

Summary of the 4th meeting of the Life Sciences Accreditation Advisory Committee

Changes to Committee

Since the 2020 meeting, the following changes to the membership of the Committee have been made:

Dr Lindsay Swinden has resigned from the AAC effective immediately.

Reports from Members included the following points:

- FT-020 Water Microbiology Committee – Two updated standards (AS 4276.1 and AS 4276.3) have been published by Standards Australia. It is noted that the revised version of AS 4276.3 has far greater options of techniques.
- Standard method AS/NZS 4276.13 has been released for public comment following a minor revision.
- The European Directorate for the Quality of Medicines & Healthcare (EDQM) Official Medicines Control Laboratories (OMCLs) network has technically revised its guidelines which cover the evaluation and reporting of test results. The technical revision includes guidance on the application of the decision rule (as per ISO/IEC 17025) for compendial testing where MU is not already accounted for in a compendial assay. It also clarifies expectations in relation to pooling/combining of test results, the averaging of test results, significant figures, rounding rules and out-of-specification test results. The revised documents will be available for public comment via the EDQM website.
- Testing of medicinal cannabis to demonstrate conformance with quality standards continues to be a growth area. Pharmacopoeia test methods might not be optimal for medicinal cannabis products. There is a lack of agreement on the microbial quality specifications to apply to the dried flower that is inhaled via vaping, as the specifications were developed in 1996 when dried flowers weren't inhaled and this is proving challenging for both industry and regulators.
- COVID-19 has resulted in requests for residual efficacy testing of disinfectants. The TGA are consulting industry to establish a suitable definition and defined test methods for use.
- Total Oxidisable Precursor (TOP) Assay. There are currently no standardised test methods for the TOP Assay. It is currently listed as a determinant in the scopes of accreditation; however, it should not be a test that NATA assesses. A forum to discuss this topic with facilities that have this included on their scope of accreditation would be beneficial.

- SARS CoV-2 testing for environmental surface samples. It is necessary to ensure that the test procedure and the extraction procedure are reviewed as part of the assessment activity.
- The ISO 16140 series were released earlier this year. Does NATA have an implementation program? NATA needs to reassure the laboratories the implementation of the series applies to new methods/matrices/sample sizes from now.

NATA cannot mandate uptake but it should be encouraged as validation and verification continue to be less than well understood and this would be risk mitigation.

- More emphasis has been placed on facilities by NATA to monitor and control field sampling for volume measurement, predominantly airborne fibre concentrations for asbestos and SMF fibres, following the release of the updated SAC.
- There needs to be more scrutiny at assessment activities. It was observed that it is critical in the pre-organisation for the assessment that there is a planning process where we are able to observe the sampling being performed.
- Automated PCM Microscope Technology for fibre counting systems are being marketed in Australia, however no laboratories have sought accreditation as of May 2021. The technology used within these systems remains a work in progress with regard to proficiency and speed of analysis.
- There has been a reduction in the Workplace Exposure Standard (WES) for Respirable Crystalline Silica (RCS). AIOH have drafted a paper to highlight the risks of reporting results in a laboratory setting to lower concentrations.
- An area that might seek accreditation is COVID-19 in air. The technique used would be cyclonic or an impinger.
- Standards Australia EV-007 Methods for Examination of Air Committee are reviewing the continuous particle monitoring methods. The committee is looking to standardise the requirements across a number of individual standards. AS 3580.9.8 is currently out for public comment, closing on the 17th June 2021.
- French organisation – Bureau International des Poids et Mesures (BIPM) who looks after the worldwide standard for measuring of ground level ozone are proposing a change in the reference ozone standard that most of the rest of the world use for traceability. They are changing the way they calculate the results and their provisional date for this change is January 2024. Those involved would be looking at about an increase of 1.2 percent in values.
- International Year of Plant Health was disrupted due to COVID-19 in 2020. A lot of activities were cancelled so it has been extended to July 2021. More information is available on the website – www.planthealthyear.org.au

- Regulators within five states were contacted to discuss sampling accreditation, but there was minimal action. It was challenging, as one regulator took it to mean that their practices were being questioned. This missed the objective as samples collected by regulators are not typically where the issues lie. Not sure where else to go with this matter, but if we can get one regulator to step forward, then we may get more.
- PFAS reference materials. An inter-laboratory study was conducted to certify reference material for PFAS analytes in a soil matrix. The participation of 11 laboratories assisted with assigning 14 property values. The material (MX019) is now available to assist laboratories with quality control and method development.
- COVID-19 reference materials and studies. NMI has released a set of reference materials (NMIA NA050 to NA055) certified for the copy number concentration of SARS-CoV-2 genome equivalents. This material is intended to allow laboratories to evaluate limits of detection and calibrate qPCR measurement systems used for the detection and quantification of SARS-CoV-2 viral genome. This set of materials has been used as part of an ongoing inter-laboratory study comparing testing protocols currently used by participants for the analysis of SARS-CoV-2 in a sewage matrix.

The next meeting of the Committee is scheduled for **Q2 2022**.