LIFE SCIENCES ACCREDITATION ADVISORY COMMITTEE

6th Meeting Minutes

12 noon Tuesday 11th July 2023

NATA Melbourne, 2 - 6 Railway Parade, Camberwell

Chair: Mr David Sheehan

Secretary: Mr Neil Shepherd

1. Meeting introduction and associated administrative matters

1.1 Confirmation of attendance and apologies

AAC Members

Mr David Sheehan (Chair)	Coliban Water
Dr Mark Lewin (Deputy Chair)	National Measurement Institute
Mr John Waters	On-Site Technology
Dr Julian Cox	University of New South Wales
Dr Dominie Wright	Dept of Primary Industries and Regional Development
Ms Joanne Wilson	Therapeutic Goods Administration
Ms Jasmine Lacis-Lee	Bureau Veritas AssureQuality
Dr Paul Wright	Tweed Shire Council
Mr Nigel West	ChemCentre
Dr Donald Neale	Dept of Environment and Science
Mr Richard Wilkinson	Tetra Tech Coffey

NATA Staff

Mr Neil Shepherd	Sector Manager, Life Sciences
Ms Tanya Daniels	Deputy Sector Manager, Life Sciences
Ms Danielle Dicker	Technical Manager
Ms Susan Harry	General Manager, Stakeholder Relations
Ms Des Hadjimichael	Lead Accreditation Specialist
Ms Carol Webster	Support Officer - Technical

Observers

Mr Michael Vercoe	IANZ

Apologies

Dr Karin Kassahn	SA Pathology
Dr Mark Dawson	Consultant
Mr John Styzinski	General Manager, Operations & Technical
Ms Maya Bryant	IANZ

1.2 Chair's opening remarks

Welcome from the Chair.

1.3 Reminder regarding conflict of interest and confidentiality

The Committee was reminded about confidentiality and the requirement to declare any conflicts of interest when necessary.

No conflicts of interest were declared.

1.4 Confirmation of the minutes of the previous meeting held 30th June 2022

The 5th Life Sciences AAC Meeting Minutes were confirmed.

1.5 Review of action items arising from the minutes of the previous meeting

The Committee was referred to the Life Sciences AAC Minutes Action Log.

An overview of actions on the log, for the period 2020 to 2022, was given by Neil S.

2. Committee membership

A detailed description of the role of the AAC, the role that the Chair and members play, and current AAC membership and composition was provided.

3. General Manager update

NATA's Technical Manager, Danielle Dicker, provided an update to AAC Members on major NATA initiatives and other matters that were considered relevant.

Accreditation Statistics:

- There has been limited growth in accreditaton numbers, with some losses due to facility amalagamations.
- The biobanking program is now operational, with the first facility accredited in January 2022, and another applicant in the pipeline.

Charter of Services Statistics:

- NATA set ten Charter of Service standards at 85%.
- Standards 4 and 5, which involved leaving an interim report on the day, were removed from statistics because they were consistently met nearly 100% of the time and skewed the data.
- The current Charter of Service performance is slightly lower due to the COVID-19 backlog, which has affected the ability to conduct assessments, but efforts are underway to catch up.
- Standard Service 9, directly related to Accreditation Advisory Committee's (AAC) turnaround times for Accreditation Review Checklists (ARC), was emphasised, and members were encouraged to complete reviews promptly or communicate if they cannot, to facilitate reallocation of the ARC.

APAC Re-evaluation:

- A re-evaluation was conducted from 6 to 10 March, 2023, focusing on ISO/IEC 17011 and relevant ILAC policy documents.
- Seven evaluators from ILAC signatory Accreditation Bodies (Abs) participated in the re-evaluation (USA - 2, Canada - 2, UAE, Taiwan, and Hong Kong).
- An application is in process to extend signatory recognition to include biobanking (ISO 20387), potentially making NATA the second organisation in the world recognised for biobanking.
- Findings included two non-conformities (related to staffing levels in the Inspection sector and overdue surveillance) and four comments (observations).
- Recommendations encompass maintaining MRA signatory status, extending recognition to biobanking, and undergoing a re-evaluation in the standard 4-year timeframe.

Conformity Standards under Revision:

- ISO/IEC 17020 is under review, which was initiated in April 2023.
- ISO/IEC 17025 has been confirmed for another 5 years after a systematic review.
- ISO 15189 has been revised and was published in November 2022. Facilities are to transition within the 3-year timeframe set by ILAC, and NATA will begin assessments against this standard in August 2023.
- ISO 17043 was published in May 2023, with a 3-year transition period. Assessments against this standard will commence in February 2024.

Initiatives:

- In January 2023, the introduction of a new multi-site accreditation policy brought changes to assessment processes and scope additions for multi-site facilities.
- The centralised review of validation / verification processes aims to reduce the need for individual site assessments by conducting sampling exercises.
- NATA established an Artificial Intelligence (AI) working group to explore the use of AI in testing and reporting, potentially impacting the accreditation process.

Action Item:

A questionnaire regarding the use of AI in assessments will be sent to AAC Chairs, and David S will ensure its distribution to AAC members for input. Feedback and responses will be collected for two weeks before sending it to Danielle D.

4. International update

Michael Vercoe spoke to his report and the following was noted/discussed:

New Drinking Water Regulator - Taumata Arowai:

- Taumata Arowai has taken on the role of the new regulator for drinking water. Over the past two years, several significant documents related to drinking water compliance testing have been introduced. These documents include the Water Services Act 2021, the Water Services (Drinking Water Standards for New Zealand) Regulations 2022, the Aesthetics Values for Drinking Water Notice 2022, the Requirements Relating to Laboratories 2021, and the Drinking Water Quality Assurance Rules 2022.
- Of particular note, the new Water Services (Drinking Water Standards for New Zealand) Regulations 2022, which establish specific limits for various determinants in drinking water, became effective on November 14, 2022. Laboratories classified as Level 2 Drinking Water laboratories were made aware that accreditation will be required by November 14, 2024, in order to continue conducting compliance testing on drinking water.

Recognised Laboratory Program for *Salmonella enteritidis*:

- The Ministry for Primary Industries (MPI) has implemented a regulartory framework to manage long-term risks to public health and international trade associated with *Salmonella enteritidis*.

Asbestos Testing and Accreditation:

- Worksafe documents mandate laboratory accreditation for bulk asbestos identification but do not require accredition for air monitoring.
- Some laboratories expressed an interest in obtaining accreditation for air monitoring, while others are accredited for analysis, sampling and conducting counts.
- Laboratories are allowed to report results as fibres per volume, which is considered an accredited result. Customers are made aware that volume and flow rates are managed externally to the laboratory.

Challenges Related to Hurricane Gabriel:

- Some laboratories have faced challenges and disruptions due to the impacts of Hurricane Gabriel.

5. Reports from committee members

Jasmine Lacis-Lee

Jasmine Lacis-Lee spoke to her report and the following was noted/discussed:

- Codex is in the fifth stage of the legislative process for implementing mandatory regulations related to allergens in food products. Step 5 typically involves the final

review and approval of the proposed regulations before they are officially adopted and implemented.

- It was noted that there is a notable absence of established ISO standards or Australian Standards specifically dedicated to the field of allergen testing.
- AOAC initiated an international working group to assess the method validation requirements for allergen analysis using ELISA. Two subgroups have been actively involved in this process: one focusing on Gluten Analysis, led by Laura Alred, and the other dedicated to Food Allergen Analysis, chaired by Melanie Downs. These efforts are aimed at revising the existing Appendix M, which serves as a reference for kit manufacturers regarding method validation requirements in AOAC reviews.
- Changes are being introduced to the process of kit manufacturers' validation, requiring validation through AOAC. New reporting requirements will be in place. All kits with AOAC validation will need to be revalidated. The recently enacted PEAL legislation, which was officially published in February 2022, is scheduled to come into effect in February 2024. Some allergens lack specific testing methods, and distinguishing between certain substances, such as molluscs and crustaceans or wheat and gluten, poses challenges.
- The Allergen Testing Special Interest Group (ATSIG) is responsible for developing a guidance document in this area of analysis and initiating a public consultation process, which will subsequently be considered by NATA.

Action Item:

ATSIG will produce a guidance document on how to validate, verify, and determine when to perform allergen testing. NATA will review the document.

Joanne Wilson

Joanne Wilson spoke to her report and the following was noted/discussed:

- Ethylene Oxide (EO) is used as an intermediate agent in the manufacture of medical devices and as a sterilising agent in healthcare. The US EPA has proposed an air pollution rule to be implemented this year, potenatially impacting EO sterilisation.
- Regarding the impact in Australia related to EO sterilisation, it was noted that there are two voluntary standards outlining the control of EO residues and the management of hydrants left on a device. The Therapeutic Goods Administration (TGA) recognises these standards as best practices, however, it is important to highlight that they are not mandatory. It was also noted that only a very limited number of sites in Australia use EO to sterilise medical devices.
- Laboratories using EO for sterilisation may need to alter their sterilisation cycles, impacting some goods used by laboratories.

Dominie Wright

Dominie Wright spoke to her report and the following was noted/discussed:

- Plant biosecurity reporting requirements under the Biosecurity Act were discussed, emphasising the identification of new pests, whether they are specific to individual states or pose a risk to the entire country.

- DAFF have recently reviewed the National Plant Proficiency Testing program in Australia, addressing the variability in methods used by laboratories for pest identification. Results have been delayed due to staff shortages at ANQAP, the provider of the program.
- At the national level, there is an ongoing effort to evaluate and modify the PT program. The aim is to specify the methods facilities employ for identifying pathogens.

David Sheehan

David Sheehan spoke to his report and the following was noted/discussed:

- The FT-020 Standards Australia water microbiology committee is currently in the process of reviewing AS2031, with a draft expected to be available early next year.
- FT0-20 is also collaborating with WG26 on developing a standardised method for detecting SARS-CoV2 in wastewater, although progress in this area has been limited so far.
- Wastewater-basded epidemology (WBE) is identified as an area of potential growth, with research facilities looking to analyse wastewater for various viruses and bacteria to support health survellience efforts.
- In his role as Chair, David S noted an increasing number of laboratories seeking to add asbestos testing to their scope but lacking preparedness. The question of whether initial guidance or a competency framework is needed for facilities considering adding asbestos testing to their scope was raised.
- It was noted that some laboratories are not fully following standard methods, and any deviations are considered in-house methods as per the criteria documents.
- A distinction was made between regulatory requirements and accreditation requirements, with a reminder that if laboratories subcontract their work, they cannot claim accreditation for that subcontracted part of the process.

Paul Wright

Paul Wright spoke to his report and provided a powerpoint presentation, the following was noted/discussed:

- There is no Australian standard or list of toxins, or toxin-producing species of cyanobacteria.
- 24 laboratories are currently accredited for cyanobacterial identification but may not be able to identify all seven toxic species.
- Toxins can have geographical variations, and some listed on Australian Drinking Water Guidelines (ADWG) Factsheets may not be toxic in Australia.
- It was also noted that name changes within relevant contexts contribute to existing confusion.

Action Item:

Julian C will raise this issue with the Australian Society for Microbiology president. David S will discuss it with Water Research Australia, and Paul W will send slides for circulation with the meeting minutes.

Julian Cox

Julian Cox spoke to his report and the following was noted/discussed:

- A review of ISO/IEC 17025 Application Document: Life Sciences – Annex: Facilities using nucleic acid detection techniques (including for genetically modified materials) is required to align the document with current practices.
- A guidance document on validation and verification is needed. Neil S noted that NATA had taken the decision to let facilities identify appropriate resources from those published rather than publish additional material which would draw from that already available.
- It was noted that there is a need for guidance for facilities where laboratory staff expertise or mentoring has become unavailable.
- Additonally, it was discussed that guidance is required for technical assessors regarding the importance of maintaining their expertise, attending conferences, and continuing their education.

Action Item:

Julian C will supply the marked-up document. Neil S will distribute to the the document to the Committee members to collaborate on achieving a mutually agreed draft, followed by public comment and eventual publication.

Action Item:

Neil S will conduct further investigation into a specific case involving a technical assessor who has not been practicing microbiology for seven years.

John Waters

John Waters spoke to his report and the following was noted/discussed:

- The issue of reporting NATA-endorsed results for standard methods in cases where sampling is done according to the standard method, but the analysis is subcontracted to an accredited facility with an "in-house" method on the scope was discussed. It was emphasised that the report should provide a clear declaration that the sampling was conducted following the standard method, while the subsequent analysis was performed using an “in-house” method.
- Attention was drawn to an issue related to the NSW EPA method TM4, which encompasses nine different methods. Instead of the current practice, where the scope indicates “NSW TM4” and references the US EPA method, it was suggested that it should specify the exact US EPA method used.

Action Item:

Clarification is needed on how to revise scopes, especially for methods like TM4, which lists multiple methods within the one document.

Richard Wilkinson

Richard Wilkinson spoke to his report and the following was noted/discussed:

- The issue regarding reporting asbestos fibres per field was raised. Currently, this practice is permitted, but the results are subsequently used to calculate fibre volumes per mL of air. Whilst NATA faclities are not responsible for this calculation, the issue here is that these results stem from the data on fibres per field, and there is no guarantee of the accuracy of the pump calibration or proper functioning. Therefore, the data on fibres per field cannot be relied upon.
- It was highlighted that an Australian Standard AS 5370 for asbestos bulk sample analysis is expected to be released for public comment soon. Concerns were raised regarding potential ambiguities in the standard method, and there was a call for technical assessors to review and provide comments to help resolve any issues.
- NATA has recently begun enforcing a requirement for smart phone timepieces to be traceable to a recognised standard. However, there has been a deviation from previously published information by NATA regarding this requirement. It was noted that the satellite technology used by smart phones is not considered traceable. This change has led to confusion and concerns within industry. It was emphasised that NATA has not provided a written clarification to facilities regarding this change in.

Don Neale

Don neale spoke to his report and the following was noted/discussed:

- It was noted that methods for measuring air on a continual basis have not significantly changed.
- Don N highlighted four Australian Standards covering ambient gaseous pollutants. Continuous measurement methods for varous parameters, including sulfur dioxide (AS 3580.4.1), oxides of nitrogen (AS 3580.5.1), ozone (AS 3580.6.1), and carbon monoxide (AS 3580.7.1), were noted. These standards play a significant role in monitoring and measuring environmental parameters for regulatory and complinace purposes.
- Currently, Proficiency Testing Australia (PTA) Air and Emissions programs are solely focused on stack emission testing laboratories. There are currently no corresponding proficiency testing programs related to ambient air quality or odour measurement.

Mark Dawson

Mark Dawson's report was acknowledged and taken as read and included the following points

- Failure to follow the required discordant result protocol for rapid kit methods, which include sample enrichment followed by a platform screen assessment and confirmation testing, may lead to false negative results, posing potential risks, especially with pathogen targets in food testing.The comprehensive assessment of in-house and multiplex PCR methods should encompass enrichment and extraction protocols rather than focusing solely on the test protocol's validation.
- TAs should ensure that the validation process considers any rapid confirmation procedures included in the test protocol.

- Maintaining up-to-date MALDI TOF and nucleic acid databases is esential for accurate testing.
- When applying standard methods beyond their intended scope, method validation is required.
- For guidance on the implementation of AS 5140, laboratories specialising in water testing may provide valuable insights.

Mark Lewin

- Concerns regarding proficiency testing reporting were raised, including:
    - Extremely small measurement uncertainty (MU) values, such as .0000007%, which are comparable to the reference values provided for proficiency testing.
    - Instances of exceptionally high values that are inconsistent with what is realistically achievable, resulting in uncertainty levels of 300% to 400%.
    - Reporting of uncertainty for non merit results.

Action Item:

Neil S to remind Lead Assessors at the next competency group meeting to thoroughly examine the entirity of the reports and the information submitted by the facility to ensure a comprehensive review of proficiency testing results and associated uncertainties.

6. Technical matters

6.1 Precedents and issues arising from assessments and from AAC review of accreditation recommendations

- A discussion highlighted the need for a specific stage in the assessment process where, if the facility has not adequately addressed all the points, it is necessary to declare, "this approach is not functioning effectively".

6.2 Proficiency testing matters

- It was noted that there is currently no commercial demand to initiate a new proficiency testing program for any particular area of testing.

6.3 Metrological traceability matters

- It was highlighted that there is currently no established standard for calibrating luminescence.

  It was noted that the responsibility for establishing the method, if deemed necessary, would lie with the facility.

  This point was in connection with the testing of light used in plant pathology assessments.

6.4 Significant projects / initiatives

- There were no significant projects or initiatives to report at this time.

7. Stakeholder and member engagement

7.1 Stakeholders

The Committee was requested to raise any issues relevant to NATA which may require stakeholder engagement including the benefit(s) and intended / desireable outcome(s).

It was noted that there were no updates from members regarding stakeholder engagement activities to be shared at this time.

7.2 Members

Nothing to report.

8. Review of accreditation criteria and processes

8.1 Review of the relevant NATA Accreditation Criteria

The following documents have been updated since the previous meeting.

General Accreditation Criteria (website link)

- Accreditation of multi-site facilities - Effective January 2023 - *(Published October 2022)*
- Remote Assessment Policy - *(Published December 2022)*
- Use of NATA emblem, NATA endorsement and references to accreditation - *(Published June 2023)*
- Accreditation of new branch sites - *(Published March 2023)*

General Accreditation Guidance (website link)

- General equipment table *(Published March 2023)*

8.2 Review of scope of accreditation descriptors (website link)

- Scope of Accreditation - service descriptors for environment
- Scope of Accreditation - service descriptors for food and beverage
- Scope of Accreditation - service descriptors for healthcare, pharmaceuticals & media products

8.3 Update on other policies including general NATA policies and ILAC and APAC documents, where applicable

Documents updated since the last meeting:

- NATA Procedures for Accreditation *(Published April 2023)*
- General Accreditation Guidance: - Liquid in glass thermometers - selection and use *(withdrawn from the website June 2023)*

9. Assessors

9.1 Summary of new appointments and retired assessors since the previous meeting

Newly appointed assessors and assessors who have retired since the last meeting were provided for the Committee's information.

9.2 Specific technical assessor training needs

The ongoing project focusing on specific technical assessor training needs and improving assessor engagement was discussed. The Committee was invited to share ideas and suggestions to enhance the effectiveness of our technical assessor development program course.

9.3 Identification of areas/disciplines where technical assessors need to be recruited

Air Quality

- ambient air
- stack testing

Aquatic Biology

- helminths
- macro/micro invertebrates
- macrophytic plants

Enteric and free-living protozoa

- analysis for free-living protozoa

Endotoxin (via LAL)

Ionising radiation

Environment / Food and Water Microbiology

- mycological analysis

Molecular Testing

- enteric viruses
- sequencing

Occupational Hygiene

- respirable crystalline silica (via XRD)
- serpentine

Plant Health Diagnostics

- entomology
- viruses

Seed Testing

- analysis of seeds

in-house calibration

AAC members were encouraged to provide feedback on individuals known to them who might be interested in becoming a technical assessor. If these individuals are open to being approached, they were encouraged to share Neil S's contact details. Additionally, it was noted that it is important to specify the type of competency these potential assessors possess.

10. Analysis and review of risks to impartiality

During the meeting, it was conveyed to the Committee that they have the option to notify NATA of any impartiality concerns at any time, not exclusively during these meetings. It was emphasised that there were currently no known impartiality-related concerns relevant to this Committee.

11. Accreditation statistics

The number of accredited, applicant and suspended facilities, along with details of current and newly accredited sites, and withdrawn facilities, since the last meeting was provided for the Committee's information.

12. Other business

12.1 J Lacis-Lee: Alignment and Training of Technical Assessors

There was a discussion regarding the importance of bringing technical assessors (Tas) together periodically, potentially once a year, to facilitate knowledge sharing and awareness of changes, updates, and new developments in accreditation. This gathering would aim to standardise TAs' approaches, leading to better outcomes.

Consistency in assessment processes was emphasised, as laboratories seek uniformity, with many acknowledging the challenges in achieving this consistency. The idea of establishing a base level of understanding among TAs to provide valuable insights was suggested.

Overall, the discussions revolved around the need for TAs to stay informed and standardised, while recognising the nuances of the assessment process and the importance of mentoring and guidance.

12.2 J Cox: Facilities employing nucleic acid detection techniques (Including for genetically modified materials) – Specific Accreditation Criteria document

Discussions revolved around key aspects of NATA accreditation in the context of phycology testing. The importance of promptly updating laboratory scopes of accreditation with new binomial identities for potentially toxic species was emphasised. It was also noted that there are significant geographical variations in identifying toxic species, prompting the need for an official list of recognised toxic species in Australia. The meeting further emphasised the need for more timely delivery of proficiency testing programs, with some laboratories exploring Polymerase Chain Reaction (PCR) for toxin gene testing alongside microscopy-based phycology. This emerging trend has raised questions about the potential for genetic testing in algae management guidelines, particularly concerning positive hits for toxin genes in samples devoid of known toxic species.

During the meeting, it was noted that an increasing number of laboratories are incorporating PCR for toxin gene detection as an adjunct to traditional phycology microscopy. Water Research Australia is currently engaged in a project aimed at assessing the feasibility of utilising genetic testing in algae management guidelines, particularly for potable and recreational waters. Some laboratories, including those in the United States, have reported positive findings, often involving the saxitoxin gene (sxtA gene), in samples where no known potentially toxic

species were microscopically observed. This raised concerns and highlighted the need for further investigation into the implications and accuracy of genetic testing in the context of algae management and safety protocols.

Additionally, there was recognition of the necessity to update the existing specific accreditation criteria (SAC) for molecular testing to ensure its alignment with contemporary practices and standards.

Action Item:

Julian C to conduct a review of SAC_07.4_Life Sciences ISO IEC 17025 Annex Facilities utilising nucleic acid detection techniques. He will then share a document with AAC members, seeking their input and feedback by August 4, 2023.

12.3 D Sheehan: Timeframe for receipt of briefing notes for assessment activities

David S noted a decreasing frequency of receiving briefing notes in a timely manner and expressed concerns about having insufficient time for preparation. It was clarified that NATA's processes have remained unchanged, but it was agreed that staff would be reminded of the minimum two-week timeframe for TAs to receive briefing notes, with exceptions made only in cases of extreme circumstances related to the facility.

12.4 Feedback from Draft Agenda for Public comment

12.4.1 Akemi Ichikawa from SafeWork NSW: Technical Documents for the validation and verification of testing

Please discuss and confirm the technical documents for the validation & verification of chemical analysis. In the last lab audit as a TA, I could not find any technical documents (replacement of the previous "General Accreditation Guidance - Validation and verification of quantitative and qualitative test methods". I think that "The fitness for Purpose of Analytical methods - Eurochem 2014" is enough good guide for this purpose. If the scientific committee could authorise the document and NATA website have the link to the document (or recommendation), it will help TAs much.

It was noted that the Committee does not endorse Eurochem 2014 as it is already a recognised document. However, the Committee acknowledges that Eurochem 2014 is a suitable guide for validation and verification of quantitative and qualitative test methods. Facilities are encouraged to familiarise themselves with relevant publications and utilise appropriate content to align with their scope of work. The Committee emphasised the importance of facilities taking responsibility for selecting and applying the most relevant guidance in their accreditation processes.

12.4.2 Dr Victoria Wansink from ACT Government Analytical Laboratory: Discussion on technical assessors' relevant experience

Discussion around ensuring assessors are still associated with laboratories or their area of speciality. Some assessors may not have been in the field for a while and given NATA under 17025 requires staff of areas we are assessing to maintain competency, should we have something about assessors also having relevant recent experience?

The Committee acknowledged the importance of assessors maintaining relevant recent experience in their respective fields. It was emphasised that NATA already monitors TAs on a case-by-case basis for each assessment activity. In this specific case, the Committee has expressed the need for specific information to facilitate further follow-up and ensure that assessors meet the requirements of having recent and relevant experience.

13. Next meeting & close

The meeting concluded on July 12, 2023, at 11:50 a.m. The next meeting is scheduled for Q3 2024.