



National Association of Testing Authorities, Australia

SISO Progress Report Supporting Information

Reporting Period

1 January 2022 to 30 June 2022

NATA ELIGIBLE ACTIVITY

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1. Maintain membership and participate in the International Laboratory Accreditation Cooperation (ILAC)

1.3 Maintain High Level Participation in Relevant ILAC Committees

The ILAC-IAF meetings mid-term meetings held during March/ April 2022 were conducted virtually because of the ongoing COVID-19 pandemic. These are summarised on the spreadsheet 'NATA - activities'. The annual meetings are also being held virtually during November 2022.

Executive Committee (EC) and IAF/ILAC Steering Committee for Single International Organisation

The Executive Committee met in March 2022 and the steering committee for the new single international organisation, of which NATA's CEO Jennifer Evans is a member, met in March and April 2022. The target date for the merger of ILAC and IAF as one single organisation project is 2024.

Joint IAF MLAC & ILAC AMC (JMC)

A meeting of the JMC was held in March 2022.

Accreditation Committee (AIC)

The AIC meeting was held virtually in April 2022 and the outcomes from other meetings, including committees, working groups, ISO technical committees and liaison with other bodies were also reported at this meeting. More detail is included below or elsewhere in this report.

ISO/IEC 17025:2017

An ISO periodic 5-year review is anticipated to determine whether the standard should be updated. A workshop is proposed at the ILAC meeting in November 2022 to discuss the standard and the regions will be invited to raise issues they have dealt with since the standard was issued. Topics to be considered include:

- MU arising from sampling
- management options A&B
- decision rules and conformity statements
- sampling in calibration

Equivalence of ISO/IEC 17025 and ISO 15189

The publication of the brochure "*Specifying accreditation for Covid-19 testing*" revealed that both ISO/IEC 17025 and ISO 15189 are used around the world for Covid-19 diagnostic testing. Also ISO 15189 and ISO/IEC 17025 are used for certain forensic tests. As the specifiers of accreditation typically are health authorities and they may not adhere to an AB's preferred standard, members were asked to consider the need for a statement of equivalence between the two standards (similar to the *Joint ISO-ILAC-IAF Communique on the Management Systems Requirements of ISO/IEC 17025, General Requirements for the competence of testing and calibration laboratories*).

Liaison with the International Telecommunication Union (ITU)

A dedicated assessment procedure for the accreditation of approved test laboratories to ITU recommendations is currently in draft and will be circulated for comment. The work is expected to be finalised in mid-2022.

Liaison with the International Organization for Legal Metrology (OIML)

The final draft of OIML D10/ILAC G24 *Guidelines to the determination of calibration intervals of measuring instruments* was reviewed by ILAC in March 2022 and is expected to be sent for ballot shortly within both OIML and ILAC.

An update on the OIML CS (Certification System) was provided and it was noted that at a recent CS MC meeting the use of ISO/IEC 17020 as an alternative standard to ISO/IEC 17065 and the development of an associated OIML guidance document was discussed.

Liaison with the International Electrotechnical Commission (IEC)

IEC Guide 115 *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector* is referenced in IEC CA Systems Operational Documents. In 2020, the IEC identified that some ABs are not recognising the Guide and so ILAC conducted a survey in the second half of 2020 to determine how many ABs were using this Guide. The feedback will be dealt with by the liaison group.

Liaison with EGOLF

Working Group 8 - *Accreditation of Fire Testing Laboratories* (a European cooperation for Accreditation (EA) endorsed scheme under ISO/IEC 17025). This scheme also affects laboratories outside of the EU if they are involved in the activities covered by the scheme.

Fire behaviour and fire resistance is part of the Construction Product Regulation (legal obligation) in the EU.

Liaison with Eurachem

The next Eurachem GA will be held virtually in May 2022 and will include a workshop on 'Quality assurance (QA) challenges of measurements, from field to laboratory, with a focus on ISO/IEC17025: 2017 requirements'.

Eurachem launched a LinkedIn page in 2021 to further increase the promotion and dissemination of Eurachem guidance documents and has a regular e-newsletter to which individuals can subscribe.

The revision of several documents of relevance to ILAC have been completed or are in progress and development of others is continuing. including:

- *Eurachem Guide Terminology in Analytical Measurement: Introduction to VIM 3 (under review)*
- *Eurachem/CITAC Guide Quality in Analytical Chemistry (under review)*
- *Assessment of the performance and uncertainty in qualitative chemical analysis (published)*

The Measurement Uncertainty and Traceability WG (joint WG with CITAC) are working on producing draft guidance on the evaluation of uncertainty from in-house validation data to supplement the *Eurachem Guide Quantifying Uncertainty in Analytical Measurement*.

- Proficiency Testing WG

A paper on current practices for performance evaluation in qualitative and interpretative PT schemes has been developed and recently published in ACQUAL highlighting the wide range of performance evaluation criteria in use, and current practices and scoring systems that may serve as a basis for further discussion and investigation towards the harmonisation of performance evaluation.

The WG is reviewing its PT leaflets to bring them up to date with the recently published 3rd edition of the Eurachem PT Guide; and working on a few new leaflets *including Let's call a PT scheme a PT scheme* and *Understanding PT Statistics and Understanding PT Performance Assessment*.

- Method Validation

- A new Joint Task Group has been established in cooperation with the UfS WG (and invited participants from EUROLAB), on validation in relation to sampling.
- A new supplement to the *Fitness for purpose* guide titled *Extent of Method Validation - Efforts to be spent by a laboratory to ensure fitness for purpose of a method* (based on a risk assessment approach) is under preparation.

- A task group is working on the draft of another supplement to the main guide, *Method Validation/Verification and assessment of response curves*.

Liaison with ISO TC 334 (former REMCO)

The outcome of the periodic ballot for the review of ISO 17034 confirmed the standard for another 5 years.

Liaison with ISO TC 276 - Biobanking

Two workshops were held in 2021 and the possibility of a joint ISO/ILAC event to share experiences with the use of ISO 20387 was raised. Several ILAC documents (P4, P5 and R6) have been updated to include Biobanking and these have been circulated for comment.

Liaison with BIPM

The bilateral statement on metrology is being considered for revision as the current statement is considered historical by BIPM and ILAC. The work is expected to commence later in 2022

Liaison with the Joint Committee for Guides in Metrology (JCGM)

A couple of key metrology guide documents are under review including the Vocabulary in Metrology, VIM 4 and the JCGM-GUM 1 that basically navigates the GUM suite. The well-known GUM will become JCGM GUM-3.

Liaison JCTLM (Joint Committee for Traceability in Laboratory Medicine)

The biennial workshop was held online in December 2021 on 'Overcoming challenges to global standardization of clinical laboratory testing: reference materials and regulations'. A summary of the workshop, once available, will be published on <https://www.jctlm.org/>

WG Scopes of Accreditation

There has been discussion at the WG on whether the *year of standard* should be included in scopes of accreditation. NATA strongly opposes this position as the inclusion of the year is not a requirement of ISO/IEC 17011. The matter is to be discussed at a face-to-face meeting of the AIC.

Consideration is also being given on the development of a Biobanking annex.

ILAC and IAF have been asked by UNIDO to circulate a questionnaire to all MRA/MLA signatories as part of a project that UNIDO is currently undertaking in relation to flexible scopes. ILAC and IAF are not involved in this project other than agreeing to distribute this information to members and to also review the final output prior to publication to ensure there is no conflict with ILAC and IAF.

WG 10 - Forensics

At the last meeting of the WG it was agreed to only make some minor updates to ILAC G19 as the work on the ISO 21043 series (Forensic sciences standards) has been placed on hold due to the pandemic. The WG prepared a new draft of ILAC G19 which was circulated at the end of 2021 and has subsequently been published.

ILAC/WADA Liaison Group

The WADA WG provided an updated Terms of Reference for approval by the AIC that allows one additional AB representative for those ABs with multiple WADA accredited labs and any objections against the suggested change must be provided no later than 3rd November 2022.

ILAC Laboratory Committee

A meeting was held in March 2022 and a Stakeholder Forum Terms of Reference and Constitution was reviewed and approved by the Laboratory Committee and then sent to the Executive Committee and Secretariat for their review and feedback.

There was discussion on assessments during the COVID-19 pandemic and the Laboratory Committee expressed the view that remote assessments lack technical rigor and advocated returning to on-site assessments as soon as possible.

The Cross-Frontier policy was discussed, and the committee members did not have a consensus position on the current document, but all agreed that if there was better uniformity in assessments, there would not be a need for this policy.

Inspection Committee (IC)

A decision on systematic review of ISO/IEC 17020 *Conformity assessment - Requirements for the operation of various types of bodies performing inspection* is expected to be received by ILAC in early 2023. The taskforce group on sampling in inspection are compiling recommendations for inclusion of points into the next revision of ISO/IEC 17020 relevant to sampling. It was suggested that the definition for inspection in the standard could be expanded to cover sampling and/or relevant clauses (approximately 20 identified) updated to address sampling.

A presentation on the application of 'new' technology in the field of inspection was provided by UKAS and the question arose as to whether there is a need for an ILAC document on the accreditation of remote inspection activities and whether the capability should be identified in scopes of accreditation. It was proposed that a workshop be held at the November 2022 meeting to share experiences.

The Grain and Feed Trade Association (GAFTA) gave a presentation on the Association's requirements for approved superintendents (cargo inspectors). These organisations are required to comply with the GAFTA Code of Practice plus GAFTA standards (supervision, sampling and weighing) or ISO/IEC 17020 (Type A), GAFTA No.123 Weighing Rules and GAFTA No.124 Sampling Rules. There are currently 576 approved organisations with most approved against the GAFTA standards and the remainder against 17020. It was noted that scopes of accreditation must include Code of Practice and No.123 & 124.

An update was provided at the last meeting on the proposal to use ISO/IEC 17020 in the OIML certification system for Issuing Authorities. OIML has subsequently drafted a *Guide for the application of ISO/IEC 17020 to the assessment of OIML Issuing Authorities in the OIML Certification System*.

Joint IAF CMC & ILAC MCC (Joint Communications & Marketing Working Group)

NATA's Head of Marketing and Communications, Brendon Moo participates on the ILAC/IAF Communications and Marketing Working Group and chairs the Podcast Working Group.

The Podcast Working Group met in June 2022 and are developing a series of podcasts to promote the role and value of accreditation and accredited conformity assessment services.

ILAC Publications

During the period January - June 2022 a couple of publications were finalised and published.

Revision of a few other documents are still in progress or have been put on hold.

Refer spreadsheet 'NATA- Publications'.

2. Maintain membership and participate in the Asia Pacific Accreditation Cooperation (APAC)

2.3 Maintain High Level Participation in Relevant APAC Committees

All APAC meetings and activities scheduled for 2022 are being conducted virtually because of the ongoing COVID-19 pandemic.

These are summarised on the spreadsheet 'NATA - activities'.

General Assembly and MRA Council

The General Assembly confirmed Jennifer Evans from NATA, Australia as APAC Chair and Raj Nathan from IAS, USA as Vice-chair effective 29 June 2022. Trace McInturff from A2LA, USA continues as Chair of MRA Management Committee with Bruce Li from TAF, Chinese Taipei as Vice-chair.

Executive Committee (EC) and MRA Management Committee (MRAMC)

At the meetings held in March 2022 the implications for APAC of the current situation in Ukraine were discussed. The following were noted:

- Sanctions imposed by specific Governments may impact on APAC Members (i.e. the ABs) and their representatives, for example, limit activities with the ABs from the Russian Federation, RusAccreditation and AAC Analitica. This is particularly the case for ABs that are Government entities.
- APAC membership rules do not appear to provide for the possibility to sanction the ABs from the Russian Federation (e.g. suspend membership).
- Current UN sanctions against the Russian Federation may impact accredited CBs. CBs may need to assure themselves that their certified organisations are not providing products that are being used in military actions.

It was agreed, that at this time no action would be taken, however the situation will be monitored closely.

At the June meetings, the legal advice sought by APAC from a NZ based law firm around compliance with NZ Government sanctions by both APAC itself, member accreditation bodies and their accredited conformity assessment bodies, was discussed.

It is clear from the legal advice that APAC must comply with NZ law (including sanctions) as APAC is an entity incorporated in NZ. In simple terms, this means APAC cannot provide its services to a sanctioned 'person' (entity or individual) or an associate of a sanctioned person. Therefore, if an APAC member is itself a sanctioned person, or if sanctions are violated by an APAC Member (e.g. member continues to offer accreditation services to a sanctioned person), APAC will be required to act, including suspension or withdrawal of the APAC membership. APAC will be writing to all its members to advise them accordingly and to take the necessary action to ensure on-going compliance.

A new Strategic Plan is under development by a working group comprising the APAC Executive Committee and the Committee Chairs. The process is again being facilitated by a consultant. A particular focus will be enhancing APAC's influence at the global level i.e. in IAF and ILAC, to be more reflective of APAC being the biggest regional group.

There is considerable disquiet about the influence of EA (the European regional group representing ABs in EU, EEA, Switzerland, UK, and some other countries eligible under 'near neighbourhood' arrangements) on accreditation and accreditation bodies internationally.

Concern was expressed about the ongoing influence of EA on significant issues under consideration by IAF and ILAC, such as the project to establish a single international organisation, the current draft ILAC document on 'cross-frontier' accreditation, and a recently published IAF document (MD25 Criteria for the Evaluation of Conformity Assessment Schemes). EA's ability to 'mobilise' its member ABs to vote in a directed way on issues was noted. APAC,

and other regions, do not seem to have the same power despite occasional requests to APAC members from the EC to vote a particular way. APAC is by far the biggest region and could have a greater influence internationally if its members acted in a more coordinated way.

It was agreed that 'polite requests' from the APAC EC are not effective and given the significance of the upcoming issues for vote, a more proactive approach will be necessary.

The APAC Executive Committee is considering how best to develop consensus positions on key issues and ensure harmonised voting from APAC membership. Under active consideration are member webinars on the issues. The first is likely to be held in coming weeks as the ILAC 'cross frontier accreditation' document is posted for voting.

Technical Committee (TC) 1

Pertinent topics presented during the meeting covered:

- Progress on the review of several publications was discussed, including a few that have recently been published This included
 - ILAC G-18 *Guide for scopes of accreditation* republished in December 2021, although consideration is now being given to the inclusion of biobanking.
 - ILAC P9 *Proficiency Testing* has been put on hold by ILAC AIC.
 - OIML/ILAC G24 *Determination of Calibration Intervals*, draft pending.
 - ILAC G19 (Forensics) ballot finished 7 May 2022.
 - ISO 17043, ILAC will draft a resolution for transition to the new standard during the November AIC meeting.
 - ISO TC 69 – ISO 13528 (Statistical methods for PTP) revision is underway and likely to proceed to FDIS in June 2022.
- The report and progress on the new draft Guidance Document on *Traceability of multi-turn coils used to calibrate clamp-style current meters* was discussed and it was agreed to circulate it to APAC Members for comment.
- The Inspection Working Group highlighted the possible need for a guide when using new technologies in inspection, for example remote inspection, use of drones, remote sensing, and use of artificial intelligence (AI).
- The APEC TEL report focused on conformity assessment of Cybersecurity. TC1 noted the report on the work of the APEC-TEL Mutual Recognition Arrangement (MRA), including the development of various national approaches, schemes, and labelling programmes for Internet of Things (IoTs) cybersecurity and performance.
- The Capacity Building Committee highlighted the need to provide training on the digitisation of conformity assessment activities.
- The Proficiency Testing Committee gave summary of activities undertaken. A survey of proficiency testing needs has been undertaken and planning for trace elements in mineral water and inorganic elemental nutrients in rice is in progress.
- TC1 noted that the APAC online training courses on accreditation of Medical Testing (ISO 15189) and Point-of-Care -Testing (POCT) have been postponed until October 2022 pending publication of the ISO 15189:2022. The need for guidance on changes to ISO 15189 and the transition period was discussed, and it was agreed that the TC1 Chair and Medical Testing WG Convener would raise this with the ILAC Medical Testing WG.
- A recent UNIDO publication on remote assessment activities in developing countries was noted and recommended for review. Also, a FAQ has been added to the ISO/IEC 17011 FAQs on when to undertake a remote assessment.

Technical Committee (TC) 2

A range of topics were covered, including:

- Clarification on clause 7.9.2 in 17011:2017 issued in May 2022 by ISO/CASCO.
- ISO has recently requested experts to assist with a guideline for remote auditing.
- Main scope standards are proposing to move away from a qualification-based approach to competence-based approach for assessors; for example, IAF has initiated a project to provide guidelines on the requirements for competence of ISO/IEC 17024 (personnel) assessors.

- Physikalisch-Technische Bundesanstalt (PTB) has approved funding to APAC to support the digitisation of APAC activities, for example, voting, record keeping and evaluation activities. Funding has also been provided by PTB to support developing countries digitisation of their accreditation activities.
- The Sustainability Working Group published a guidance for the 'Accreditation of Validation and Verification Bodies for Carbon Footprint of Products' based on ISO/IEC 17029, ISO 14065:2020 and ISO 14064-3:2019 in March 2022.
- TC2 requested the APAC MRA Council to discuss and clarify the scope of recognition of accreditation bodies as signatories to ISO/IEC 17029:2019 and ISO 14065:2020 under the APAC MRA. Given the breadth of sectors, schemes and programmes in which ISO/IEC 17029 validation and verification can apply, a question was raised whether multiple V/V programmes would be included within a single APAC MRA ISO/IEC 17029 recognition or whether there needed to be separate evaluation activities. The APAC MRA Council is asked to provide clarity on this issue and on the extent to which guidance is required for the consistent specification of V/V scopes of accreditation. It is recognized this topic may need dialogue with IAF and the other accreditation cooperation regions.
- A presentation was provided by PEFC (Forestry and Trade Certification Body) on Sustainable Forest Management (SFM) to ISO/IEC 17021-1 and Chain of Command (CoC) to ISO/IEC 17065.

APAC Communication and Promotion Committee (CPC)

NATA's Sector Manager Life Sciences, Neil Shepherd attends the CPC and Co-Chairs the Food Regulators Working Group (WG) with a representative from JAS-ANZ.

ILAC/IAF update:

- ILAC uses only Twitter and IAF LinkedIn
- World Accreditation Day materials have been finalised and are ready for download.
- Case studies are being developed in the areas of public sector assurance and business benefits of accreditation.
- Meeting of communications professionals from accreditation bodies (ABs) held
- YouTube videos available and library building.
- Looking to develop podcasts.
- Dark Matters series to cover cybersecurity concerns, counterfeit certificates, doping and other fraudulent behaviours.

EA Communications and Marketing

- Currently only using Twitter for social media. Developing a strategy to differentiate content on different platforms.
- YouTube videos seen a priority.
- Working on promotions linked to several "world days" that can be related to accreditation.

There was a noticeable uptake in the use of social media from all accreditation bodies and it was noted that many lack specialist communications staff and knowledge. APAC is considering how training can be provided in the use of social media.

Updates were also provided by the various working groups of this committee.

Communication WG reported on the following developments:

- APAC tag line *Confidence/Acceptance/Equivalence* approved
- APAC branded slide deck has been published
- Brochure on IT security
- In development APAC brochures on supporting stakeholder development, and validation and verification bodies

Food WG reported on the following developments:

- Report Survey of ABs completed
- Follow up webinar with ABs to discuss survey results held
- APEC concept note endorsed

- WG meeting to be arranged to develop survey for food regulators.

Business WG reported on the following developments:

- Survey of business groups undertaken.
- WG has identified a four-pillar communications strategy - *Collect information, Promotion, Collaboration, Involve stakeholders*

Health WG reported on the following developments:

- Survey to gauge involvement of regulators with ABs
- Stakeholder 'sensitisation' to biobanking accreditation
- Webinar with health officials and regulators

APMP-APAC Proficiency Testing Working Group (PTWG)

NATA's Sector Manager Calibration, Paul McMullen represents APAC as a member of this joint APMP-APAC working group.

An APEC sponsored workshop on Water Quality was held on 23-24 March 2022. This was a preliminary workshop to the APMP managed PT scheme on water quality. The project was developed to support the World Health Organization initiative to improve water quality. Paul McMullen was on the development team, a convenor and presenter.

APAC Training Workshops

None conducted during this period; however, preparations are underway for several workshops that involve NATA staff as presenters.

APAC Publications

During the period January - June 2022 several publications were finalised and published or are awaiting publication. This includes both revisions of existing documents and new documents.

Refer spreadsheet 'NATA- Publications'.

3. Participation in Mutual Recognition Arrangement (MRA) evaluations and related activities

Post evaluation work has continued in the first half of 2022 for the evaluation of the Mongolian Agency for Standardization and Metrology, Accreditation Department (MNAS) that was conducted virtually in 2021 with NATA's CEO Jennifer Evans as Lead Evaluator and NATA's Sector Manager Calibration, Paul McMullen participating as an Evaluator on the team.

NATA's General Manager Operations and Technical, John Styzinski has participated as an Evaluator for the witness assessment associated with the evaluation of the College of Physicians and Surgeons of BC Diagnostics Accreditation Programme in Vancouver Canada conducted virtually in 2021. The witness assessment has been conducted in April 2022 and post evaluation work has also been carried out during the first half of 2022.

NATA's General Manager Compliance and Governance, Tony Vandenberg participated as a Provisional Evaluator on the evaluation of the Bureau of Laboratory Quality Standards, Department of Medical Sciences, Ministry of Public Health (BLQS-DMSc), Thailand in February 2022. The evaluation was conducted virtually.

In June 2022, NATA's Technical Manager Danielle Dicker participated as a Provisional Evaluator in the evaluation in USA of A2LA. This was the first evaluation that a NATA evaluator has participated in face-to-face since the COVID-19 pandemic.

Refer spreadsheet 'NATA - activities'.

4. Represent Australia's interests in relevant international standardisation activities related to conformance

4.1 Participate in Relevant ISO Technical Committees

ISO/TC 212/WG 1

NATA's Sector Manager Legal and Clinical Services, Andrew Griffin represents NATA/Standards Australia and ILAC at the ISO TC 212 meeting where progress on the update of ISO 15189 *Medical laboratories - Requirements for quality and competence* and other working group documents are discussed. Andrew Griffin is a member of WG 1 and is the project lead for revision of ISO TS 20658 *Medical laboratories - Requirements for the collection, transport, receipt and handling of samples*.

A meeting was held in April 2022 to review and discuss the resolutions proposed to the 1027 comments received from the ISO/DIS 15189 ballot that closed in January 2022. At the end of the meeting the next steps were listed as:

- additional changes resulting from the meeting would be made to the draft FDIS.
- the Annexes will be updated.
- a final draft FDIS will be circulated for discussion at the May meeting.
- the responses to the French comments are to be reviewed and relevant changes made to the French version of the document.

Following a few minor edits at the May meeting, a 'clean' copy of the document and the comment tables has been submitted to ISO for preparation for FDIS ballot.

Members were reminded that only editorial changes can be made following the FDIS ballot and that any technical comments will be held over to the next 5-year systematic review and revision. As a result of a recommendation from this WG, a Terminology Task Force has been set up in TC212 with representatives from each WG.

The ISO DIS 15189 was recently posted for ballot and approved by the majority of member countries. The revised document is expected to be published by the end of 2022. A question was raised as to the need for an ILAC transition policy, and it was determined that this will be discussed at the next meeting.

With the imminent publication of ISO 15189:2022 (4th edition) there is a need to start the revision of ILAC G26. ILAC G26 was written to support ABs setting up accreditation programs for medical laboratories rather than a guide to the application of ISO 15189. The ILAC ISO 15189 WG was asked to set up a task force to prepare a first draft to be presented at the first ILAC Accreditation Committee (AIC) meeting in 2023 and/or a session regarding the future and content of the document.

At the meeting held in May 2022 Dr Frank Schneider (USA) was recommended as the new Deputy Convenor to replace Dr Stewart Bryant (AUS) who was thanked for his service in the role for the past six years.

The Convenor Sheila Woodcock indicated that she is on the new ISO TC304 WG5 Healthcare Quality Management, that is developing a management system standard to be used for accreditation of healthcare facilities.

Updates were provided by the project leads for other documents that WG 1 is progressing:

- ISO 20658 *Medical laboratories — Requirements for collection and transport of samples*.

A draft DIS version of the revised document had been circulated, together with the comment table and Project Leader Andrew Griffin led the discussions. He noted the importance of aligning the document with the revised ISO15189. With some minor edits proposed, it was recommended that the document be submitted for DIS ballot.

- ISO/PWI 5649 *Medical laboratories - Concepts and specifications for the design, development, production and use of in-house in vitro diagnostic medical devices (laboratory developed tests)*

A project update was provided and there was discussion about the document scope and whether it had changed enough to require approval by ballot. This is to be followed up by the project leader.

- ISO TR23834 *Guidance on application of ISO15189 in anatomic pathology*

A report and a draft outline of the proposed format of this new document, which aligns with ISO Directives, was presented by the project leader and it was noted that this document is also dependent on final revisions to ISO15189.

ISO/TS 20914 Medical laboratories – Practical guide for the estimation of measurement uncertainty: 2019

This document, a joint WG1 and WG2 initiative, is due for review later this year and several points were presented for discussion, including options for the review process at 3 and 6 years. After discussion it was decided to submit a recommendation to confirm the document in its current form for an additional 3 years when it comes up for systematic review in Q3 2022.

ISO 22870 Point-of-care-testing (POCT) – Requirements for quality and competence:2016

The revision process for ISO15189 specifically incorporated the requirements for POCT, and so once it is published, ISO 22870 will become obsolete and WG1 recommends that it be withdrawn.

PWI Medical laboratories – Guidance on application of ISO 15189 to emerging measurement technologies

This project had to await the final revision of ISO15189 but can now be progressed. The project leader made a short presentation explaining the principles of the proposed document and how he plans to work with a small team to prepare a working draft document for review and discussion at the next meeting.

ISO TC 34/SC 9: Microbiology WG 3 Method Validation

NATA's Sector Manager Life Science, Neil Shepherd is a member of Standards Australia FT 035, Australia's mirror committee of ISO TC 34 SC9 food microbiology and participates on WG3.

FT 035 Food Microbiology adopts where possible ISO food microbiology methods and participation in method development at the ISO level provides Australia with an opportunity to ensure technical issues are resolved in align with Australian views where possible which improves the chances of direct text adoption.

WG3 is revising and updating ISO 16140 and continues to work on developing standards for method verification, validation of reference methods, single-laboratory validation, intermediate validation, and validation of confirmation methods. The WG3 met virtually in January 2022. Progress on the review and updating of the method validation standards was discussed, including:

- *ISO 16140-2 Microbiology of the food chain - Method validation - Part 2: Protocol for the validation of alternative (propriety) methods against a reference method - options were presented for determination of dilution factors, bacterial toxins are to be included with the exception of mycotoxins. Standards exist for Cereulide, Staphylococcus, Histamine and Botulinum. A 2nd draft of ISO 16140-2 will be prepared by Aug 2022 and circulated for comment in September 2022; and a 3rd draft prepared for discussion at the next WG3 meeting in October 2022.*
- *ISO 16140-3 Microbiology of the food chain - Method validation - Part 3: Protocol for the verification of reference and validated alternative methods implemented in a single laboratory will come into effect following the validation status of methods (aiming for 2027) and user laboratories can use the validation data.*
- *16140-4 Microbiology of the food chain - Method validation - Part 4: Protocol for method validation in a single laboratory A 2nd draft is being created following comments received.*

- ISO 16140-7 *Microbiology of the food chain — Method validation — Part 7: Protocol for validation of identification methods of microorganisms* Draft comments were considered and changes will be made to flow charts for both parts 6 and 7 of ISO 16140
- Further review is required for both ISO 16140-1 and ISO 16140-2, however this will not occur until after publication of the current draft of ISO 16140-2.
- Commercial sterility testing - develop a protocol for a broad range of foods to be included in future revision of 16140-2 or a new part of the 16140 series.
- Revision of ISO 17468 *Microbiology of the food chain - Technical requirements and guidance on establishment or revision of a standardized reference method* Comments received on the CD were discussed. This standard is to be progressed to a DIS. Optimization studies are still being worked on and additional guidelines will be drafted later in 2022.

WG3 members will assist with collating questions and answers and updating the FAQ file (Excel) twice per year.

The CEN/TC 463 and ISO/TC 34/SC 9 Plenary was held in June 2022. Both CEN (European Committee for Standardization) and ISO committees are very active with 36 working groups and 7 ad hoc groups. There are currently in excess of active 100 projects.

The plenary provided an opportunity for the WG convenors to present progress on WG projects and seek advice and endorsement from the full sub-committee.

More than 70 resolutions were passed at this meeting, of note:

- Creation of 4 new WGs
 - WG 33 Detection of *Cronobacter*;
 - WG34 *Enterobacteriaceae*;
 - WG35 Sampling techniques; and
 - WG 36 Isothermal molecular technologies.
- 3 new Ad Hoc groups were formed
 - AHD E Terms and Conditions;
 - AHG F Collaboration on interlaboratory studies and
 - AHG G Braining storming on Anti-microbial resistance.
- Progress with projects has been made despite the pandemic and virtual meetings have been held.
- Some projects have not progressed as a result of difficulty in arranging interlaboratory studies to gather validation data. Priorities for validation remain pathogens including *Salmonella*, *Listeria monocytogenes* and *Cronobacter*.

ISO TC 281 Fine Bubble Technology (FBT)

NATA's Sector Manager Life Sciences, Neil Shepherd attended the ISO TC 281 Fine Bubble Technology CAG as a member of Standards Australia (SA) mirror committee ME 090. Continued participation supports the development of standards using Fine Bubble Technology applications of which benefit agriculture, manufacturing and human and animal health.

The CAG sets the scene for the 2022 series of meetings of ISO/TC 281:

- WG schedule and progress for current projects for next full meeting
- DTS 4240-1 to be converted from TS to ISO.
- Reminder to all participants to vote on drafts on ISO website.
- Wanting to move back to F2F and have parallel meetings to get through schedule.

ISO/IEC AI Workshop

Nick Di Cresce attended the inaugural IEC and ISO Workshop on Artificial Intelligence on 24th and 25th May. The online event started a multi-stakeholder dialogue about at the AI ecosystem, including emerging trends, technology, requirements, and applications, as well as the role of standards.

Whilst there are no actions at this time, NATA and accreditation will potentially be affected by this industry in the future. Highlights from the presentations include:

- AI use cases
 - Running of services e.g. traffic management, security
 - Fraud detection and identify verification
- Potential areas for AI standardisation
 - Using AI for risk/impact assessment
 - Data quality, collection, modelling
 - Ethics and bias of AI
 - Governance of AI
- Conformity assessment implications
 - Testing and evaluating individual components of AI
 - Development of criteria for the evaluation of AI
 - Development of AI verification and validation procedures

4.2 Participate in Relevant ISO/CASCO Working Groups

ISO/CASCO Working Group 57 ISO/IEC 17043 revision

NATA's Sector Manager Calibration, Paul McMullen participates on the ISO/CASCO Working Group 57 that is responsible for the revision of ISO/IEC 17043:2010 *Conformity assessment — General requirements for proficiency testing*. ISO/IEC 17043 is used by all Accreditation Bodies for the assessment of competence of providers of proficiency testing schemes.

The revision of ISO/IEC 17043 has progressed and the ballot for CD2 ISO/IEC 17043 closed in October 2021 and was approved despite significant numbers of comments received. A drafting group was appointed from WG 57 to review the comments in preparation for the next full WG57 committee meeting planned in January 2022 to progress the draft to the DIS stage.

Regarding ISO/CASCO WG 57 revision of ISO/IEC 17043. The Working Group have addressed the 800 public comments received from the CD2. We expect the DIS to be made publicly available for feedback in 2 to 3 months.

It is expected that the DIS would be published between March - July 2022 with a 5-month comment period. Paul McMullen will coordinate DIS comments received from NATA members.

5. Represent Australia's interests in the OECD Working Party on Good Laboratory Practice as the national compliance monitoring authority

OECD Working Party on GLP

NATA's GLP Program Advisor, Louise Calder is the current Chair of the OECD Working Party.

The OECD Working Group on GLP held its annual meeting as a hybrid meeting in April 2022; the meeting is the major forum for discussion and development of policy and procedures relating to OECD GLP compliance monitoring. Due to Russia's aggression to Ukraine, the OECD Council decided to suspend the participation of Russia and Belarus in OECD bodies. Consequently, Russia was disinvited for the WP GLP meeting.

An optional technical session was conducted on IT, advisory documents and technical issues raised.

Louise Calder is an evaluator on the on-site evaluation (OSE) of Argentina Industrial Chemicals and Pesticides to be undertaken later in 2022.

6. Provide Technical Support for Government Free Trade Agreements & Mutual Recognition Arrangements; Liaise with Foreign Accreditation Bodies focussing on economies of Australia's major or emerging trade partners; Lead & Participate in Regional Technical fora & capacity building activities

NATA continues to engage with the DISR Trade Facilitation Section on a range of topics of mutual interest and during this period engagement has primarily been of a routine nature around ongoing programs and activities.

6.1 Provide technical support for Government FTAs and Mutual Recognition Arrangements

NATA has responded to requests from the DISR Trade Facilitation Section and provided inputs/comments on a range of matters, including:

- Review of Australia/India Free Trade Agreements aspects relating to conformity assessment.
- Review of a draft WTO Technical Barriers to Trade Committee guidance paper on conformity assessment procedures.
- Providing comment on a WTO notification from China of new legislation on conformity assessment requirements for imported goods.
- Discussion on the Republic of Korea Clean Hydrogen Trade Initiative
- Provided input on the TBT Chapter of the Australia-India CECA agreement and feedback on the India CECA text proposal
- Provided feedback on the proposed AANZFTA activities for 2022
- Provided information on our knowledge of the International Code Council (ICC)
- Performance review of the Memorandum of Understanding with the Commonwealth.

NATA provided a submission to The Treasury on a consultation Regulatory Impact Statement that related to amending the Competition and Consumer Act 2009 The issue being addressed is the making of Mandatory Standards for consumer safety under Australian Consumer Law.

For many years, this process has led to references to Australian Standards being out of date and/or changes to the requirements of the standard. While NATA supports the overhaul of the legislation, one of the key elements being promoted is the adoption of 'Trusted Overseas Standards' that would offer an 'equivalent' level of consumer safety. The RIS largely ignores the practical difficulties of establishing equivalence and also lacks any commentary on conformity assessment.

6.3 Cooperation between NATA and IANZ

NATA and IANZ technical management attend each other's respective technical advisory committee meetings due to the close economic relationship between Australia and New Zealand.

Whilst there has only been a couple of AAC meetings held by NATA during the reporting period, relevant IANZ staff have attended (virtually) when available, NATA and IANZ have continued to liaise with each other over technical matters of mutual interest.

6.4 Further develop the consumer education program

NATA held an event in early June 2022 "Why Accreditation Matters' to coincide with World Accreditation Day (9 June) and celebrate NATA's achievements over the last 75 years as a global leading accreditation body. The event was held as a live webinar and an in-person event in Sydney showcasing the world of accreditation with the broader community in Australia and overseas. It presented some inspiring stories of how accreditation has, and continues to, deliver confidence and assurance to every person in their daily lives.

Presentations highlighted the role of accreditation and why it matters, how testing is eliminating cervical cancer, value of accreditation in cyber security, and how standards and accreditation are supporting emerging technologies.

6.5 Promote development and assist with capacity building for countries in the region

A PACER Plus Implementation Unit (PPIU) has been established and whilst the activities under the PACER Plus SPS/TBT agreement remain in the initial stages, the PPIU has met with the TIA partners, including NATA to better understand existing activities in the Pacific (to avoid duplication) and opportunities under PACER Plus (to shape future work programs). A meeting was held with the advisor to discuss potential opportunities for future accreditation work.

7. Other activities with public interest outcome (as agreed)

7.1 Management of Deeds of Agreement

Information on MOUs and Deeds of Agreement, including those current, under negotiation or renegotiation is provided in the spreadsheet 'NATA- MOUs'. The following agreements are noted:

Commonwealth

Department of Industry, Science and Resources

A review of the Commonwealth MOU has commenced in preparation for renewal in 2023. While it is not due to expire until August 2023, the intention is to renew earlier to add recognition of NATA's new biobanking accreditation program for compliance with ISO 20387. Initial discussions have been held with DISR staff who have seen the merit in including biobanking in the scope of the MOU since it will be part of NATA's MRA evaluation planned for March 2023.

NATA is undertaking a self-assessment against our undertakings/ obligations that will be circulated to relevant Commonwealth agencies for their own self-assessment and feedback on NATA's performance.

Services Australia and Department of Health

The governance and working group meetings have continued under the tripartite Deed of Agreement between NATA, the Department of Health and Services Australia. There are 4 working group meetings and 2 governance meetings per year. The Deed has placed considerably more reporting responsibilities on NATA including the preparation of quarterly reports on activities undertaken during the period.

National Blood Authority

An MOU has been agreed between the NBA and NATA in relation to accredited laboratories performing tests on blood and blood products.

State and Territory

7.2 Representation on Standards Australia Committees

Refer spreadsheet 'NATA- Committee Positions'.

Other activities