



Respirable Crystalline Silica (RCS) Measurement

AIOH / NATA Statement of Common Interests

Background

Australia, like many countries, is grappling with the health implications of lung diseases associated with exposure to respirable crystalline silica (RCS) and the need for appropriate action, including effective workplace monitoring, for the protection of workers.

Legislated Workplace Exposure Standards (WES) are fundamental to these efforts. Under the current Australian model Work Health and Safety (WHS) Regulations, the WES establishes a statutory maximum upper limit of exposure to workers for hazardous chemicals such as RCS. The RCS exposure standard is expressed as a Time Weighted Average (TWA) breathing zone concentration and the current value is specified as a TWA-WES of 0.05 mg/m³.

It is important to note that the WES for RCS is measured as an 8-hour TWA. This means that the WES is based on exposure that occurs in an 8-hour working day, 5-day working week. In circumstances where a longer working day (or working week) occurs, the WES is adjusted to compensate for the greater exposure during the longer work shift and the decreased recovery time between shifts (Safe Work Australia, 2013). The application of an extended work shift reduction factor to the 0.05 mg/m³ WES reduces this limit further. As an example, where 12-hour shifts are implemented, the WES can be reduced to 0.025 mg/m³ when applying the Brief and Scala model of exposure standard adjustment.

It is understood that further lowering of the legislated limit is under active consideration by policymakers. However, for regulation of this nature to be effective, it is essential that reliable measurement at the levels specified is actually possible.

With this in mind, AIOH and NATA have agreed to collaborate in driving awareness of the issues and to facilitate efforts towards outcomes that are both effective and aligned with the public interest.

Laboratory context

The accuracy and reliability of RCS exposure assessment is dependent on both the sampling and analytical components.

Some of the factors contributing to errors and uncertainties of the sampling component of RCS exposure assessment include:

- spatial and temporal variability and non-homogeneity of dust clouds
- representativeness of the sampling of 'normal' exposure patterns
- conformance of the sampling device to the respirable dust size-selective collection efficiency curve (see AIOH 2020)
- variations in sampling flow rate and uncertainties in flow rate measurements
- transportation and handling of the samples.

To illustrate, variations in measured dust concentrations between left and right lapels of up to 100% have been reported (Vaughan et al 1990). While more detailed discussion of sampling variables is beyond the scope of this document, this example may serve to highlight the significance of sampling-related uncertainties, which is *over and above* the more commonly reported analytical uncertainties.

In terms of the reliability of laboratory analysis of RCS on filter samples, it is worth recalling that the analytical Limit of Detection (LOD) is generally defined as *"the lowest concentration of the analyte present in a sample that can be detected, using a given measurement procedure, with a specified level of confidence"* (see Eurachem Guide 2014). See also Note 1. The limit of quantification (LOQ) is defined as *"the lowest level of analyte that can be determined with acceptable performance"* (see Eurachem Guide 2014). The LOQ is usually 2 times the LOD (see Eurachem Guide 2014).

However, the overall reliability of an analytical method is not the same as the lowest achievable LOD/LOQ when measuring pure reference grade RCS. In real world monitoring, interfering substances will typically be present and there are other factors such as particle size distribution and variability in sampling which also affect the actual LOQ. Disparity between analytical LOD calculated on supplied pure reference samples and real-world performance is not unusual for measurements associated with environmental monitoring. In this regard, a clear understanding of all contributing variables is fundamental to effective method validation.

One estimate for the true qualitative LOD (see Methods for the Determination of Hazardous Substances (MDHS) 101/2: 2015) is expressed in the following way: "...probably about 10 μ g for the strongest quartz peak and around 20 μ g for the strongest cristobalite peak." This translates to an LOQ for the analytical component for quartz of around 0.02 mg/m³ based on an 8-hour sample and 1056L of air sampled. For cristobalite, the corresponding limit is more like 0.04 mg/m³. A survey of laboratory LOQ estimates is available here: https://amcaw.ifa.dguv.de/substance/methoden/052-L-Quartz.pdf.

Importantly, this is without taking note of the associated measurement uncertainties, which can be quite high. In the aforementioned MDHS 101/2 method, the stated uncertainty is expressed as \pm 50% for samples in the range of 0.02-0.05 mg/m³. On this basis alone, a result at 0.025mg/m³ would reflect a true value somewhere between 0.012 mg/m³ and 0.038 mg/m³ – rendering any determination of compliance against a limit 0.025mg/m³ highly problematic.

The AIOH has previously stated (see Position Paper 2018) that the LOQ plus associated analytical measurement uncertainty, combined with uncertainties associated with interfering minerals (independent of FTIR or XRD analysis), and sampling (e.g. flow rate & sample duration), means that *reliable* determination of RCS levels less than 0.050 mg/m³ in real world occupational exposure situations is fraught with difficulties.

As an interesting point of reference, when assessing whether accurate sampling and analytical methods are available to measure exposure for comparison with a recommended exposure standard, the European Commission (2017) states that 'Measurement techniques should be able to assess exposure at: 0.1 times the [Occupational Exposure Limit] OEL for 8-hour TWA.'

The situation becomes even more challenging in circumstances where longer working shifts apply, meaning that the adjusted TWA-WES is correspondingly lower.

Implications

To demonstrate compliance with the WES, PCBU's must be confident that the measurements obtained are accurate and representative of workplace exposure. Health and safety regulators must also be confident that the measurements obtained are accurate and reliable, in circumstances where enforcement action may be required. If the WES is set at a level where the analytical method approaches its LOQ, some samples

taken at the same site may not show evidence of exposure because of the relative variability of both the sampling and analysis.

For specifiers and users of RCS data, it is important to understand that limitations in measuring RCS exposure below 0.05 mg/m³ are likely to lead to significant issues in enforcing the proposed WES in practical application of the legislation and for PCBU's to meet the requirements under WHS legislation.

For occupational hygienists, it is important that the bias of exposure results is not large in order to have confidence that the control measures are protecting the workers to the required standard (i.e. less than half of the WES). The better the analytical precision, the more likely it is that differences in results between tasks or operators are identified (Stacey, 2007).

For laboratories, appropriate technical guidance should be consulted, such as that available from the AIOH (see https://www.aioh.org.au/resources/publications1/position-technical-papers/technical-papers) and from NATA (see NATA 2018).

A revision to ISO 24095 (2009) is currently in development and specification of the published version within the Australian guidance for measurement of RCS in the workplace may be considered appropriate by regulators.

Conclusion

Both the AIOH and NATA are focussed on ensuring RCS exposure measurements are conducted with integrity and that the results provide meaningful conclusions for appropriate interpretation to ensure that workers are protected against RCS exposure.

There are known challenges regarding the measurability of RCS at concentrations below the current 8-hour TWA-WES of 0.05 mg/m³. Conventional technologies used for analysing respirable dust samples collected to AS 2985 (2009) are at their limits in reliably quantitating RCS at the current exposure standard. Ongoing developments in analytical technology may be capable of reducing the analytical LOD/LOQ, however the sampling-related contributions to overall uncertainty will remain significant and indeed become proportionately more important in the event that the analytical uncertainty becomes more tightly constrained.

AIOH and NATA are committed to working with industry and government stakeholders to facilitate mutual understanding and to contribute to effective public policy. To this end, AIOH and NATA mutually agree to:

- establishing communication within their respective membership regarding these issues to foster improved understanding and to facilitate effective feedback from affected parties
- explore opportunities for joint participation in educational, consultative or other public interest activities
- seek opportunity for engagement with state and federal agencies with the intention of constructively contributing to effective public policy.

Contact details for more information:

Dr Sharann Johnson FAIOH, COH Honorary Secretary Australian Institute of Occupational Hygienists Email: <u>secretary@aioh.org.au</u> Neil Shepherd Sector Manager, Life Sciences National Association of Testing Authorities Email: <u>Neil.Shepherd@nata.com.au</u> **Note 1**: This is typically determined by the establishment of the standard deviation (s_{LOD}) of replicate analysis ($n \ge 10$) of a small amount of silica sampled onto a filter.

References

AIOH (2018). *Respirable Crystalline Silica and its Potential for Occupational Health Issues* - Position Paper. Australian Institute of Occupational Hygienists Inc (AIOH) – see <u>https://www.aioh.org.au/resources/publications1/epublications</u>.

AIOH (2020). *Size-Selective Samplers for Respirable Dust Sampling – Guidance Information*. Australian Institute of Occupational Hygienists Inc (AIOH) Technical Paper – see https://www.aioh.org.au/static/uploads/files/aioh-pub-technicalpaper-sizeselectivesamplers-f-wfrpsyalyjbr.pdf.

AS 2985 (2009). Workplace atmospheres-method for the sampling and gravimetric determination of respirable dust. Standards Australia: Homebush NSW – see https://infostore.saiglobal.com/en-au/Standards/Product-Details-123338 SAIG AS AS 274551/?ProductID=123338 SAIG AS AS 274551.

Eurachem Guide (2014). *The Fitness for Purpose of Analytical Methods – A Laboratory Guide to Method Validation and Related Topics,* B. Magnusson and U. Örnemark (eds.) (2nd ed). ISBN 978-91-87461-59-0 - see https://www.eurachem.org/images/stories/Guides/pdf/MV guide 2nd ed EN.pdf

European Commission (2017). *Methodology for derivation of occupational exposure limits of chemical agents* - The General Decision-Making Framework of the Scientific Committee on Occupational Exposure Limits (SCOEL), Luxembourg: Scientific Committee on Occupational Exposure Limits – see https://op.europa.eu/en/publication-detail/-/publication/3c8ef3e0-48fc-11e8-be1d-01aa75ed71a1.

ISO 24095 (2009). Workplace air - Guidance for the measurement of respirable crystalline silica. The International Organization for Standardization (ISO) – see https://www.iso.org/obp/ui/#iso:std:iso:24095:ed-1:v1:en.

<u>NATA (2018).</u> General Accreditation Guidance – Validation and verification of quantitative and qualitative test methods. National Association of Testing Authorities (NATA) – see <u>https://www.nata.com.au/phocadownload/gen-accreditation-guidance/Validation-and-Verification-of-</u>

Quantitative-and-Qualitative-Test-Methods.pdf

Safe Work Australia (2013). *Guidance on the Interpretation of Workplace Exposure Standards for Airborne Contaminants*. See https://www.safeworkaustralia.gov.au/doc/guidance-interpretation-workplaceexposure-standards-airborne-contaminants.

Stacey, P (2007). Measurements of Silica in Air: Reliability at New and Proposed Occupational Exposure Limits. *J Occup Environ Hyg*, *4*; pp D1-D4.

UK Health and Safety Executive (2015). Methods for the Determination of Hazardous Substances (MDHS) 101/2: 2015 (see https://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs101.pdf)

Vaughan NP, Chalmers CP, Botham RA (1990). Field comparison of personal samplers for inhalable dust, Ann Occup Hyg, 34 pg. 553