurately and precisely. This is true even when one considers only the PAT program results for OSHA's SLTC laboratory, whose PAT program precision values are far above those reported in the 2013 SLTC study. While the IHPAT program does not include any samples measuring respirable silica at concentrations at or below 50 μg/m^3 and involves labs that know they are participating in a performance test for accreditation, it nonetheless provides a more credible assessment of measurement feasibility than the limited and unrepresentative data set on which OSHA relies. The sample matrices used in the IHPAT program include interfering materials that are commonly found in workplace samples in the real world and that increase variability in sampling results. In addition, if one considers results for labs other than just the SLTC, the PAT program allows inter-laboratory variability to be taken into account. And, of course, the IHPAT program database includes a vastly larger number of sampling events than the 2013 SLTC study, where a mere ten replicate samples were analyzed. Finally, OSHA's argument that the IHPAT data relies on laboratories with inferior QA/QC practices is baseless, as it relies on an outdated report. Moreover, the performance of OSHA's own SLTC laboratory in the IHPAT program is no better, on average, than other participating laboratories.

Fourth, one cannot assume that precision in the analysis of low-level RCS exposures will be improved by using higher flow-rate samplers. A principal reason for this is that while RCS filter loadings will increase, so will loadings of potential interferences, with the result that detection limits for RCS may remain unchanged and precision will not improve. Because there will be a larger mass of interferences, additional sample handling procedures such as acid washing will be required, resulting in reduced precision. The samples also may require analysis using alternative secondary or tertiary peaks, or the overall X-ray intensity may be diminished due to increased filter loading.

Fifth, OSHA's proposed switch from the 1968 ACGIH definition of respirable dust to the ISO/CEN definition will result in an increase of roughly 20% in the amount of RCS that is collected and measured in future workplace sampling. This means that in effect, the current 100 $\mu g/m^3$ PEL will have been lowered to about 80 $\mu g/m^3$, and the proposed 50 $\mu g/m^3$ PEL would be equivalent to roughly 40 $\mu g/m^3$ when measured under the current definition. These lower exposure values will increase the variability of measurements of workplace samples, rendering the reported results even more unreliable. The switch to the ISO/CEN definition of respirable dust also has implications for OSHA's feasibility determinations, since the data serving as the basis for those determinations is based upon measurements using the old ACGIH definition.

In sum, OSHA has not demonstrated that it is feasible to reliably and precisely measure RCS at concentrations of 50 $\mu g/m^3$ and below.

Introduction

In the preamble to the NPRM and in the much more detailed Preliminary Economic Analysis (PEA, Docket ID: OSHA-2010-0034-1720), OSHA attempts to justify its contention that analytical methods are adequate to reliably measure respirable crystalline silica exposures at a level of 50 µg/m^3 with an acceptable degree of accuracy and precision. However, as shown below, OSHA's arguments on this point do not withstand analysis. To the contrary, a fair assessment of the available data refutes OSHA's claim that sampling and analytical methods are adequate to reliably measure silica exposures at the proposed PEL of 50 µg/m^3 and the action level of 25 µg/m^3.

1. The March 2013 SLTC Study

In the NPRM preamble, OSHA implies that extensive data from their Salt Lake Technical Center lab demonstrates that the full "sampling and analysis error" (SAE) was only +/- 14% at the 95th percentile for lower filter concentrations at 20 and 40 µg per filter (roughly equivalent to 25 and 50 µg/m^3 for full 8 hour shift samples). However, it turns out that OSHA was referencing a single study performed at the SLTC Laboratory during March 2013, using the OSHA XRD Method ID-142. For several reasons, that study does not establish the reliability of sampling and analysis for RCS at exposures of 50 µg/m^3 and below.

First, the March 2013 SLTC study did not test real samples, or attempt to simulate real sample matrices. Rather, it appears that the samples were prepared from dilutions of pure silica stock standard, with a little carbon added for visibility (presumably to detect leaks around the edge of the filter). No materials were added to simulate a sample matrix (as is done in the PAT program). Instead, the pure silica samples were first deposited onto PVC sampling filters, then dissolved in THF, and then re-deposited onto the silver membrane analysis filters. No other method (such as muffle furnace or plasma asher) was used to destroy the initial PVC sampling filter.[1] Moreover, since it was known that no interferences were present, no other processes or analytical procedures designed to remove or adjust for interferences in sample matrices (*e.g.*, acid washing or use of secondary or tertiary XRD angles) were applied to any of the test samples. This is a major difference from the way exposure samples are handled in the real world. Actual field samples collect dust that is generated by cutting, grinding, or otherwise fracturing various mineral materials such as brick, tile, concrete, etc. These materials most often contain only small percentages of crystalline silica, and the non-crystalline silica materials most often form the largest portion of the filter loading for real IH samples. These materials contain interferences that in many cases necessitate additional sample preparations and modifications to the XRD analysis. These additional procedures to overcome interferences reduce the precision of measurement, and/or raise the quantification level that can be attained for the samples. None of these factors entered into the March 2013 SLTC study.

The importance of the sample matrix in any silica analysis cannot be overstated. The respirable dust generated by the processing of industrial or construction materials often contains less than 10%, and in some instances less than 5% crystalline silica. In many, if not most instances, the non-silica materials comprising the greater portion of the respirable dust create variability and biases in the analysis of actual industrial samples containing RCS. However, the SLTC analyses described in the PEA were performed only on pure calibration standards and thus could not evaluate the additional variability resulting from the presence of interfering minerals on the sample filter.

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[1] See Docket items No. OSHA-2010-0034-1847 and OSHA-2010-0034-1968.

OSHA notes that XRD type methods have lower interferences than either the IR or colorimetric procedures, but this does not mean that they are absent. On pages IV-27 to IV-28 of the PEA, OSHA acknowledges the following interferences:

> The OSHA Technical Manual lists the following substances as potential interferences for the analysis of crystalline silica using XRD: aluminum phosphate, feldspars (microcline, orthoclase, plagioclase), graphite, iron carbide, lead sulfate, micas (biotite, muscovite), montmorillonite, potash, sillimanite, silver chloride, talc, and zircon. The interference from other minerals usually can be recognized by scanning multiple diffraction peaks quantitatively. Diffraction peak-profiling techniques can resolve and discriminate closely spaced peaks that might interfere with each other. Sometimes interferences cannot be directly resolved using these techniques. Many interfering materials can be chemically washed away in acids that do not dissolve the crystalline silica in the sample. Properly performed, these acid washes can dissolve and remove these interferences without losing substantial amounts of crystalline silica.

It should be noted that while the acid washing procedure described above can remove interferences without losing "substantial" amounts of crystalline silica, such a procedure also invariably adds variability to the analytical method. No such procedures were performed on the samples from the SLTC studies, because pure standards would contain no such interferences. However, that also means that the SLTC studies do not reflect the additional variability caused in samples that require interference removal. In addition to acid washing described by OSHA, some methods also resort to ashing samples. The omission of these sample handling procedures in the SLTC studies would serve to greatly lower the variability from what would be present if real samples had been analyzed.

Sections 4.0 – 4.4 of Method ID-142 discuss various ways in which the analyst can attempt to identify and compensate for interferences by modifying the analysis. That discussion illustrates the fact that when matrix interferences are present, considerable analyst intervention is required, and analyses are often performed at secondary or tertiary analytical peaks that are more variable and have less sensitivity (higher quantification limits). Indeed, at page IV-28 of the

PEA, OSHA itself acknowledges that "analysts need to have a high degree of scientific training to properly interpret XRD data." This means that for real samples containing interferences, the XRD analyst is involved in decisions as to whether the automated computer results (that are sufficient for the analysis of pure silica standards) require modifications for the analysis of particular samples due to interferences. Such decisions certainly increase variability, both within a single laboratory and, more importantly, across laboratories, thereby contributing to elements of both intra-laboratory and inter-laboratory variability that the SLTC studies do not evaluate.

Second, all of the samples for the March 2013 SLTC study appear to have been analyzed together, or within a short time of each other (all in March, 2013), and this may account for the much better precision in this study compared to the others conducted at SLTC, which involved many more samples analyzed over longer periods of time. Samples analyzed on the same day or within a few days of each other will likely all be analyzed against the same calibration curve, with the same analyst, and likely would be prepared from the same stock standards as used for the calibration of the instrument. OSHA also gives no indication that the spikes were blind, that is unknown to the analyst. All of these conditions serve to greatly increase accuracy and decrease variability in the sets of samples analyzed.

Third, the "sampling and analytical error" (SAE) metric that OSHA calculated from the March 2013 SLTC study is a *one-sided* 95th percentile statistic for which the coefficient of variation (CV) or relative standard deviation (RSD) is expected to be lower than a properly calculated precision value which reflects a *two-sided* 95th percentile interval. Thus, as shown on page IV-34 of the PEA, the equation OSHA used to calculate the SAE uses a standard deviation constant of 1.645, which produces a 95% confidence interval for *one-sided* distribution but only a 90th percentile value for a *two-sided* distribution. In evaluating analytical variability, the relevant distribution is definitely two-sided, because unacceptable results can be either too low (below the mean) or too high (above the mean). The correct 95th percentile standard deviation constant of +/- 1.96, as identified on page IV-34 of the PEA, should, therefore, have been used to determine precision in the March 2013 SLTC study.

In short, the March 2013 SLTC study did not use actual IH samples, did not attempt to simulate real samples by including an interfering matrix, and was not blinded. All Coefficient of Variation (CV) values reported from the SLTC study are based only on analyses of pure standards, which are not suitable material to estimate total analytical variability when real world samples having interfering matrices are being analyzed. Moreover, the fact that these are results from a single lab means that inter-laboratory variability was not taken into account.

2. <u>The 2010 SLTC Study</u>

In 2010, the SLTC lab conducted another study analyzing replicate samples of silica filter loadings of 20 and 40 µg. Ten replicates of quartz at each of those loadings and ten replicates of cristobalite at each of those loadings were analyzed by two different XRD instruments. See Docket ID OSHA-2010-0034-1670. The results of this study showed much higher variability than the results of the March 2013 SLTC study. Using the Rigaku XRD instrument, the estimate of CV_1 for quartz was 16.1% based on the first analytical line of the 10 samples at 20 µg and 12.8% for the 10 samples at 40 µg. For the PanAnalytical XRD instrument, the estimate of CV_1 was 21.6% for the 10 samples at 20 µg and 13.4% for the 10 samples at 40 µg. These are much higher than the comparable values reported in the March 2013 SLTC study, where the reported CV_1 values for the 40 µg and 20 µg quartz loadings were 7.3% and 8.6%, respectively. This suggests that the results from the March 2013 SLTC study may very well be an aberration even for the SLTC laboratory, and results for longer term testing at the SLTC laboratory appear to confirm this point.

3. Precision at the SLTC Lab over the Longer Term and in the PAT Program

OSHA contends that the SLTC laboratory has a continuous history of meeting a 95th percentile precision in the range of 17-20%. But all of these were 90th percentile SAE precision values; true two-sided 95th percentile values would be significantly higher. Moreover, based on the description in the PEA, these were not actual field samples or simulated samples. Rather, they appear to have been laboratory calibration check samples of pure silica analyzed daily when the tests were performed, and apparently prepared from pure standard, possibly the same lot of standard as was used for the calibration curves. These samples do not contain any interfering matrix materials, so that sample handling and interference removal steps that otherwise would be required for analyzing actual industrial IH samples did not have to be taken. Consequently, the results of these analyses are not representative of the variability to be expected when analyzing. actual field samples. Even so, precision values in these longer term analyses are far higher than what OSHA reports for the March 2013 SLTC study. Thus, as reported at page IV-34 of the PEA, the SLTC lab's average CV_1 for quartz analysis over a range of 50-300 μg RCS per sample from February 2007 through July 2010 was 0.129, while at loadings of 50-60 μg RCS per sample, it was 0.144 over a comparable period. These RCS loadings are higher than those analyzed in the March 2013 SLTC study. Yet, for the closest comparable loading ranges (40 μg in the March 2013 SLTC study and 50-60 μg in the longer term tests), the CV_1 in the longer term tests (0.144) was twice as high as the reported CV_1 in the March 2013 SLTC study (0.073).

Moreover, when interfering matrices are introduced, the performance of the SLTC laboratory deteriorates dramatically – as illustrated by the SLTC's results in the PAT program, where its average CV_1 value for PAT rounds 160-180 was 0.19 when analyzing silica filter loadings ranging from 55 to 165 μg. See PEA at IV-40. That is almost three times higher than the CV_1 reported for the March 2013 SLTC study at silica loadings of 40 μg. The most obvious reason for this dramatic difference in performance is the fact that PAT samples are prepared to simulate real world samples containing potentially interfering matrices, while the internal tests performed at the SLTC lab are essentially calibration checks using pure standards.

4. The SLTC Studies allowed for only minimal sampling error.

In the absence of an actual sampling step, OSHA incorporated an assumed 5% sampling error into its calculations of precision in the SLTC studies, and it appears to be too low. The 5% error estimate used by OSHA was based only on variability in the volume of air sampled by typical field sampling pumps. However, for crystalline silica and respirable particulate measurements, pump flow rate also is critical in defining the "cut point" of the respirable particle sizes that will collect on the filter, rather than falling into the cyclone. A 5% error in flow rate could result in a much greater error in the measurement of RCS, depending on the size distribution of the material present at individual sites. The assumed 5% sampling error should, therefore, be regarded as a minimum value.

5. Precision at High versus Low Silica Filter Loadings

OSHA asserts that (selected) PAT program data (presented in Table IV.B-9 on page IV-39 of the PEA) demonstrate that accuracy and precision are unimpaired at low concentrations. But these data do not justify that conclusion.[2] For one thing, virtually all the data selected by

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[2] The small PAT data slice examined by OSHA involved PAT rounds 156-165 dating from January of 2004 through April of 2006. It is not clear why OSHA chose this particular subset of PAT data to examine. It is only a

OSHA reflect silica loadings that are much higher than the RCS mass that would be collected when exposures are in the range of 25-50 µg /m^3, so OSHA's analysis of these data is only of tangential relevance to the measurability issues raised by the proposed standard. Filter loadings in the "low" concentration filter range (49-70 µg /filter) selected by OSHA for this data test are well above the proposed PEL of 50 µg /m^3 based on a full 8 hour sample collection volume of 816 liters. Furthermore, OSHA made a calculation error in analyzing the data portrayed in Table IV.B-9. OSHA reported that for the eleven PAT samples with a mean concentration in the range of 49-70 µg /filter, 81% of the participating laboratories were within +/- 25% of the true value. This led OSHA to conclude that there was essential equality in precision for the "low concentration" data and the higher concentration data in the table, since (by OSHA's calculation) 80% of all labs in this data set reported values that were within +/- 25% of the true value. In fact, however, only 73% of the reported results for silica filter loadings in the 49-70 µg range were within +/- 25% of the true value, while 83% of the reported results for silica filter loadings higher than 70 µg were within +/- 25% of the true value, a very significant difference. The following table is a reproduction of the OSHA Table IV.B-9 from pages IV-39 to IV-40 in the PEA, with some added rows at the bottom calculating additional values. The eleven samples OSHA considered to be in the lower concentration range are highlighted in red, the other 29 samples at higher concentrations are in black. Note that the overall average silica loading of these PAT samples is around 0.10 mg/filter (100 µg /filter), which would correspond to the RCS mass collected over an eight hour period at a flow rate of 1.7 liters/minute when the RCS exposure level is around 120 µg /m^3.

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fraction of the silica PAT tests run for over 30 years; it is not the most recent rounds of tests, and these rounds occurred at a time of change and experimentation within the AIHA PAT program. After round 158, AIHA changed the means of calculating acceptable results by limiting the RSDs for the combined results, artificially reducing any calculated average RSD greater than 20% to equal 20%. After round 160, AIHA started preparing PAT samples using liquid suspensions, not aerosols.

Table IV.B-9—The Percentage of Laboratories Reporting Values Within Plus or Minus 25% of Mean by PAT Round and Sample Number

Round Number	Sample Number	Number of Labs	Mean (mg)	RSD	Percent of Labs Within 25% of Ref Value
156	1	62	0.0566	0.2389	66%
156	2	62	0.1200	0.1812	81%
156	3	62	0.0678	0.2139	71%
156	4	62	0.1145	0.2333	73%
157	1	64	0.0906	0.2661	66%
157	2	64	0.0854	0.2725	53%
157	3	64	0.0700	0.1923	72%
157	4	63	0.0671	0.2100	75%
158	1	62	0.0700	0.2346	69%
158	2	62	0.1330	0.2027	74%
158	3	62	0.1005	0.1959	84%
158	4	62	0.0624	0.2545	71%
159	1	63	0.1077	0.1779	68%
159	2	63	0.1141	0.1999	81%
159	3	63	0.1058	0.1999	73%
159	4	63	0.0792	0.1997	76%
160	1	62	0.0879	0.2000	69%
160	2	62	0.0541	0.1999	56%
160	3	62	0.1361	0.2000	60%
160	4	62	0.1006	0.1999	53%
161	1	60	0.0952	0.1365	87%
161	2	60	0.1380	0.1792	73%
161	3	60	0.1293	0.2000	73%
161	4	60	0.0604	0.1793	83%
162	1	61	0.1551	0.1596	85%
162	2	61	0.0606	0.1316	90%
162	3	61	0.1227	0.1496	85%
162	4	61	0.0709	0.1630	79%
163	1	63	0.1118	0.2000	84%
163	2	63	0.1651	0.1541	87%
163	3	63	0.0508	0.1827	75%
163	4	63	0.0866	0.1684	75%
164	1	61	0.1020	0.1855	77%
164	2	61	0.1237	0.1817	82%
164	3	61	0.1609	0.1294	87%
164	4	61	0.0759	0.1956	79%
165	1	62	0.0837	0.2000	66%
165	2	62	0.0490	0.1577	79%
165	3	62	0.1149	0.1572	84%
165	4	62	0.1573	0.1989	77%
Average			0.1057	0.1705	80%
Average for <70 µg /filter			0.0608	0.1995	73%
Average for >70 µg /filter					83%

As can be seen, when OSHA’s calculation error is corrected, the reported results for the lower range of silica filter loadings in this data set are found to exhibit significantly greater variability than results for the higher silica loadings. Moreover, OSHA has not explained why it considers the results to be acceptable when only 80% of all labs report results that are within +/- 25% of the true value. After all, the NIOSH Accuracy Criterion “requires that, over a specified concentration range, the method provide a result that differs no more than ±25% from the true value 95 times out of 100,”[3] and the relevant concentration range for this purpose generally is “a range of concentrations bracketing the permissible exposure limit (PEL).”[4] While the NIOSH Accuracy Criterion may not apply directly to PAT program results, it certainly suggests that the 80% “success rate” cited by OSHA for concentrations well above the proposed PEL is nothing to shout about.

6 . The PAT Program

The PAT program administered by IH professionals from AIHA and NIOSH contains an extensive database of silica analyses that goes back more than 30 years, and to this day, it serves as the standard for certification for silica analyses for all IH laboratories in the United States and many other laboratories around the world. Accordingly, one would assume that the PAT program would be a logical source of data for determining precision and accuracy in analyses of crystalline silica. OSHA, however, asserts that the PAT data are unsuitable for that purpose. This rejection of the PAT data is puzzling, since OSHA’s SLTC laboratory itself participates in the PAT program – and unlike the SLTC studies, which reflect only the intra-laboratory

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[3] NIOSH Manual of Analytical Methods (January 15, 1998) at 36.

[4] See Key-Schwartz, R. *et al*., "Determination of Airborne Crystalline Silica," in NIOSH Manual of Analytical Methods, 4th rev. ed. Cincinnati, OH, US Dep't of HHS, Public Health Service, Centers for Disease Control and Prevention, NIOSH, DHHS (NIOSH) Publication No. 03-127, at 273.

variability, PAT data reflect both intra-laboratory and inter-laboratory variability. Moreover, in contrast to the analytical studies performed at the SLTC lab (which use only pure silica standards), all of the samples in the PAT program are prepared so as to simulate actual industrial samples. For each PAT round, the silica is embedded in sample matrices that are typical of what might be produced in industries that are likely to engage in monitoring for silica. The four matrices currently in use (on a rotating schedule) are coal dust (mining industry), calcite (present in concrete), talc dust (a soft, clay-like mineral that could roughly simulate the non-silica portion of bricks, tiles, or many other construction or industrial materials), and lastly a mixture of coal dust and talc. This use of potentially interfering matrices is of signal importance if real world analytical variability is to be determined. For these reasons, URS believes that the three-decade old PAT program, despite its limitations, is a far more credible indication of the true variability of IH silica analysis than the tests that the SLTC lab performed on pure calibration standards.

OSHA contends that PAT program variability is skewed very high by a few "outlier" laboratories that have less rigorous quality control standards. But that claim is refuted by the fact that the performance of its own SLTC lab in the PAT program is almost right at the average for the group. Thus, the SLTC's CV_1 for PAT rounds 160-180 was 0.19, while the CV_1 for all PAT participants in rounds 156-165 was 0.195. See PEA at IV-37. OSHA also says that the use of different analytical methods increases variability in the PAT program. But all labs currently participating in the PAT program use either the XRD or IR methods approved by OSHA for use in the proposed Silica rule. See PEA at IV-37, Table IV.B-7 (showing that none of the AIHA accredited laboratories uses the colorimetric procedure). And, even for the older PAT rounds discussed in the PEA, the colorimetric method was almost phased out, with no more than two or three laboratories (out of 60 to 80) still using the colorimetric method. That is too small a number to have a significant impact on the mean reference value or RSD calculated for each PAT round.

OSHA relies heavily on a report by Eller et al. (1999b) to suggest that some PAT program labs were not following best practices for optimizing accuracy and precision (see PEA at IV-41), and OSHA magnifies the problems found by that study. However, the Eller report was finished in 1999, and focused on a single PAT round: Number 133. This round was sent out for testing in April of 1998. All of the PAT rounds analyzed by OSHA in the PEA (rounds 160-180) are from 2004 through 2010, starting more than five years after the Eller report was published. It is therefore significantly outdated. In PAT round 133 examined by Eller, there were 82 participating laboratories. The average number of participating laboratories from PAT rounds 160 through 180 was only 59, so 28% of the laboratories had dropped their silica certification (or stopped participating in the PAT program) over a relatively short time. Presumably this included most of the weakest laboratories identified in the Eller study. In addition, other laboratories undoubtedly adopted many of the practices recommended by Eller, if they were not doing so already. So, the PAT program results described in the PEA should not be taken to reflect the less-than-adequate practices followed by the "outlier" laboratories in Eller's report on PAT round 133.

In short, the arguments OSHA makes against using the PAT program data to evaluate the precision of analytical methods for respirable crystalline silica are not well founded. The PAT program results – which reflect the analysis of samples containing simulated interfering matrices and which show both intra-laboratory and inter-laboratory variability – provide a far more sound and realistic basis for evaluating variability in the analysis if RCS than the single March 2013 SLTC study of ten replicate pure silica samples on which OSHA mistakenly relies.

7. Higher Flow-Rate Samplers

OSHA argues that lower detection levels can be obtained using some newer style cyclones that can sample respirable fractions of dust at faster rates, and thus collect more material on the sampling filters for a given sampling time. The main problem with this is that the non-target materials from the samples, along with the additional loading and potential interferences, will be increased in exactly the same proportion as the increase in crystalline silica that is deposited on the sample filter. For many industrial materials, this likely will not result in a lower detection limit. The samples may have more interferences requiring additional sample handling such as acid washing, resulting in reduced precision. The samples also may require analysis using alternative secondary or tertiary peaks, or the overall X-ray intensity may be diminished due to increased filter loading. OSHA does not address these problems. Another problem is that the new cyclones do not necessarily perform identically to the older cyclones in terms of particle size distribution, which can affect the mass of RCS collected.

8. Switch to the ISO/CEN Definition of Respirable Dust

OSHA has proposed adopting new definition of respirable dust that will have the effect of lowering the existing PEL. OSHA has proposed to adopt the ISO/CEN model, which will raise the particle size “cut point” for the sampling of respirable dust from 3.5 µm to 4.0 µm. This is done by adjusting the flow through the sampler cyclones to a different set point flow during sampling. The alternative set points that comply with ISO/CEN criteria are determined by the cyclone manufacturer, and vary for different types of cyclones. While this change can have variable effects depending on the particle size distribution of the dust being sampled, the overall general effect is to increase the total amount of dust sampled per unit volume of air. According to the discussion in the PEA, many materials will show an increase of sampled respirable dust on the order of 20-25%. This has the effect of lowering the PEL, in that many samples formerly measured at about 80 µg/m^3 might now exceed the existing 100 µg /m^3 PEL. This will not improve the precision of the analysis, but it will make the proposed 50 µg /m^3 PEL even more difficult both to measure and to achieve.