



National Association of Testing Authorities, Australia

SISO Progress Report Supporting Information

Reporting Period

1 January 2023 to 30 June 2023

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 mid- term meetings were held face-to -face for the first time since the COVID-19 pandemic in May 2023 in Belfast. These are summarised on the spreadsheet 'NATA - activities'.

Executive Committee (EC) and IAF/ILAC Joint Executive Committee (JEC)

The Executive Committee and IAF/ILAC Joint Executive Committee determined the meeting format for the 2023 IAF/ILAC Annual Meetings and 2024 IAF/ILAC Mid Term and Annual Meetings. The IAF and ILAC Executive Committees agreed unanimously to hold the 2023 IAF/ILAC Annual Meetings, as in-person meetings only. The IAF and ILAC Executive Committees agreed by majority decision to hold the 2024 IAF/ILAC Mid Term Meetings, as a series of virtual meetings only. The IAF and ILAC Executive Committees agreed unanimously to hold the 2024 IAF/ILAC Annual Meetings, as in-person meetings only.

ILAC Arrangement Committee (ARC)

The ARC meeting reviewed the outcomes of other meetings held, including committees and working groups; ISO technical committees and liaison with other bodies were also reported. More detail is included below or elsewhere in this report.

It was reiterated that the Joint Executive Committee is the forum to receive and monitor feedback from key stakeholders, such as the World Trade Organization (WTO). The role of the ILAC Stakeholder Forum was confirmed - it is to increase awareness and attract stakeholders, look into building competence and consider new technologies; and look for organizations with more experience to enable ILAC to bring the right people together to highlight not only problems but also good practices.

WG14 - Biobanking

The ARC Chair is following up with the ILAC Secretariat regarding the use of the ILAC Mark for biobanks, noting if there are concerns, what the impact would be and what next steps are necessary to begin accepting applications for recognition of biobanking under the ILAC Arrangement. An application has already been received from APAC.

The ARC Chair is also raising an issue for discussion with the ILAC Executive regarding the need for witnessing for small scopes and how the peer evaluation process should progress. The Chair will present the outcome of the discussion at the next ARC meeting.

Accreditation Committee (AIC)

The AIC meeting also reviewed the outcomes from other meetings of relevance, including committees, working groups, ISO technical committees and liaison with other bodies. More detail is included below or elsewhere in this report.

ISO/IEC 17025

The systematic review of ISO/IEC 17011:2017 has been completed and the Standard has been reconfirmed for another 5 years with no revisions needed at this time. A workshop for outstanding ISO/IEC 17025 issues was held that discussed sampling (including measurement uncertainty, and sampling in calibration), management system requirements and decision rules.

Presentation from International Organisation of Vine and Wine (OIV)

The International Organisation of Vine and Wine (OIV), a future stakeholder made a presentation to the AIC.

The OIV is an intergovernmental organisation which deals with technical and scientific aspects of viticulture and winemaking, including:

- standards for the Viti vinicultural sector
- research and publications

- databases, statistics and sector information
- education and publication

The OIV provides grape and wine producing and consuming countries with information to develop regulations, minimise barriers to trade, promote sustainable production and protect consumers and currently has 49 member states/countries, including Australia. The OIV is currently conducting a project called LABWORK project, with the aims of

- developing a tool to support the process of managing and validating the methods that are included in the Compendium of International Methods of Analysis of Wines and Musts, and
- use of a digital workplace for managing the inter-laboratory method validation studies respecting the confidentiality of analysis results.

Liaison with ITU (International Telecommunication Union)

Information on the *ILAC_ITU Assessment Procedure in the Field of Telecommunications* procedure, which is currently still in draft, was provided. The purpose of the document is to inform ILAC MRA signatory accreditation bodies about ITU requirements that must be met by testing laboratories seeking to be registered on the ITU list of recognised laboratories - no specific requirements. Australia has testing laboratories on this list.

Liaison Eurachem

An update was provided by Eurachem on documents in draft or revision that are used by laboratories and of relevance to accreditation bodies. The documents cover topics including terminology, proficiency testing, quality in analytical chemistry, measurement uncertainty, method fitness for purpose, method validation/verification, sampling uncertainty and fitness for purpose of analytical equipment.

Liaison with the Joint Committee for Traceability in Laboratory Medicine (JCTLM)

The new JCTLM database was launched in October 2022 accessible at <https://www.jctlmdb.org/>

Metrology Update

The responses to a survey conducted in April 2023 on ILAC P10 *ILAC Policy on Metrological Traceability of Measurement Results* and use of Certified Reference Materials, was presented. The survey results did not show any clear outcomes / directions, however there was feedback that it is not ILAC's role to specify requirements regarding the use of sector specific Reference Materials. It was considered that the policy is adequate, however a decision was made to include an informative annex that provides further guidance on how to assess reference materials produced by non-accredited or recognised providers.

A topic specific working group TC 69 has been established to support the revision of ISO 5725 *Accuracy (Trueness & Precision) of Measurement Methods and Results*.

Liaison with the International Organization for Legal Metrology (OIML)

OIML, an international standard-setting body, aligns with the World Trade Organization's Technical Barriers to Trade agreement. It has numerous published documents, including the recently released D-37, a guide that applies ISO/IEC 17020 *Conformity assessment - Requirements for the operation of various types of bodies performing inspection* to assess OIML Issuing Authorities within the OIML Certification System.

An update on the OIML Certification System (CS) was provided; there are currently 12 Issuing Authorities (either ISO/IEC 17065 or ISO/IEC 17020) and 26 Test Laboratories (ISO/IEC 17025). Use of accreditation bodies experts instead of OIML approved experts to act as Management System experts for peer assessments is going to be formalised in an OIML-CS publication.

A project group has been established that is working on electric vehicles - OIML G22 (22 Ed) *Electric Vehicle Supply Equipment (EVSE) - Metrological and Technical Requirements; Metrological Controls and Performance Tests*. Additionally, a new international standard is being developed for electric vehicle charging stations (NMI Australia is involved and are currently seeking consultation).

Digital SI and Digital Calibration Certificates (DCC)

A digital SI framework has been developed which allows all aspects of the international measurement system to be accessed and interpreted digitally, enabling machine-to-machine communication and analysis. It meets the FAIR (Findable, Accessible, Interoperable, Reusable) Principles.

Digital SI is data that can be exchanged, read and interpreted completely by machines, has demonstrable metrological traceability from the SI to the final measurement and direct measurement or conformity data for a product that can be utilised at product level. It is not barcodes, QR codes, PDF files, or anything needing to be printed and evaluated by people or keyed or scanned into another system.

CIPM has formed a Task Group and Expert Group “Digital SI”, with members from the following organisations - CIE, CODATA, IEC, ILAC, IMEKO, ISC, ISO, NCSL International, OIML. They have issued a *Joint Statement of Intent* on the digital transformation in the international scientific and quality infrastructure. Long term goals include a globally agreed, uniform, unambiguous, authoritative and dependable data exchange based on SI units that facilitate use of DCC.

The digital SI framework provides:

- quality infrastructure benefits - measurement traceability at a level of detail previously unimagined and immediate update / exchange of data including amendments;
- accreditation benefits - improved security of data, less likely to be counterfeit or produced by a “bad actor”, a digital accreditation symbol and direct validation of conformity activity against laboratory scope;
- laboratory / customer benefits - reduce cost of paper and processing time, easier to demonstrate regulatory conformity, easier “audit trails” for measurement traceability, measurement data can push corrections directly to end machines to improve measurement quality / reduce uncertainty, and equipment is easier to evaluate for calibration intervals which drives optimisation of recalibration.

Germany has been very active in this work with Physikalisch-Technische Bundesanstalt (PTB) – the National Metrology Institute of Germany hosting the 3rd conference on DCC, and Deutsche Akkreditierungsstelle (DAkkS), the national accreditation body of the Federal Republic of Germany having a digital accreditation symbol in beta testing. Information on the test and setup can be obtained from susanne.kuch@dakks.de The digital accreditation symbol is:

based on Public-Key-Infrastructure (PKI) using digital identities of accredited conformity assessment bodies (CABs)

machine readable, electronically verifiable, tamper proof

secure authenticity and integrity of the accreditation symbol

secures integrity of an issued attestation of an accredited CAB

customer can verify the digital accreditation symbol (identity of the CAB, status of accreditation of the specific activity, integrity of the issued attestation content) issued as a seal

DCC + digital accreditation symbol = eAttestation

PKI infrastructure is based on international standards

every stakeholder worldwide can verify the digital accreditation symbol

- every AB can use the technical setup which is in line with ISO/IEC 17011 to secure authenticity and integrity of its own issued accreditation symbol by using digital seal.

UNIDO Project on Flexible Scopes

UNIDO conducted a benchmark study of accreditation bodies that apply flexible scopes and is intending to publish the results and include detail on best practices for the application of flexible

scopes of accreditation, and to serve as guidance to accreditation bodies that are interested in applying the concept of flexible scopes.

Accreditation Committee (AIC) - ISO 15189 Medical laboratories — Requirements for quality and competence WG

The WG decided to align ILAC G26:11/2018 *Guidance for the Implementation of a Medical Accreditation Scheme* with 15189:2022 without necessarily doing a broader revision; and proposed that all current ILAC documents where ISO 15189 is mentioned be reviewed in order to update them as necessary.

An update was provided on the EA Laboratory Committee Healthcare WG meeting held in December 2022, noting presentations were made on the new version of the IVD Regulation (IVDR) and the classification criteria of in-house-IVD versus non-in-house-IVD, and on risk management (ISO 22367) with a focus on IVDR. There was also discussion at the WG meeting re the usefulness of ISO/FDIS 20658 for standalone sample collection in view that ISO 15189 covers all preanalytical, analytical and post-analytical steps. There was an EA resolution that ISO/IEC 17025 can be used to accredit standalone medical testing sample collection which accommodates the unique situation of UKAS being the only accreditation body in the region to use the standard to accredit such activities.

Inspection Committee (IC)

A workshop was conducted on accreditation of inspection activities that utilise new technologies, with presentations covering:

Technology in the Inspection Sector

This presentation highlighted the use of technology in inspections and the challenges associated with its integration, recognising that technology is evolving fast.

Use of technology offers the benefits of increased accuracy, repeatability, more comprehensive and reduced inspection time, although not without challenges.

Two main challenges were discussed: data security and competence.

- Data security - Effective data security entails implementing robust governance frameworks, encryption protocols, and access controls to manage and secure large volumes of inspection data.
- Overcoming competence challenges involves comprehensive training programs and collaborative initiatives to foster proficiency and overcome resistance to change.

By tackling these challenges head-on, we can successfully integrate technology into inspections, unlocking its transformative capabilities.

Digitalisation in conformity assessment: current practices, challenges and implications for future

Utilization of digital inspection systems and remote monitoring for various equipment types in marine and offshore environments (e.g. drills, subsea devices, wind turbine vessels, and offshore platforms), and in the renewable energy sector were discussed - the aim is to improve accessibility, reduce risk, and lower costs.

- employed digital diagnostic tools (DDTs), smart sensors, and remote inspections to capture data, analyse it using onsite and cloud computers, and generate 2D/3D visuals, audio, and video recordings. DDTs enable round-the-clock onsite or remote monitoring and inspection capabilities and typically utilise the following advanced technologies to capture (input), analyse (logic) and report (output) the information (data). DDTs offer better insights for new and existing applications and the reported data allows all stakeholders to offer new services, including predictive maintenance, remote inspections and data-based sharing services for conformity assessment.
- the constant stream of data can be used 24/7 for testing and certification purposes pre-deployment (at the premises), or for predictive maintenance and validation post deployment.

- presented challenges faced in implementing digital strategies and suggested solutions, include developing a clear digital strategy, digitalizing internal processes and systems, recruiting competent personnel, creating new digital business models, and ensuring compliance with relevant standards and regulations.
- need for greater regulation relevant to digitisation and, with it, greater demand for new conformity assessment schemes and international standards.

Inspections with Drones

Inspections are conducted after the removal of potentially contaminated materials. Inspectors wear protective clothing and masks, maintaining a safe distance of 1 meter during the inspection.

A pilot project was carried out to compare the results of standard inspections with drone inspections:

- both types of inspections were conducted interchangeably to ensure accuracy
- the drones used for inspection must not obstruct airflow or disperse any remaining residue.
- validation of the inspection process requires that results obtained from standard inspections align with those obtained from drone inspections. While quantitative validation can be straightforward using AI, achieving qualitative validation may be complex. Proficiency testing should be implemented to address this challenge.

Competence in new technologies is essential for interpretation of data rather than relying solely on traditional knowledge. Data-driven evaluation will be crucial.

Other considerations

- competence of inspector and technical assessor
 - skills for flying drone
 - legislation
- traceability to location where pictures are taken
- initial validation of method
- separate inspection activity on scope of accreditation

Grain and Feed Trade Association (GAFTA)

An update was provided by GAFTA, focussing on the revision of the GAFTA Sampling Rules No. 124. A new version is effective for contracts dated from 1 June 2023 and superintendents must apply them from this date. The fundamentals of the procedures of drawing and preparing contractual samples have not changed.

GAFTA-approved superintendent must meet one of the following requirements:

- Hold a valid certificate of conformance to the GAFTA Standard for Supervision, Sampling, and Check Weighing OR
- Hold a valid certificate of accreditation to the latest version of ISO17020 as a Type A Inspection Company, with the appropriate scope (refer to the Code of Practice).

GAFTA Standard members will be audited to the new rules at their next annual audit after 1 June 2023, ensuring all members are audited to the new rules within 12 months. It is expected to achieve similar timeline for ISO accredited members, such as those accredited by NATA.

The ILAC Executive is to consider a formal relationship with GAFTA (i.e. MoU).

Australia has inspection bodies assessed to these requirements by NATA.

IAF Working Groups (WG)

A common theme of the working group meetings were proposed measures to improve coordination and collaboration between IAF and ILAC as IAF technical activities overlap with ILAC and accreditation body undertakings.

Management Systems Certification WG (MSCWG)

The meeting focused on the following topics:

- The draft recommendations to the IAF Technical Committee regarding Audit duration guidance and transfer of certificates were discussed.
- A presentation was made on IAF CertSearch, a global database of accredited management system certifications. The members were briefed on the positive member ballot, certificate statistics, the consultation process, the IAF Task Force, the mandatory document, and the overlap with existing data upload requirements for accreditation bodies.
- The status of various upcoming meetings, including the Auditing Practices and Accreditation Auditing Practices Groups (ISO/IEC 14001) were discussed. Additionally, the progress of task forces for the revision of several documents covering competence of accreditation body assessors and experts, and audit time was addressed.
- Several proposals were presented, including strengthening cooperation between the MSC WG and ISO/IEC 17011 WG, participation of permanent committees (ABIEG, MLA, CABAC UAC), and participation in regional groups.

Information Communication Technology and Data Security WG (ICTDS WG)

The aim of this working group is to promote the consistent application of accreditation and certified certification in Information & Communications Technology and Data Security domains, encompassing ISO/IEC 20000 and ISO/IEC 27001 standards, as well as related standards and schemes.

The meeting focused on the following topics:

- The information report on progress of the transition requirements for ISO/IEC 27001:2022 and updated IAF liaison officers to the related ISO technical committees.
- Information security management system (ISMS) related business - the status of both ISO/IEC 27001 and ISO/IEC 27006-1, with the recommendation that a mandatory document on the transition requirements for ISO/IEC 27006-1 be developed.
- A working group (SC 27/WG 1) Auditing Practices Group (APG) has been established for ISO/IEC 17001 with the aim and purpose similar to that of the APGs for other standards.
- This ICTDS WG has requested that the technical committee approve the establishment of a task force for engaging with the ISO/IEC 27001 APG.

Validation and Verification WG (VWVG)

The meeting focused on the following topics:

- Outstanding action items:
 - Proposal of a workshop on the International Civil Aviation Organization (ICAO) and the Carbon Offsetting and Reduction Scheme for International Aviation (CORSA);
 - Planning of an ISO/IEC 17029 workshop; and
 - Survey of IAF accreditation bodies on ISO/IEC 17029 and ISO 14065 programs.
- Information items:
 - ISO 14019 validation and verification Sustainability Information - background, drivers (regulators, security exchanges, investment funds, B2B supply chain due diligence etc.) and where it would fit in.
 - ISO 14020 Environmental labelling - terms of reference broadened to include environmental, social and economic aspects (fairtrade, rainforest alliance). Update including background and market research on the revised ISO 14020 family of standards.
 - Update on IAF Sustainability WG - formed by IAF Executive Committee in January 2022 to cover sustainability assurance schemes (WS 01), ESG Verification, Reporting and Rating (WS 02) and Net-Zero/ Carbon market (WS 03). This is based on ISO/IEC 17065, ISO/IEC 17021-1, ISO/IEC 17029 and ISO/IEC 17024.

Other topics covered:

- Transition status for several standards: ISO 14064-3:2019, ISO 14065:2020 (including ISO/IEC 17029:2019) and discussed issues encountered, challenges, or areas for clarification.
- Timeline for the IAF Multilateral Recognition Arrangement (MLA) transition, use of MLA mark, public and private scheme approval process, proposal to extend the MLA to ISO 14067 and draft idea of linking IAF MLA mechanism to EU CBAM (carbon border adjustment mechanism).

ILAC Publications

During the period January - June 2023 a couple of publications were updated and published.

Revision of a few other documents are in progress, and a few documents have been drafted and are under consideration.

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

The APAC meetings and associated activities were held face-to-face in June 2023, for the first time since the COVID-19 pandemic, in the United States. These are summarised on the spreadsheet 'NATA - activities'.

The following APAC annual meetings have been scheduled:

- 2024, 12 - 19 July, Dubai, UAE, hosted by GAC, ENAS, EIAC
- 2025, 20 - 28 June, Bengaluru (Bangalore), hosted by NABCB and NABL
- 2026, 20 - 28 June, Indonesia, hosted by KAN
- 2027, 19 - 27 June, Australia, hosted by NATA

Prior to the APAC meetings, the host economy arranged a seminar with speakers representing a range of organisations including the WTO, UL Solutions, International Code Council, AOAC and Los Angeles Department of Building & Safety (LADBS). There was a panel discussion with the United States (US) accreditation bodies on the US and accredited conformity assessment structure in support of global supply chains.

General Assembly and MRA Council

The APAC Chair, Jennifer Evans, NATA's CEO presented her report, and the following was noted:

- the IAF/ILAC regional evaluation of APAC has concluded;
- re-registration of APAC under the new Incorporated Societies Act 2022 (NZ);
- application of sanctions by APAC, its Members and Affiliates against Russian Federation - as APAC is constituted in NZ, it must follow NZ Law - No grounds to take action against the Russian Members;
- expanded structure of APAC - additional working groups under the Communication and Promotion Committee (CPC), Digitalisation established under the Capacity Building Committee (CBC), and the Digital Transformation in Accreditation in Asia Pacific (ADAPT) project; and
- APAC's Strategic Plan 2023-2025

The MRA Council approved the following MRA Management Committee (MRAMC) recommendation in relation to Biobanking:

- (1) that subject to the MRAMC acting as the ad-hoc group and determining whether any further guidance is required and agreeing that APAC has access to a sufficient number of competent evaluators;
- (2) APAC has applied to ILAC for Biobanking recognition.

Attendees were made aware of the North American Accreditation Forum (NAAF), a newly established forum of accreditation bodies and stakeholders who promote and support the principles of the World Trade Organization (WTO) and the United States, Mexico and Canada Agreement (USMCA). Members must be signatories of ILAC or IAF.

Digital Transformation in Accreditation in Asia Pacific (ADAPT) Project

The APAC-PTB Digital Transformation in Accreditation in Asia Pacific (ADAPT) project commenced on 1 May 2022 with a 3-year duration and set out to achieve 3 main objectives:

- APAC and its developing economy members are able to take informed decisions on digitalization-related matters;
- APAC increasingly develops digital formats to improve services and to collaborate with its members; and
- the capacities of developing economy accreditation bodies for providing digital services are strengthened.

The project initiation phase has now been completed and the project has progressed into the implementation of activities. The key activities of the project are:

- Develop a more effective digital management platform for APAC.
- Online discovery, experience sharing, capacity building events/workshops/surveys.
- Support the digitalization of peer evaluation processes.
- Explore the potential for the development of software for a common AB digital management platform.

A Digitalization WG, that meets monthly, has been established as a subgroup of the ADAPT project steering committee (PSC) and its roles are to:

- Plan and implement activities that have been agreed by the PSC to form part of the ADAPT project.
- In conjunction with the APAC Digitalization Network (AND), advise the PSC on areas that are suitable for further digitalization, including prioritization of the possible activities, specifying end-user requirements, and undertaking user acceptance testing.

In addition to meetings of the PSC and Digitalization WG, several events have taken place, including:

- Initial online event for all APAC Members: “Project Introduction and Sensitization on Digitalization for Accreditation Bodies” - introduction and overview of the project;
- Baseline Survey to establish the current levels of digitalization within APAC Member accreditation bodies, their needs, and expectations from the project;
- Presentation on the ADAPT project given to the APMP Digitalization Focus Group;
- Second online event to provide feedback to APAC Members on the findings of the Baseline Survey and the overall Activity Plan for the project;
- A workshop with APAC Lead Evaluators to build on the earlier input gained during the project appraisal process, to capture further feedback on how digitalization can enhance the APAC peer evaluation process and in particular, identify how the ADAPT project can help in this process;
- SoSafe cyber security online training programme launched for volunteer participants from APAC; and
- Online event to inform APAC member accreditation bodies about cyber security in their digital platforms, information and data security within the framework of operating in accordance with the requirements of ISO/IEC 17011, and to share some experiences from other sectors.

APAC Digitalisation Network (AND) Report

Meetings have targeted the following topics:

- Digitalisation efforts undertaken by members
 - Scope
 - Resourcing
- Identifying processes that may or may not be suitable for digitalisation
- Identifying resources to support accreditation bodies beginning digitalisation
- Development of a Common Digital Baseline for accreditation bodies
- Sharing challenges and successes

The idea of a common digital baseline for accreditation bodies was viewed as an essential resource to support other activities the Network might undertake as it describes a standardised point of reference for digitalisation efforts. A working group have been meeting separately from the network to develop a self-assessment mechanism (SAM) that can be used by accreditation bodies to:

1. Benchmark the organisation
2. Scaffold future digitalisation initiatives

The SAM will achieve this by breaking down ISO 17011 and common business functions into a set of assessable indicators.

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

Executive Committee (EC)

APAC is subject to the NZ Incorporated Societies Act, recently revised in 2022, as APAC is an entity incorporated in NZ as mentioned earlier. As a consequence of the revision of the Act a number of relatively minor changes are required to APAC's Constitution and procedures to comply with the latest version. A Constitution Review Working Group (CRWG) has been established to identify the necessary changes. The CRWG will also review APAC's membership categories and the requirements for each category to determine whether changes are needed.

The EC remains concerned about the extent of APAC's influence at the international level. APAC is the biggest region in terms of membership so should be in a position to exert more influence on decision-making in IAF and ILAC. A working group has been established to investigate how APAC can establish and promote an 'APAC position' on specific issues, where relevant, as they arise.

The working group will also consider future APAC representation in IAF, ILAC and the new international organisation, in particular how APAC ensures it holds positions of influence.

Mutual Recognition Arrangement Management Committee (MRAMC)

APAC confirmed its schedule of evaluations, noted the areas in which evaluators are required and all evaluation decisions since the previous meeting were confirmed. This included the continuation of NATA's signatory status and extension of scope to include Biobanking. More detail is provided later in this document.

All APAC MRA evaluations conducted since March 2023 are to be conducted on-site and in full compliance with APAC procedures, unless a special request for exemption is received which will require approval by the MRAMC.

Peer evaluators (Leads) have to be employed by an accreditation body and there is currently a need for additional APAC evaluators for Biobanking - ISO 20387 and Medical Testing - ISO 15189. NATA has put forward names of potential peer evaluators for these standards.

There is a moratorium on ISO/IEC 17025, ISO 17034, ISO 17043 and ISO/IEC 17020 evaluators.

It was noted that there is no training available for peer evaluators requested to evaluate a Region - the APAC Chair will raise this at the relevant IAF/ILAC meeting in Montreal November 2023.

Technical Committee (TC) 1

The committee noted the following international standards developments:

- a) systematic review results:
 - o reconfirmation of ISO/IEC 17025:2017
 - o reconfirmation of ISO/IEC 17011:2017
- b) publication of:
 - o ISO 15189:2022
 - o ISO/IEC 17043:2023

A recent ISO/CASCO presentation on ISO/IEC 17043:2023 and ISO clarifications have been identified as being useful resources - potentially for assessor training or training of NATA staff.

A couple of the ILAC/IAF FAQ's on ISO/IEC 17011 have been identified as APAC training course materials, specifically FAQ 21 and FAQ 29 <https://ilacfaq.org/category/jwg-a-series/assessment-program-and-accreditation-cycle-jwg-a-series/>)

Reports from subgroups were presented and are summarised below.

Reference Material Producers Working Group (RMP WG)

NATA's Sector Manager Calibration participates on TC1 as convener of the RMP WG and delivered their WG report.

Key topics reported were:

- Update of the ISO Technical Committee for Reference Materials (ISO TC 334) activities in standards development. More detail is provided later in this document.
- Need to revise APAC's guide for reference materials (TEC1-008) once the new ISO 334XX standards are published.

A RMP/Proficiency Testing Providers (PTP) Workshop is being arranged to discuss technical issues relating to proficiency testing provision and reference material production.

Proficiency Testing (PT) Subcommittee

- Discussed challenges expected when rolling out accreditation services to the 2023 version of ISO/IEC 17043 *Conformity assessment — General requirements for the competence of proficiency testing providers*;
- the APAC webpage on proficiency testing, that includes results of PT need surveys and the APAC and EPTIS database links is being updated. The website will direct users to individual accreditation bodies accrediting PT providers and users will need to search for specific programs on the provider sites;
- the APAC Accreditation of PTPs (ISO/IEC 17043) and RMPs (ISO 17034) e-learning course is now on the APAC Knowledge Centre;
- the APAC Accreditation of Proficiency Testing (ISO/IEC 17043:2023) training course was held in Tashkent, Uzbekistan on 19-21 April 2023. NATA's Sector Manager Calibration was one of the facilitators and attended virtually; and
- the 54th Joint EA-EUROLAB-EURACHEM Working Group "Proficiency Testing in Accreditation" outcomes were noted.

APEC TEL MRA Task Force

- 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 (IoT) cybersecurity and performance was noted. APEC recognizes APAC as 1 of 4 APEC Specialist Regional Bodies.
- The ongoing issue of fraudulent test reports; more in market surveillance is being conducted to address this issue:

Calibration Working Group

A topic identified for future discussion was the use of a QR code on a calibration certificate by a conformity assessment body (laboratory) and how this should be assessed by an accreditation body - this would not just apply to calibration certificates.

Machine-Readable Standardised Scope of Accreditation Database

A presentation on the development of a 'Machine-Readable Standardised Scopes of Accreditation Database' in the field of calibration was noted - Qualer Search (<https://search.qualer.com>) was developed by NCSLI as proof of concept.

Qualer Search is the first metrology search engine that enables you to find potential partners based on services provided and their location - it is the first application that uses the Metrology Information Infrastructure data standard (MII) The search engine uses metrology taxonomy - taxonomy is important so one can tag appropriate data especially as we are moving more and more to AI. (www.metrology.net/home/metrology-taxonomy).

APAC TC1 Joint Biobanking and Medical Testing WG

A meeting of this WG was held and updates provided on biobanking and medical testing.

ISO 15189 *Medical laboratories — Requirements for quality and competence* Updates were provided on standards of relevance to ISO 15189, including ISO 22870 *Point-of-care testing (POCT) — Requirements for quality and competence* which has been withdrawn with the release of ISO 15189:2022, and that ISO 20658 *Medical laboratories — Requirements for collection,*

transport, receipt, and handling of samples is at the final draft stage. At completion for transition of ISO 15189 the POCT standard will no longer be recognised.

A guidance document is being prepared for accreditation bodies on how to assess against the standard - not a guidance document for laboratories to implement the standard - to ensure harmonisation for traceability requirements, CRMs, sampling. MU etc.

Biobanking - Flexibility around scopes is required. Some guidance is already provided on this in an APAC document on biobanking scopes (APAC TEC1-001) and additional guidance will also be provided in an ILAC document. Once the LAC document is updated to include biobanking, the APAC document may be turned into a general biobanking guidance document.

Technical Committee (TC) 2

Technical Committee 2 focuses on certification activities. This has relevance to NATA because much of the product testing accredited by NATA becomes inputs to certification. Additionally, the certification of personnel is rising in focus in many areas where the competence of testing facilities has been of concern (e.g., controlled environments, sampling). The objective of TC2 is to:

- consider technical issues relating to the accreditation of certification bodies (CBs) and validation and verification (VVBs) bodies; and
- support the consistent interpretation and application of accreditation requirements by APAC Members in the areas of:
 - management system certification (e.g. ISO/IEC 17021-1)
 - person certification (e.g. ISO/IEC 17024);
 - product, process and service certification (e.g. ISO/IEC 17067 and ISO/IEC 17065);
 - validation and verification (e.g. ISO/IEC 17029 and ISO 14065); and
 - other conformity assessment activities that are covered by the IAF Technical Committee.

The following topics of interest were presented and discussed;

- certification of Management Systems (IMS, etc.) is a growth area. APAC is tasked to be more active in this area;
- use of AI in Personal Certification assessments e.g. having an AI tool prepare an exam.
- current ISO ballot on ISO/IEC 17067 to expand its scope to include description of certification schemes related to Management Systems, Verification and Validation, etc.
- EU proposal to restrict trade based on sustainability conformity assessment results. The EU's Carbon Border Adjustment Mechanism (CBAM) is the landmark tool to put a fair price on the carbon emitted during the production of carbon intensive goods that are entering the EU, and to encourage cleaner industrial production in non-EU countries trade based on sustainability and validation and verification results. Under this regulation only EA accreditation bodies will be acceptable - APAC will form a taskforce on this issue.
- looking to explore the formation of a ICTT and DATA security working group.

APAC Capacity Building Committee (CBC)

The purpose of the CBC is to:

- Address gaps and needs among APAC members with regard to coherence and coordination in capacity-building activities;
- Harmonise the accreditation practices among APAC members by organising relevant training activities;
- Facilitate the sharing of experience and technical information among APAC members;
- Support the development of new accreditation schemes for APAC members; and
- Support the enhancement of members' capacities in operating existing accreditation schemes of common interest to APAC members.

The outcome of the ISO/IEC 17043 Training in Uzbekistan was noted. Additional information is provided later in this document.

Planning has commenced for ISO/IEC 17025 training for calibration laboratories scheduled for October 2023 in Vietnam. NATA's Sector Manager Calibration and Technical Manager are presenters/facilitators for this training.

A recommendation was discussed to postpone the proposed course on ISO 17034 (Reference Materials) scheduled for March 2024 by 8 months. If postponed as recommended, it would align with the scheduled delivery of the Reference Material Standards that are currently being revised by ISO.

APAC Communication and Promotion Committee (CPC)

Topics discussed included:

- Presence of APAC and APAC members and affiliates on social media. Several accreditation bodies commended NATA on our online presence and information, including recognition of key events such as World Accreditation Day.
- Brochure developed covering business continuity.
- A position paper is being developed on the MRA usage aimed at company executives.
- A newly formed environmental WG is planning a series of webinars to discuss accreditation and certification activities related to environmental issues.
- A webinar is proposed for the medical and point of care testing (POCT) industries by the Health Sector WG.
- The Food Regulators WG is revising the survey for food regulars and has proposed a workshop for accreditation bodies to highlight accreditation activities in the food space.

APAC Evaluation of NATA

NATA is required to be evaluated every four years by APAC to maintain MRA signatory status.

From 6 March to 10 March 2023, NATA underwent its APAC re-evaluation for testing including medical, calibration, inspection, proficiency testing providers and reference materials producers. An application for entry into the MRA for biobanking was also included. The evaluation was conducted against the requirements of ISO/IEC 17011 *Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies* and relevant ILAC policy documents by a team of seven evaluators from ILAC signatory accreditation bodies.

NATA's continued signatory status of ILAC and APAC has been reconfirmed by the APAC MRA Council and our signatory status has also been extended to include Biobanking. We are only the second Accreditation Body in the world to be recognised for biobanking.

APAC Training Workshops

APAC Lead Evaluators Workshop

This workshop was organised by APAC for recognised Lead Evaluators - attendance was mandatory for NATA's four Lead Evaluators.

The workshop allowed the exchange of views between all participants - from various APAC signatories - to establish agreed positions for the conduct of APAC evaluations aligned with prescribed processes. Topics covered included:

- Timeframes for each step within the peer evaluation process, especially in relation to:
 - compiling evaluation teams and proposing them for MRA Management Committee approval;
 - accreditation bodies addressing nonconformities and corrective actions;
 - submission of evaluator performance monitoring reports;
 - Evaluation Review Panel (ERP) reports and updated Evaluation Reports prior to MRA Council ballot.
- The role and importance of Deputy Team Leaders;
- Selecting and monitoring provisional evaluators;
- Witnessing accreditation assessment activities and completing relevant forms;
- The difference between nonconformities and comments; and
- Expectations around reviewing corrective actions to close out nonconformities;

- Making recommendations for evaluator promotion (to Lead Evaluator);
- Digitalisation and streamlining of the evaluation process.

APAC Workshop on ISO/IEC 17043 and Accreditation of Proficiency Testing Providers (PTPs)

This 3-day APAC training workshop, conducted as a hybrid event, was hosted by the O'ZAKK, Uzbekistan and focussed on the use of ISO/IEC 17043, *Conformity assessment - General requirements for proficiency testing, to accredit bodies that undertake proficiency testing programmes*. NATA's Sector Manager Calibration was a presenter/facilitator for this workshop and participated virtually.

Participants were accreditation managers and assessment personnel involved with the recognition of PTPs. The facilitators discussed changes in the revision of the standard and technical sessions conducted focused on areas that are challenges in harmonized implementation. Participants were encouraged to share their experiences and ask questions.

APAC Publications

During the period January - June 2023 several publications were finalised and published.

Refer spreadsheet 'NATA- Publications'.

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

Refer spreadsheet 'NATA - activities'.

Brett Hyland, NATA's Stakeholder Engagement Manager participated as an Evaluator in the evaluation of ENAS, United Arab Emirates that was conducted virtually in January 2023. Preparation for this evaluation commenced in the latter half of 2022.

NATA's CEO, Jennifer Evans participated as the Lead Evaluator for the evaluation of AERSCC, Nepal in April 2023.

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

4.1 Participate in Relevant ISO Technical Committees

TC212 Clinical Laboratory Testing and in vitro Diagnostic Test Systems

ISO/TC 212/WG 1

Andrew Griffin, NATA's Sector Manager Legal and Clinical Services, represents NATA/Standards Australia and ILAC at the ISO TC 212 meetings that has responsibility for ISO 15189 *Medical laboratories - Requirements for quality and competence* and associated documents. 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*.

ISO 15189:2022 was published in December 2022 and it was agreed that the transition period for implementation be the end of December 2025.

The objectives of the revision for the latest version of the standard

- consider mandatory wording / Standard structure required by ISO CASCO
- requirements to be aligned with other international (ISO) standards e.g. ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*
- consider changes in ISO 9001:2015 *Quality management systems – Requirements*
- increase the focus on the welfare of the patient by planning and implementing actions to address risks
- be less prescriptive
- incorporate requirements for point of care testing (POCT)
- not duplicate requirements covered in supporting documents

Other documents under development of relevance to ISO 15189 include:

- ISO/CD 5649 *Concepts and specifications for the design, development, production and use of in-house in vitro diagnostic medical devices (laboratory-developed tests)*
- ISO/CD TS 23824 *Guidance on application of ISO 15189 in anatomic pathology*

Several additional documents have also been proposed and are under consideration by the WG that are of relevance to ISO 15189 as follows:

- ISO 17849 PWI *Validation and verification of quantitative and qualitative methods*
- PWI* *Medical laboratories - Guidance on application of ISO 15189: 2012 to emerging measurement technologies*
- PWI* *Guiding principles for use of AI in medical laboratories*
- PWI* *Medical laboratories - Guidance on personnel training and competence*

* PWI = Preliminary Work Item

ISO TC 276 Biotechnology

A NATA representative attended the 12th ISO TC 276 Plenary and WG Meetings, as a proxy to NATA's Deputy Sector Manager Legal and Clinical Services who is a member of TC 276, to ensure that Australia's views were contributed, and emerging topics are brought to our attention. Attendance also enabled us to keep abreast of the activities of the Working Groups and liaison interactions.

NATA is one of only two accreditation bodies currently recognised under the APAC MRA for the accreditation of biobanks.

A review of the Strategic Business Plan for ISO TC 276 is to be conducted, with the document ready for presentation at the 13th Plenary Meeting in June/July 2024.

Non-human biobanking is an expanding field and was a major topic of discussion. It is considered a potential area of interest for accreditation. Given the attention in non-human biotechnology, several standards have been proposed to be considered by the relevant WGs.

ISO/TC 276 WG 2: Biobanks and bioresources

ISO 20387 *Biotechnology — Biobanking — General requirements for biobanking* is up for systematic review in July 2023 - a 20-week ballot opens on 15 July 2023 for voting as to whether a review is needed. The overall opinion of those attending WG2 session was that a review will be definite and will be open for comment and technical input.

It was noted that the development of most documents requires more input from technical experts and/or manufacturers. Australian delegates were asked numerous times if there was potential for Standards Australia (SA) to source technical experts for their input.

ISO/TC 23511:2023 *Biotechnology – General requirements and considerations for cell line authentication* is to be revised with a recommendation that it is converted from a technical standard (TS) into an ISO Standard.

A proposal was tabled for *Biotechnology – Biobanking – General requirements for (semi) automated storage and retrieval systems*. A Project Team has been formed to determine which technical committee should be allocated to this project.

A large discussion was had regarding the process of provenance. It was decided that ISO/TS 23494-2 *Biotechnology – Provenance information model for biological material and data – Part 2: Common provenance model*; will proceed to New Work Item Proposal (NP) ballot.

ISO/TC 276/WG 3: Analytical methods

WG 3 was expanded into a Sub-Committee (SC) on Analytical methods, in order to structure current and forthcoming projects into three (3) more specific application fields. It is proposed that they will be:

- *Gene delivery,*
- *Cell characterization, and*
- *Nucleic acid characterization.*

ISO TC 334 Technical Committee on Reference Materials

TC 334 is responsible for ISO 17034 and the associated Guides which are in the process of being converted to ISO standards. TC 334 carries out and encourages a broad international effort for the harmonization and promotion of reference materials, their production and application. It aims to be the global centre of excellence with respect to issues relating to reference materials..

TC 334 stakeholders are the standardization bodies, metrology organizations, further liaison partners, both internal and external to ISO, such as accreditation bodies, and reference material producers and users of reference materials at large. Because reference materials are firmly integrated in metrological principles and activities, the cooperation with the CIPM (International Committee for Weights and Measures), with CCQM (Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology/ Comité Consultatif sur la Quantité de Matière), and its bureau the BIPM (International Bureau of Weights and Measures/ Bureau International des Poids et Mesures) is an important part of international harmonization and communication.

The work program of ISO TC 334 was noted; and other topics discussed included:

- difficulties in finding a reference list of suitable Reference Materials currently available. The COMAR database had limitations and many commercial and public RM Producers are not contributing to COMAR
- ongoing development and revision of existing ISO guides into new ISO 334XX Standards; and
- whether the Standards that support the production of Reference Materials are to include mandatory requirements.

4.2 Participate in Relevant ISO/CASCO Working Groups

ISO/CASCO Working Group 31 ISO/IEC 17020 revision

The systematic revision of ISO/IEC 17020 is due; and a decision has been made to revise the Standard and a working group established. ISO/IEC 17020 is used by NATA and other AB's for the accreditation of Inspection Bodies.

NATA's GM Compliance and Governance, Tony Vandenberg has been appointed as a Co-Convenor of the WG and NATA's Sector Manager Inspection, Amir Murad is representing Standards Australia on the WG. The working group experts play an important role in the review process by addressing the reasons for the review, considering ISO/CASCO's direction, and collaborating with the WG to achieve consensus. The expertise ensures that the standard is current and reflects best practices in inspection activities and other areas of interest e.g. role of artificial intelligence in inspections and the impact on accreditation.

The 1st meeting was held in April 2023 and discussed risk, definitions, structure, resources and the inspection process. The next meeting is scheduled for September 2023. The group aims to reach the Draft International Standard (DIS) stage by mid-2024, followed by the Final Draft International Standard (FDIS) in early 2025, with the publication targeted for November 2025.

The working group has been divided into task groups focusing on risk, resources, definitions, inspection processes, and structures to ensure efficient progress for the revision of the standard.

4.3 Participate in Relevant Codex Alimentarius Committees on Methods of Analysis and Sampling (CCMAS)

The work on allergens is of interest to Australia and will impact accreditation, as it is expected to lead to the advancement of method validation. The establishment of several working groups were proposed and approved for the following topics:

- to develop a discussion paper on best practices for selecting validated analytical methods for allergenic proteins and validating such methods;
- to develop a discussion paper identifying commodities and provisions where two types of methods are listed;
- to develop numeric performance criteria for nitrates and nitrites for food matrices and review existing methods to assess if they meet these performance criteria;
- work on an eBook to include sampling plan applications; and
- food types - cereals, pulses and legumes; fish and fish products; fruit juices

Several methods of importance for various foods were endorsed, including:

- numerical performance criteria for lead in foods within General Methods of Analysis for Contaminants and revoking of previously accepted methods;
- dried meat;
- analysis for fermented soybean products;
- peroxide value in cooked rice wrapped in plant leaves;
- regional standard for fermented Noni juice - NMI Australia lead this effort;
- sampling plans for contaminants and toxins in food and feed; and
- sum of components approach as performance criteria for toxins in foods.

4.4 Participate in relevant Association of Official Analytical Chemists (AOAC) work on related to the development of allergen testing methods and Panel on Alternative methods (ISPAM)

Analytical Solutions Forum (ASF)

The ASF is AOAC's horizon scanning and idea incubator and provides a multi-faceted approach to serving and advancing the needs of the analytical, food, feed, and agricultural safety communities. This session of the ASF included an address on critical food safety trends in 2022 and expectations for 2023 and beyond. Key points covered:

- AOAC domestic and international sections, their emerging issues and recent or upcoming meetings; and

- horizon scanning to identify needs before they become public health emergencies and for the proactive development of new scientific programs to meet these challenges.

Analytical International Methods and Standards (AIMS)

The AOAC AIMS program was launched in 2022 with the WG on nonculturable organisms. Their scope of work includes developing standard method performance requirements (SMPR's) for nonculturable foodborne bacteria and viruses. The meeting discussed further development of the SMPR for *Cyclospora* and then engaged stakeholders and attendees in a discussion on *Legionella*.

Stakeholder Program on Agent Detection Assays (SPADA) Meeting

The AOAC SPADA celebrated the approval of its first standards for next generation sequencing for amplicon sequencing quality and reporting guidance and requirements for nucleotide sequences used for biothreat agent detection, identification, and quantification. This session highlighted these accomplishments and launched the development of SMPRs for amplicon sequence detection, identification, and quantification methods for biothreat agents. Validation guidance for next generation sequencing methods were also launched.

Stakeholder Program on Infant Formula and Adult Nutritionals (SPIFAN) Meeting

The AOAC SPIFAN meeting featured an update on the AOAC SPIFAN Vanillin Working Group Regional Collaboration with the AOAC China Section. The SPIFAN meeting also provided an update on the latest decisions of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) meeting. The meeting also included an update on the launch of the AOAC Working Group on Heavy Metals.

Botanical Ingredients and Dietary Supplement Integrity (BIDSI) Program Meeting

BIDSI is a new AOAC program to re-engage and support the analytical science needs of the botanical and dietary supplement community. This session included updates from the US NIH Office of Dietary Supplements and Global Retailer and Manufacturer Alliance (GRMA), a presentation on ethylene oxide and a soft launch of standards development activity for pyrrolizidine alkaloids. An overview of the Reviewed and Recognized (R2) program from the AOAC Research Institute designed to assess instrument-based laboratory methods against pre-determined performance standards was also provided.

Cannabis Analytical Science (CASP) Program Meeting

AOAC CASP was established as a forum for development of the analytical tools and solutions for the cannabis and hemp industry at large. The Cannabis Regulators Association (CANNRA) shared perspectives on the status of laboratory testing. There was also a discussion on future directions of CASP and updates on the launch of the AOAC Proficiency Testing program for cannabis and hemp and on the completion of the ALACC appendix.

Gluten and Food Allergens (GFA) Program Meeting

The AOAC GFA program has served as a forum for developing consensus standard method validation guidance for qualitative methods. This session discussed the final draft of the qualitative guidelines for gluten and collected comments on the qualitative guidelines for food allergens.

Expert Review Panel for Microbiology Methods for Food and Environmental Surfaces

The AOAC Expert Review Panel (ERP) for Microbiology Methods for Food and Environmental Surfaces discussed the reviews of proposed modifications for a suite of assays and a separate modification and consideration for Final Action status recommendation for AOAC 2005.04, *Escherichia coli* O157:H7 in Selected Foods. The ERP also discussed topics related to the method validation.

Working Group on Per- and Polyfluoroalkyl Substances (WG on PFAS)

AOAC launched this working group in February and the WG started drafting SMPRs for PFAS in food, including the discussion on the target PFAS compounds and food matrices. During this session, an overview of work on a guidance document on PFAS analysis in food and feed was

presented by experts from the European Union Reference Laboratory for halogenated POPs and this will aide in the working group discussions on method performance requirements and other important points needed for the SMPR development.

Working Group on Heavy Metals

During this session, AOAC relaunched its Working Group on Heavy Metals as a way to transition work from the AOAC Community on Heavy Metals. The main objective is to re-examine current SMPRs in response to new and pending regulations for heavy metals in foods and revise or develop consensus standards in support of Official Methods of Analysis.

International Society for Biological and Environmental Repositories (ISBER) 2023 Annual Meeting

This is the annual biobanking conference that brings together experts from all areas of biobanking. The primary reason for attendance was to get a clearer understanding of the emerging international biobanking industry, and what influence and benefits NATA and Australia can achieve by offering accreditation.

Australia had a strong presence at the conference with one Accreditation Advisory Committee (AAC) member for NATA's Biobanking accreditation program being a past president and the other AAC member co-host of the event. Several members on the ISBER committee are also well known to NATA. These contacts provided introductions to new international networks and potential future stakeholders.

Biobanking is the most recent program introduced to NATA and as mentioned earlier in this document has been added to NATA's MRA scope. There is only one other accreditation body that has it on their scope (A2LA)- who were also present at the conference.

It was evident from the conference that accreditation and meeting the requirements for accreditation are still very much in their infancy internationally in biobanking - this is reflected in what we are seeing in Australia. Globally biobanks are very much a part of the disruptive challenge, fuelled by advances in technology and developments in data mining and AI. There is a move to not just focus on the biobank, but to also focus on the biospecimen - what's in the biobank.

In the history of biobanking development, quality was an afterthought and accreditation not considered at all. However, that has changed - it is now widely acknowledged that biospecimens are too hard to come by and too valuable - the introduction and maintenance of quality is essential to ongoing success in an increasingly competitive environment. Accreditation is a representation of that focus on quality.

Biobanking is an industry that is moving from the emerging phase to the growth phase of development and this change has been driven by technological developments, the requirement/ requests for more data and the emergence of AI applications.

The next ISBER conference is in Melbourne in June 2024 and NATA has staff on the organising committee.

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

The OECD Working Group on GLP held its annual meeting (37th Meeting) in March 2023. The meeting is the major forum for discussion and development of policy and procedures relating to OECD GLP compliance monitoring. NATA's GLP Program Advisor attended on behalf of the Australian GLP compliance monitoring authority (NATA) and is the current Chair of the OECD Working Party.

Activities and outcomes from the meeting included:

- Discussion on format for Annual Overviews and reporting non-compliance
- Preparation for 16th Training Course for GLP Inspectors
- Finalising the Cloud based Computer systems and GLP document.
- Discussion of reports from on-site evaluation visits
- Discussion with representative from the Industry discussion Group
- Development of documents relating to emerging technologies and internal guidance for supporting activities performed away from the test facility.
- Discussion of technical issues
- Update on new GLP implementation for mutual acceptance of data (MAD) adherents and OECD members

The following topics were included a closed session (for MAD adherents only)

- Update on working with non-members.
- Acceptance of data generated from non-MAD adherents

An optional session was held prior to the annual meeting that covered:

- Steering Group Meeting for 16th OECD Training Course for GLP Inspectors
- Questions and Interpretation Regarding Recently Published OECD GLP Documents
 - o OECD Doc. No. 22 Advisory Document on GLP Data Integrity
 - o OECD Doc. No. 23 Quality Assurance and GLP and No. 24 Position Paper on Quality Improvement Tools and GLP
- Free Discussion on Subjects regarding IT including cloud computing.
- Questions regarding new format of Annual Overview
- Free Discussion on Subjects Raised from Technical Issues

NATA's GLP Program Advisor also attended the 8th Global Quality Assurance (QA) Conference that is held once every three years. It brings together Quality Assurance professionals from around the world.

The objective of attending the conference was to expand NATA's knowledge of OECD GLP in the international context. The conference provided information on how the Principles are applied globally by facilities, regulators and compliance monitoring authorities (CMAs). It was also an opportunity to hear how GLP applies to emerging issues and provided the opportunity to promote and share experiences, consider regulatory and guidance updates and to exchange information.

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 WTO CAP guidelines document
- Review of conformity assessment annex in Australia-EU Free Trade Agreement
- Provided feedback on the Indo Pacific Economic Framework Digital Trade Chapter
- Provided information for the APEC SARs survey
- Provided comments on WTO trade policy reviews
- Renegotiation of the Memorandum of Understanding with the Commonwealth.

6.2 Pursue bilateral cooperation between NATA and foreign Accreditation Bodies focussing on economies of Australia's major or emerging trade partners

In February NATA hosted a delegation from the Standards Council of Canada that discussed a range of topics including accreditation practices, areas of new program growth and development, trade considerations between the countries and other synergies that enhance the relationship between our organizations.

NATA's GMBS and Head of Marketing attended a conference in April hosted by A2LA that provided an opportunity to collaborate on topics associated with the accreditation industry and to experience how another accreditation body engages with its stakeholders including members, assessors, accredited organizations, and anyone working in an industry that relies on accreditation, ISO, and quality and conformity assessment.

6.4 Further develop the consumer education program

NATA held an event in June 2023 "Accreditation Matters: Now and into the Future" to mark World Accreditation Day (9 June). The event was held as a series of five in-person events (Brisbane, Sydney, Melbourne, Adelaide and Perth) showcasing the world of accreditation with the broader community. 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 why accreditation has a vital role to play and focussed on

- the future with the impacts of automation and artificial intelligence;
- how continuous improvement provides a quality and competitive edge;
- why accreditation is fundamental to risk management; and
- how governance is essential to deliver quality outcomes.

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

NATA's Education department designed and delivered two courses for the Pacific Island Forum to upskill its members in quality management principles and the ISO/IEC 17025 testing and calibration standard. The courses were conducted as virtual training programs and based on two of NATA's standard courses. The attendees came from laboratories across the Pacific Islands and many did not work in accredited facilities and/or have a current quality management system.

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

The Commonwealth MOU has been under re-negotiation during this period as it expires in August 2023.

Department of Agriculture, Fisheries and Forestry (DAFF)

The MOU with DAFF is currently under review and will be updated to incorporate a variation agreement into the MOU and to reflect the current needs of both parties.

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. The review and re-negotiation of the Tripartite Agreement has commenced at the working group meetings that includes representatives from the three parties to the Deed. It is an agenda item at the upcoming governance meeting.

State and Territory

7.2 Representation on Standards Australia Committees

Refer spreadsheet 'NATA- Committee Positions'.

Other activities

Australian Institute for Non-Destructive Testing (AINDT) – Asia Pacific Conference for Non-Destructive Testing (APCNDT) 2023

The APCNDT was held in Melbourne from 28 February to 3 March 2023 and brought together people from all over Australia and the Asia Pacific region. NATA's Chief Executive provided the keynote address on the future quality practices and technological challenges of NDT in Industry 4.0, and how accreditation will continue to compliment the industry by increasing confidence in process and outcomes as they become increasingly abstracted.

The conference showcased and discussed the state of the industry including new technologies, robotics, automation AI, NDT applications in Industry 4.0, quality management, personnel certification and industry connections.

Subcommittee on Animal Health Laboratory Standards (SCAHLs)

NATA's Deputy Sector Manager Life Sciences attended SCAHLs 46 in March 2023 and discussion included the following topics:

- Update on Ehrlichia canis (E canis) project
- Data sharing for antimicrobial resistance
- Update on POC guidance document.
- Update on official testing policy
- Plan for simulation exercise for disease incursion, operation Waterhole.

Attendance at SCAHLs keeps us informed of developments that have implications for the animal health laboratories that we accredit in support of the export of prescribed goods, including meat exports from Australia and imported foods into Australia that are covered under the Deed of

Agreement and Memorandum of Understanding that we have with the Department of Agriculture, Fisheries and Forestry.

Australian Building Codes Board (ABCB)

NATA's Sector Manager Materials, Assets and Products who participates on the ABCB's WaterMark Technical Advisory Committee (WMTAC) and Lead Free Certification Procedures Working Group attended the ABCB's two workshops in February and March 2023 respectively - one for the certification bodies (CB) that are involved in the WaterMark Product Certification Scheme and the other for testing laboratories.

The workshop for CBs specifically discussed lead free WaterMark certification of plumbing and drainage products. Whilst some products are manufactured in Australia, many of these products are imported. The CB workshop provided an overview of the lead free plumbing products project, scope of products required to be lead free, protocol for the evaluation of products containing copper alloy intended for use in contact with drinking water, accreditation of WaterMark conformity assessment bodies, testing matters including accreditation of test laboratories, and evaluation of products for lead free certification

The workshop for testing laboratories included presentations from:

- ABCB: Changes to allowable lead levels in the National Construction Code, and the impact on the WaterMark scheme;
- JAS-ANZ: Certification of products meeting the new low-lead requirements; and
- NATA: Accreditation for NSF/ANSI/CAN 372 - Screening method and analytical method, laboratory reports and scopes of accreditation.

A meeting of the Lead Free Certification Procedures Working Group was held in April 2023 to address any outstanding Lead Free implementation matters, including:

- the lead free certification trade mark not being approved as yet.
- training on new WaterMark scheme.
- transition timeframe still September 2025; implications if delays in transition to lead free plumbing products.
- some European manufacturers may exit the Australian market.
- market surveillance will be targeted product inspections rather than annual factory audits.
- issues raised concerning test laboratories however no specific examples given.