



## National Association of Testing Authorities, Australia

### SISO Progress Report Supporting Information

#### Reporting Period

1 July 2021 to 31 December 2021

#### 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 scheduled during the July-December 2021 period were conducted virtually as a consequence of the ongoing COVID-19 pandemic. These are summarised on the spreadsheet 'NATA - activities'. The mid-term meetings scheduled for March-April 2022 in Montréal, Canada will now be held virtually. It is hoped that the next annual meetings can be held face-to-face in Montreal, Canada in November 2022.

#### General Assembly (GA)

##### ILAC Secretariat

The General Assembly, acting on the recommendation of the Executive Committee, approved the extension of the Deed of Agreement for the provision of the ILAC Secretariat by NATA, Australia, for a maximum period of two years from 1 January 2022 to 31 December 2023. This is in accordance with the Deed of Agreement signed in 2019 which contained provision for an extension to the agreement for up to two years.

##### Biobanking Accreditation

The General Assembly endorsed the recommendation of the Arrangement Council (ARC) to extend the ILAC Mutual Recognition Arrangement (MRA) to include accreditation of Biobanking as a Level 2 activity, to the criteria specified in the Level 3 normative document, ISO 20387 *Biotechnology — Biobanking — General requirements for biobanking*. ILAC will therefore accept applications for recognition as soon as the documents within ILAC applicable to the MRA are updated to cover this new scope.

##### Cooperation between Accreditation Bodies

An update was provided on the progress of the new ILAC Policy XXXX *Cooperation between Accreditation Bodies*, currently draft 7 that will replace the current guidance document ILAC G21:09/2012 *Cross Frontier Accreditation - Principles for Cooperation*. The document has been updated to take into account feedback from Dutch lawyers - legal advice concluded that the ILAC Policy is not expected to raise serious competition law issues.

##### Remote Assessment Techniques

The outcome of an ILAC survey on remote assessment techniques, introduced in response to the COVID-19 pandemic was presented:

- 79% of respondents would like to see a blend of remote and on-site in the future
- 80% of respondents stated that remotes provide the same level of confidence as on-site

It was noted that the Laboratory Committee consider that remote assessments lack technical rigour and advocate returning to on-site assessments as soon as possible.

##### ILAC Member Recognition Categories

The GA attendees were advised that the ILAC affiliate member category will cease from 31 Dec 2021. A survey is being conducted on the proposed recognition levels. Regional bodies have been asked to report back by 30 June 2022 on what 3 levels of recognition would look like instead of current 5.

An update was provided from each of the Committee Chairs; refer to the separate meeting reports below.

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

The steering committee for the new single international organisation, of which NATA's CEO Jennifer Evans is a member, met in August 2021.

There was discussion about revision of the new membership rules and rights for all members, and the next steps and timeframes in the establishment of the new organisation, including establishment of the Secretariat and various alternatives such as merging IAF into ILAC, merging ILAC into IAF, or merging IAF and ILAC into a new legal entity. The expectation is that the new organisation would be registered in June 2024.

### **Joint IAF MLAC & ILAC AMC (JMC)**

Consideration of the need for witnessing of all scopes as part of every evaluation of a single accreditation body was discussed at the September 2021 JMC meeting. A Task Force Group (TFG) has been established to review the process and to consider the experiences gained as a result of the COVID-19 pandemic.

### **Arrangement Committee (ARC)**

The outcomes from working group meetings were covered at this meeting.

#### WG9 – Management of Extraordinary Events

The proposed guidance document on management of extraordinary events was circulated within the ARC in June 2021.

NATA does not support the publication of this document as it has been in draft for nearly 10 years and numerous extraordinary events have occurred during this time. Accreditation bodies have managed events without the availability of this guidance document and it is not felt that the draft provides any guidance of value.

It was discussed and generally agreed that any new document on the subject of extraordinary circumstances should be a common document between ILAC and IAF; and that the draft document should be compared to the current IAF document (ID3) and discussed at the respective Joint Working Group. A proposal is to be put forward by the ARC Chair to the ILAC Executive for a combined ILAC-IAF document to be considered.

#### WG14 – Biobanking

A proposed roadmap to extend the ILAC MRA for the accreditation of biobanking was presented at the ILAC ARC in April 2021 and members were asked to comment on the proposal following that meeting. The roadmap was amended as a consequence of the comments made; this culminated in the resolution presented to the GA, as detailed above, following endorsement by the ILAC Executive. The WG determined what additional support will be needed for the harmonisation of accreditation of biobanking, including review and update of current ILAC Policy and Guidance documents.

### **Accreditation Committee (AIC)**

#### 17025:2017 issues

Some issues were identified with the implementation of ISO/IEC 17025:2017, and it was proposed to hold workshops on the topics raised; including:

- Decision rules (conformity with requirements).
- Sampling measurement uncertainty (sMU)
- Option A/B

These are currently on hold until a face-to-face meeting can be held to discuss them further.

In some regions, decision rules are becoming an issue between laboratories and their customers with laboratories concerned that ABs do not acknowledge this. The Laboratory Committee is aiming to develop a communication regarding decision rules at a level that customers can understand.

A summary of ILAC's liaison with other partners was provided at the meeting, including the International Telecommunications Union, OIML, IEC, ISO/CASCO, Eurachem and BIPM.

Information of particular interest is summarised below.

### Liaison with the International Telecommunications Union (ITU)

The ITU provides a database of worldwide recognised laboratories testing products for compliance with the ITU Recommendations and/or their normative references according to any of the testing routes of the ITU Conformity and Interoperability (C&I) Programme. The ITU database is used by manufacturers to identify laboratories able to perform required testing.

There is a proposal that test laboratories (TL) must be accredited against the ITU Recommendations.

Australia currently only has one laboratory registered on the database that is accredited, Austest.

### Liaison Eurachem

Two new leaflets are to be published on the topic of proficiency testing:

- *Do you speak proficiency testing?*
- *Understanding PT Statistics.*

Other groups within Eurachem have published and/or are working on the revision of Eurachem Guides that on topics of relevance and used by conformity assessment bodies (CABs) within Australia. These include:

- *Terminology in Analytical Measurement: Introduction to VIM* ; revision
- *Eurachem/CITAC Guide to Quality in Analytical Chemistry*; revision is progressing in order to bring it into line with ISO/IEC 17025:2017
- *Eurachem/CITAC Use of uncertainty information in compliance assessment* has been updated and published to align with recent international guidance, particularly ILAC G8
- *The importance of method validation* has been published
- *Quality Assurance for Research and Development and Non-routine Analysis*
- *Accreditation for Microbiological Laboratories*
- *Selection, Use and Interpretation of Proficiency Testing (PT) Schemes*

### WG 3 - Reference Material Issues

ISO / TC 334 (formerly REMCO) is giving consideration to changing current guides into standards.

The Standard ISO/IEC 17034 is due for its 5 year systematic review; a vote on whether or not the Standard needs revision closes in Feb 2022. NATA has already submitted its vote via the Australian mirror committee (QR-010) confirming the current version of the Standard, as we do not consider that revision is required.

### Biobanking

With the development of an international standard for biobanking in recent years, and the accreditation of biobanks being a reality, ISO TC 276 WG2 responsible for biobanking is seeking examples of biobanking scopes from accreditation bodies and has proposed a workshop to share experiences (potentially a joint one with ILAC).

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

The JCTLM Members and Stakeholders biennial meeting and workshop on *Overcoming challenges to global standardisation of clinical laboratory testing: reference materials and regulations* is to be held on 6-10 December 2021.

The workshop will develop and publish recommendations on how to address challenges related to reference materials, such as country and region specific regulations, to facilitate standardisation of results globally which is becoming increasingly important in this discipline.

## **Inspection Committee (IC)**

### Grain and Feed Trade Association (GAFTA)

GAFTA now requires accreditation to ISO/IEC 17020 *Conformity assessment — Requirements for the operation of various types of bodies performing inspection* for superintendents and to ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* for testing laboratories. There is a specific GAFTA Code of Practice requirements document for ISO/IEC 17020 accreditation.

There are about 200 Inspection Bodies and 150 laboratories globally.

Inspection bodies in Australia have achieved accreditation to these requirements.

### Independence and ISO/CASCO

There was considerable discussion on the term “independence” and how it is interpreted for Inspection. ISO/IEC 17020:2012 makes extensive use of the term “independence”, but does not provide a definition and makes a general reference to ISO/IEC 17000 *Conformity assessment — Vocabulary and general principles* without specifying the version of the standard. The previous version of ISO/IEC 17000 (i.e. 2004) didn't include a definition for “independence”; however, the 2020 version now a definition.

The Inspection Committee's position (notably EA members) has been that the implied definition of the term “independence” in ISO/IEC 17020 was derived from the thinking that there was a strong correlation between the terms “third party” and “independence” which originated from the definition for “conformity assessment activity” in ISO/IEC 17000:2004.

As a result, “independence” in ISO/IEC 17020:2012 was understood as meaning that there should not only be a freedom from control or authority from another person or organisation, but also a lack of user interest in the item inspected.

ILAC consulted ISO/CASCO on the matter and was advised that an assessment must consider the issue of independent taking into account all the requirements of ISO/IEC 17020 and the definitions of first, second and third-party conformity assessment in ISO/IEC 17000.

The CASCO Secretariat concluded that the inclusion of the definition of independence in ISO/IEC 17000:2020 cannot be construed as the single basis to change or modify the understanding of ISO/IEC 17020:2012. It was agreed that elements raised by ILAC in a paper on ‘Independence’ in ISO/IEC 17020:2012, together with other requests for clarifications and discussions in the community of users (including ILAC) will be considered during the next systematic review.

### Remote inspections

A presentation was made by a UKAS representative on remote activities, highlighting both from an accreditation body point of view conducting assessments and from an inspection body point of view that perform “remote inspections”. It was suggested that a workshop be held to share experiences.

### OIML Certification System (CS)

An update on the OIML CS and associated issues was presented. Issuing Authorities for type approval must comply with ISO/IEC 17065; however the use of this standard has been a barrier in some economies. OIML proposed that ISO/IEC 17020 be used as an alternative for Issuing Authorities to demonstrate their competence to address concerns and is developing a document to address differences between the two standards.

The CS Management Committee approved the use of ISO/IEC 17020 as an alternate pathway to ISO/IEC 17065 for Issuing Authorities (IAs) from 1 Jan 2023. It was proposed that an ILAC-OIML Assessment Procedure for ISO/IEC 17020 be developed, similar to the existing Joint Assessment Procedure for ISO/IEC 17025.

It is noted that NMIA is the only Issuing Authority in Australia.

### Revision of ISO/IEC 17020

The vote for the revision of 17020 is due in 2022 with the outcome to be known in 2023.

### Taskforce Group (TFG) for Sampling in Inspection

The Chair indicated that the TFG will put forward recommendations that points relevant to sampling be included in the next revision of ISO/IEC 17020. It was suggested that the definition for inspection in the standard could be expanded to cover sampling and/or relevant clauses updated to address sampling. These will be presented to the Inspection Committee for consideration.

### **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 Podcast Working Group. There are shared communication and marketing activities between the ILAC/IAF Communications and Marketing Working Groups and the accreditation body participants.

Brendon Moo is actively involved in the development of a consumer education program, and production of a series of podcasts for ILAC as a new communications initiative, and production of educational material including a documentary film to celebrate NATA's 75 Anniversary and its role in accreditation for the benefits of Australians and on the global stage.

### **ILAC-WADA Liaison Group**

The ILAC/WADA Liaison Group Terms of Reference have been updated to allow an additional Accreditation Body (AB) representative for ABs with more than 1 WADA laboratory accredited. There are currently 25 representatives from 25 ABs on the ILAC-WADA Liaison Group; NATA's representative is John Styzinski, General Manager Operations and Technical.

The MoU between ILAC and WADA is being renewed for another 5 years and will be signed at the WADA Foundation meeting on 25 Nov 2021.

WADA laboratories are expected to comply with the new requirement of the International Standard for Laboratories (ISL) clause 4.4.2.4 re Independence and Impartiality by 1 Jan 2022. The new requirement necessitated some laboratories to make changes to their structure and some economies needed to make regulatory changes. WADA will determine the course of action for those laboratories not complying by the due date and inform the relevant AB of the outcome.

Several new and updated technical documents (TDs) and technical letters (TLs) have been issued by WADA and these are listed on the WADA website with their effective dates.

It was agreed that the UKAS' toolbox for decision-makers could be used as an aide-memoire; the document was circulated within the Liaison Group to determine whether it could be published by ILAC.

The ISL training course scheduled for 2021 was cancelled due to the COVID-19 pandemic, however, it is anticipated that a course will be held in 2022.

### Athlete Passport Management Units (APMU)

ISO/IEC 17020 will be accepted for accreditation of APMUs and a WG was formed to progress it. NATA's General Manager Operations and Technical is a member of the WG. A draft scheme requirements document prepared by the Lausanne APMU was shared with the WG for consideration; it is anticipated that a final version will be available early in 2022.

There are 16 WADA laboratories hosting APMU and whether accreditation will be mandatory is still to be decided by WADA. Several questions were raised (e.g. timeline for implementation; training requirements for assessors; ILAC signatory status of AB for 17020 etc.) and these will be considered by the WG.

### **ILAC Publications**

During the period July-December 2021 a couple of publications were finalised and published.

Revision of a few other documents are still in progress.

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**

Meetings scheduled during the July - December 2021 period were conducted virtually as a consequence of the ongoing COVID-19 pandemic. These are summarised on the spreadsheet 'NATA - activities'.

All APAC meetings and activities scheduled for 2022 will be held virtually.

#### **APAC Communication and Promotion Committee (CPC)**

NATA's Sector Manager Life Sciences, Neil Shepherd Co-Chairs the Food Regulators Working Group (WG) with a representative from JAS-ANZ. This is one of a number of WGs under the APAC CPC.

The WG meets intermittently to discuss how to improve stakeholder engagement between APAC accreditation bodies (ABs) and regional food regulators and the last meeting held in December 21 discussed upcoming webinar plans.

#### **APMP-APAC Proficiency Testing Working Group (PTWG)**

The APMP-APAC PTWG is a formal collaboration of APMP and APAC, recognised in the past year, which is mainly responsible for the following objectives:

- To support quality and technical infrastructure in the Asia Pacific region through the coordination of proficiency testing schemes\* that are technically managed by members of APMP and offered to members of APAC and APMP;
- Through the running of the PT schemes enhance good metrology in the region in order to support trade and public safety;
- To report the working groups activities to the relevant technical committees of APMP and APAC;
- To conduct enquiries of APAC members as to proficiency testing needs in the region and reporting back to APMP;
- To address technical queries relating to the running of proficiency testing, when required.

\*The joint PT schemes are partially funded by APAC and the NMI/DI coordinating the scheme.

NATA's Sector Manager Calibration, Paul McMullen represents APAC as a member of this joint APMP-APAC working group. The Terms of Reference for the Working Group have been finalised and an update of the APMP-APAC MoU drafted for consideration by the Executive Committees of APMP and APAC.

The PTWG is keen to explore possibilities on how to work closer with APEC or the APEC Sub Committee on Standards and Conformance (SCSC) to raise recognition of the role of this joint PTWG in support of global trade and to explore means for addressing the proficiency testing needs of traceable measurements related to the pandemic.

The full APMP-APAC PTWG reviewed joint APMP and APAC PT programs undertaken and approved recommendations for future PT programs. It was made clear that APAC sponsored PT programs should only be offered where they do not compete with commercially available programs.

A survey of APAC members on the needs for PT programs undertaken shows 50% of respondents are seeking PT programs in Mechanical testing.

## **APAC Training Workshops**

### Accreditation of Biobanks (ISO 20387)

APAC held a workshop on the accreditation of biobanks that covered the requirements of ISO 20387 *Biotechnology — Biobanking — General requirements for biobanking*. NATA's Technical Manager, Sector Manager and Deputy Sector Legal and Clinical Services, and Sector Manager Life Sciences attended the workshop.

### APAC CPC Webinar

The APAC CPC hosted a webinar in December with presentations from JAS-ANZ, NABCB and NATA and an open forum to discuss stakeholder engagement. The level of engagement between the regional ABs and the regulators in their economy was one of the topics discussed. NATA's Sector Manager Life Sciences, Neil Shepherd represented NATA as its presenter.

## **APAC Publications**

During the period July - December 2021 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**

Several evaluations postponed during 2020 due to the COVID-19 pandemic were conducted virtually in the first half of 2021 and during the reporting period follow-up work was undertaken for some of the evaluations conducted. Refer spreadsheet 'NATA - activities'.

The evaluation of the Mongolian Agency for Standardization and Metrology, Accreditation Department (MNAS) was conducted virtually in March 2021, with NATA's CEO Jennifer Evans as Lead Evaluator. NATA's Sector Manager Calibration, Paul McMullen was added to the evaluation team and also assisted with post-evaluation work during the latter half of 2021.

The evaluation of PJLA, USA was conducted virtually in May 2021 with NATA's Sector Manager Inspection, Julian Wilson as the Lead Evaluator. Post-evaluation work was undertaken during the latter half of 2021.

NATA's General Manager Operations and Technical, John Styzinski participated as an Evaluator on the evaluation of the College of Physicians and Surgeons of BC Diagnostics Accreditation Programme in Vancouver Canada conducted virtually in May and June 2021. Post evaluation work was carried out during the latter half of 2021.

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

### 4.1 Participate in Relevant ISO Technical Committees

#### ISO/TC 212

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*.

#### Plenary

Progress reports from each of the working groups (WG) of ISO/TC212 were presented at the plenary and of particular interest to note, in addition to the summary below for WG1, are the following:

- ISO TC276 WG2 provided an update, noting that ISO20387 *Biotechnology – Biobanking – General requirements for biobanking*, the main biobank standard is being revised. It is unclear whether ISO 20387 is to be revised or amended. It is likely to be an amendment as the Standard was published in 2018 and therefore does not require systematic review until 2023. This will be clarified by NATA's mirror committee representative, Deputy Sector Manager Legal and Clinical Services, Gillian Treloar. This is of relevance to NATA as biobanking accreditation is being offered by NATA in Australia.
- ISO/TS 20914 *Medical laboratories – Practical guide for the estimation of measurement uncertainty* 2017. This document was developed as a joint project between WG1 and WG2. Being a technical specification (TS), it will be subject to review 2022 and it is important for WG1 to contribute to the revision to ensure it remains a relevant document for medical laboratory users.
- ISO/DTS 5798 *Quality Practice for detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by nucleic acid amplification methods* is out for ballot and if approved will be published. This publication is only applicable to human specimens.
- ISO/TS 20658 *Medical laboratories – Requirements for collection and transport of samples* is to be converted from a technical specification to an International Standard with a new resolution needed to approve the change of document type.

#### ISO/TC 212/WG 1

- ISO 15189 *Medical laboratories - Requirements for quality and competence*  
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.
- ISO 22870 *Point-of-care-testing (POCT) – Requirements for quality and competence* 2016  
The automatic systematic review of ISO 22870 was recently posted for ballot. This document is directly linked to ISO 15189:2012 and is expected to be withdrawn once the new ISO 15189 is published.

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*.
- ISO/PWI 5649 *Medical laboratories - Concepts and specifications for the design, development, production and use of in-house in vitro diagnostic medical devices*
- ISO TR23834 *Guidance on application of ISO15189 in anatomic pathology*

Proposals for new projects for WG 1:

- Validation and verification of quantitative and qualitative methods
- Use of patient samples for QC

### **ISO TC 147 SC 4 Water Microbiology**

NATA's Sector Manager Life Science, Neil Shepherd is a member of Standards Australia FT 020, a participating member of ISO/TC 147 SC4 that is required to participate in votes on standards under development.

An update was provided on the progress from various working groups relating to several methods:

- Legionella by PCR (WG17)
- Quality Control of Membrane Filters (WG22)
- Waterborne and Nosocomial Bacteria (WG 25)
- SARS-CoV-2 in Wastewater (WG26)

The progress on the PCR and SARs CoV-2 methods are of particular interest as they are applicable to Australia and NATA accreditation.

### **ISO TC 281 Fine Bubble Technology (FBT)**

NATA's Sector Manager Life Sciences, Neil Shepherd attended the ISO TC 281 Fine Bubble Technology Plenary and Technical Committee WGs 1-3 as a member of Standards Australia (SA) mirror committee ME 090. FBT has applications for agriculture, cleaning of surfaces and water decontamination and SMART farming and food sustainability.

A summary of the work being carried out by each of the working groups was provided.

- WG 1 General principles including terminology
- WG 2 Fine bubble characterization and measurement
- WG 3 Applications of fine bubble technology

## **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 a 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.

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.

## **4.3 Participate in Relevant Codex Alimentarius Committee on Methods of Analysis and Sampling (CCMAS)**

### **AOAC Annual Meeting and Exposition**

NATA's Sector Manager Life Sciences, Neil Shepherd attended the annual meeting and exposition. This meeting attracts a global audience of participants and developments in methodology in the US and Europe provides a perspective on where testing demand will occur in Australia going forward.

Allergens, cannabis and food fraud testing continue to expand and are directly applicable to testing in Australia and offer opportunities for business growth for NATA and capacity building in the national interest.

Point of Care Testing (POCT) is emerging as an opportunity for accreditation. Care is needed to ensure accreditation criteria and staff training keeps pace with these developments.

Topics of discussion relevant to accreditation and the Australian context were discussed, including:

- Molecular methods available for food authenticity. Standard Method Performance Requirements (SMPRs) have been developed for several determinations by the cannabis analytical science program (CASP). Additional SMPRs are being developed for specific product types at stakeholder requests.
- POCT/Point of Need (PON) testing for molecular test kits is expanding. NATA will consider the likely changes to the accreditation space as testing moves away from the traditional facility. PON testing applications include optical, electro-chemical, handheld Fourier transform infrared spectroscopy (FTIR) and portable mass spectrometers.
- Food fraud SMPRs are under development for olive oil, honey, bovine milk, spices (turmeric saffron, vanilla). Next generation sequencing (NGS) is also being used routinely for food fraud detection. It was noted that portable devices are being used by USDA for onsite investigation of food fraud and increased data generated is being analysed.
- Some methods will target multiple adulterants such as colourants, bulking agents other plants will accept 2 of 3 as that's still telling you its adulterated. Complimentary methods used DNA/chemistry.
- Global data sharing for some methods e.g. PFGE -WGS and WGS/MS used for detecting food safety outbreaks and food fraud. Privacy issues for data sharing between some economies are recognised.
- Food allergens and gluten, in particular where gaps exist in methods for allergen confirmation, gluten specificity and validation guidance for antibody based methods.
- "Blue sky thinking" bringing new and novel smart technologies into the food processing arena to address complex food safety challenges. This includes the incorporation of sensing devices to provide real-time quality assessments. Such advances can ultimately include pathogen sensing and identification in real time.

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

**OECD Working Group on GLP**

NATA's GLP Program Advisor, Louise Calder is the current Chair of the OECD Working Group and activities carried out during this reporting period were associated with performing this role, including addressing actions from the last Working Group meeting, reviewing OECD documents and preparing the material for the seminar for Vietnam.

NATA's GLP Program Advisor was the presenter for the OECD GLP Seminar for Vietnam held in December 2021.

## **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 DISER 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 DISER Trade Facilitation Section and provided inputs/comments on a range of matters, including:

- Contributing to content for the 2021 Yearly Review Framework for the APEC Connectivity Blueprint
- Provision of comments on the agenda for the second APEC Sub-Committee on Standards and Conformance (SCSC) meeting that covers topics including food and product safety.
- Providing feedback and commenting on:
  - FTAs e.g. EUFTA TBT Chapter, EUFTA Conformity Assessment Recognition Annex, and Malaysia-Australia FTA;
  - WTO TBT 9<sup>th</sup> Triennial Review
  - WTO TBT China's notification G/TBT/N/CHN/1627 ;
  - Activities in SE Asia and AANZFTA activities/ end of AECSP; and
  - WTO Conformity Assessment Procedures Guidelines
- Responding to a request in relation to CE marking for Australian exporters.
- Providing comments on the draft Digital Trade Policy
- Responding to queries in relation to FTAs e.g. EUFTA
- Developing proposals for APEC self-funded projects e.g. APEC Food Safety Cooperation Forum
- Performance review of the Memorandum of Understanding between the Commonwealth and NATA.

### **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.

Several of NATA's Sector Managers participated in the annual meetings of the IANZ Professional Advisory Committees (PAC) meetings scheduled during this reporting period.

A presentation at the Calibration and Metrology PAC on behalf of IANZ CEO highlighted changes in leadership (CEO (Brian Young) and some Council members), IT system review, an overview of IANZ's new New Zealand Quality College, and the training of their technical experts.

IANZ is undertaking a number of projects:

- Alignment of program processes
- Increase collaboration with Regulators -
- Streamline capital expenditure process
- New AIMS system which will links assessment findings, CARS and closeout

- A number of HR projects, including Workforce Assurance Model Standards, review of People and Culture strategy and development of People and Culture strategy.

IANZ have also introduced a requirement for each facility to identify and empower a key technical person (KTP to improve governance in facilities).

IANZ avoided significant lockdowns due to COVID and consequently were slow to embrace virtual assessments.

IANZ have worked on relationships with various Stakeholders including JAS-ANZ, the Ministry of Health, the Ministry for Primary Industries, WorkSafe and the construction sector.

#### Calibration and Metrology PAC

NATA's Sector Manager Calibration participated in the meeting that was held virtually.

The Chief Metrologist of New Zealand presented a report detailing significant changes in leadership of the MSL, establishment of a Science and Technical Advisory Group (STAG) to provide strong scientific leadership and oversight of MSL's strategic plan, capital expenditure, resourcing of standards and scientific projects, update on proficiency testing activities provided by MSL and the apprentice scheme initiative offered by MSL.

The program manager provided an update on new accreditations, assessment staff (internal and external), PT activities undertaken by the calibration laboratories and programme statistics (number of accreditations).

#### Biological and Chemical PAC

This meeting was held face-to-face and attended by the Sector Manager Life Sciences.

The NZ Government has mandated a water sampling accreditation program in the aftermath of a waterborne disease outbreak (Havelock North) - this initiative, which excludes recycled waters, has a 3 year implementation period.

China has indicated that modification to its GB (standard) methods is not permitted; this is a problem for IANZ as they permitted this and for NATA which under pressure have also allowed modification.

IANZ has not considered accreditation for Biobanking yet, unlike NATA and several other accreditation bodies.

Concerns were raised over the performance of some accredited facilities in proficiency testing. It was also noted that facilities are unhappy with PTA Asbestos program where the same samples are sent year on year and so the answer is already known.

#### Health Accreditation Program PACs

The main concern for the Health accreditation programs is a planned reform within the health sector. IANZ are expecting changes which may "water down" the accreditation process and require different "models" for accreditation.

High risk findings will be sent directly to the CEO of the relevant organisations as it was deemed IANZ has a duty of disclosure.

IANZ have identified their Scope of Accreditation do not meet ISO 17011 requirements and will need to be revamped.

#### Medical Testing PAC

IANZ worked closely with the Ministry of Health (MoH) to establish a technical and clinical advisory forum for COVID-19 testing.

#### Medical Imaging Services PAC

IANZ's radiology program is considering the use of Government published standards rather than RANZCR standards; there was a discussion that the RANZCR Standards can be too onerous for practices to meet. There could also be a "DIAS" type model introduced with a level of "self

assessment". A 2-tier accreditation model for Radiology and Pathology might be considered similar to some Canadian provinces.

Sourcing technical assessors is a continuing issue, especially in the Radiology space. IANZ staff are undertaking a Bone Densitometry course in order to become Technical experts so that there is not a need to source external technical assessors.

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

NATA's General Manager Compliance and Governance and Sector Manager Life Sciences presented at an ASEAN seminar on remote assessments in July 2021. The seminar was a virtual event organised by the ASEAN consultative Committee on Standards and Quality (ACCSQ) Working Group on Conformity Assessment (WG 2), Project: "Strengthening Quality Infrastructure in ASEAN".



## 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

##### Services Australia and Department of Health

The governance and working group meetings have commenced 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 places considerably more reporting responsibilities on NATA including the preparation of quarterly reports on activities undertaken during the period.

With regard to the ACSQHC, at it probable that NATA will require a formal agreement of some sort. At this stage, however, it is not clear whether the Commission will become a party to the current tripartite Deed or if their expectations will necessitate an additional agreement.

##### Department of Agriculture, Water and the Environment (DAWE)

The new schedule to the DAWE MOU for eDNA testing has been signed. eDNA has potential for widespread adoption to support biosecurity controls in Australia and overseas. Methodology will target specific pests and diseases and will be approved by DAWE. NATA has developed a biosecurity engagement plan that involves both the life sciences and inspection sectors.

##### Australian Signals Directorate, Australasian Certification Authority

The updated MOU with the Australian Signals Directorate for the evaluation of ICT security products under the Australasian Information Security Evaluation Program ("AISEP") has been signed.

##### National Blood Authority

The NBA is expressed its interest in maintaining an MOU with NATA regarding laboratories performing tests on blood and blood products. A draft has been provided and NATA is awaiting confirmation that they wish to proceed.

#### State and Territory

##### State Health Department MOUs

The MOUs with the South Australian, Western Australian and Queensland health departments have now been signed. These MOUs now include wastewater monitoring for detection of background levels of the SARS-CoV-2 virus in the community.

### 7.2 Representation on Standards Australia Committees

Refer spreadsheet 'NATA- Committee Positions'.

#### **Other activities**

##### DAWE National Biosecurity Forum

NATA's Sector Manager Life Science, Neil Shepherd attended the National Biosecurity Forum presented by DAWE. The forum focussed on:

- taking a future focus - a national biosecurity strategy
- shared responsibility and partnerships
- Australia's preparedness for the next national biosecurity threat