



## National Association of Testing Authorities, Australia

### SISO Progress Report Supporting Information

#### Reporting Period

1 July 2023 to 31 December 2023

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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

NATA's representatives on the committees participate as appropriate in the activities of the committees and working groups and the development of ILAC policies and/or guidance documents. The ILAC-IAF meetings were held in Montreal in November 2023.

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

#### ILAC/IAF General Assembly (JGA)

Progress on the establishment of the new single international organisation for accreditation, including next steps, was discussed:

- name (proposed to be "Global Accreditation Cooperation") and brand;
- reviewing and updating processes and practices; and
- expanding body's reach.

Issues to be considered included:

- location of registration - NZ is proposed
  - information on the new body
  - need to a member of a regional body to become member of new body
  - a member can be a member of more than one regional body
  - the Chair and Vice Chair should not be from the same Accreditation Body or regional body
  - approval of decisions at the General Assembly requires a 50% pass vote
  - committee structures
  - proposal for absolute majority for voting threshold in Executive Committee
  - code of conduct to be a separate document that members will need to commit to
  - in multi-Accreditation Body economies to have a multiplication factor for voting
  - stakeholders to have membership and voting rights
- All of the matters will be considered in the next draft of the Constitution and General Rules for the new single body expected to be available mid-January 2024 which will then be circulated again.
- The Constitution and General Rules are expected to go out for vote in March 2024 with a decision on the name of the organisation in Q2-2024.
- Establishment of the new single body is anticipated for Q2 2024 with finalisation of all documents by Q3-2025

Reports from other Joint ILAC/IAF committees were presented.

#### MLA/MRA Joint Management Committee (JMC)

- schedule of evaluations of the regions, including the Asia Pacific Accreditation Cooperation (APAC)
- transitions to updated standards currently occurring within ILAC, including date for completion
  - ISO 15189 Medical testing- 31 Dec 2025
  - ISO/IEC 17043 Proficiency testing providers- 31 May 2026
  - first progress reports from the regions to be presented at the October 2024 ILAC meetings

#### Joint Development Support Committee (JDSC) -

- update on the JDSC activities
- training course for ISO 15189 Medical testing delivered by NATA's Sector Manager, Andy Griffin in July 2023

Reports were provided by the recognised regional groups (AFRAC, APAC, ARAC, EA, IAAC, and SADCA)

### **ILAC General Assembly (GA)**

The ILAC Chair's Address and Executive Committee Report was presented, indicating that mid-term meetings will be held virtually going forwards.

The ILAC – NATA Deed of Agreement for Provision of Secretariat Services ended 31 December 2023; however a 3-month handover period was added to facilitate the transition to the new ILAC (and IAF) Secretariat. The General Assembly expressed its appreciation to Annette Dever, Sharon Kelly, the Secretariat staff, and NATA for their outstanding support and contribution to ILAC.

The ILAC Secretariat 2024 - 2026 has become an ILAC/IAF Secretariat in readiness for the single body establishment. The new Secretariat takes over from 1 January 2024 - tender for new secretariat only received one application - Axis Mundi.

ILAC's membership currently consists of:

- 113 Full Members (signatories to the ILAC MRA) representing 117 economies;
- 17 Associates representing 19 economies;
- 20 Stakeholders; and
- 6 recognised Regional Cooperation Bodies

There are over 88,000 laboratories, 13,900 inspection bodies, 604 proficiency testing providers and 260 reference material producers accredited by the ILAC Full Members (signatories to the ILAC MRA).

Elections for the ILAC Committees for 2024-2026 were conducted. Jennifer Evans (NATA's CEO) term as the ILAC Arrangement Management Committee Chair expired at the end of December 2023, however she is still on the ILAC Executive Committee in her capacity as the Asia Pacific Accreditation Cooperation (APAC) Chair. The General Assembly expressed its appreciation to Jennifer Evans for her outstanding contribution to ILAC as Chair of the ILAC Arrangement Management Committee.

The ILAC MRA Mark is currently registered (or provisionally registered) in 109 economies (registered in 101 economies & provisionally registered in 8 economies). 95 ILAC Full Members have signed the ILAC R7-F1 Agreement and have provided the ILAC Secretariat with an example of their "Combined ILAC MRA Mark" for approval - NATA is one of these members.

### ILAC/IAF Stakeholder Forum update

The 2<sup>nd</sup> ILAC Stakeholder Forum meeting was held, and a proposal put forward for a Stakeholder survey on 'Harmonisation of Accreditation'.

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

Reports from other liaison International Organisations were presented. In particular for noting:

#### Bureau International des Poids et Mesures (BIPM)

A general update was provided that mentioned issuing of a Joint Statement on Digital Transformation (BIPM, ILAC, ISO, ISC, OIML, etc.....) and gave an overview of the SI Digital Framework of relevance for metrology laboratories.

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

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

The MRA Users Group (WG3) will be disbanded on the proviso that liaison with the Stakeholder Forum continues.

The development of a document for 'Management of Extraordinary Events' has been put on hold since efforts are focused on creation of a single organisation. It was agreed to disband WG9, responsible for its development, and to provide the draft document to the relevant Committee/WG that will be responsible for combining/amalgamating ILAC and IAF documents.

There was considerable discussion on a draft ILAC Policy for Cooperation between ILAC Arrangement Signatories as there are significant concerns related to confidentiality / sharing of information between Accreditation Bodies and recognition of conformity assessment bodies (laboratories/ inspection bodies) under the ILAC Mutual Recognition Arrangement. It was agreed that a small task force group (TFG) be established to look at the comments with two representatives from each region on the TFG. It was noted that IAF has a TFG to look at cooperation, however, the group has not been tasked with writing a document. There was some discussion that IAF and ILAC should work together on creating a joint document.

An ILAC interpretation statement "ILAC Statement on non-EU accreditation in the EU" is now available on the ILAC website: <https://ilac.org/ilac-mra-and-signatories/benefits> for information and use as required by ILAC members, accredited CABs and stakeholders. The need for this statement was identified following the European Union Court Justice Ruling in May 2021: "Ruling of the EU Court of Justice on the interpretation and application of the EC Regulation 765/2008 in all Member States: in Europe, accreditation, with public authority status, can only be performed by the single National Accreditation Body" regarding the accreditation of a CAB based in the EU, by a third country (non-EU) AB, and the subsequent examples that emerged of some ILAC members either publishing statements or advising CABs directly that accreditation of a CAB based in the EU, by a third country AB is an 'illegal' or 'unlawful' activity.

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

The outcomes of other meetings of relevance were also covered at the AIC meeting. More detail is provided below or elsewhere in this document.

### BIPM update

An overview of the International Committee for Weights and Measures (CIPM) MRA was provided and it was noted that there are currently 64 Member States as well as 36 Associates (non-signatories to the metre convention). An overview was also provided on the CIPM MRA database, KCDB, specifically the service category identifiers and Calibration and Measurement Capabilities (CMCs).

### International Organization of Legal Metrology (OIML) update

The update included OIML technical work and on-going projects including G22 *Electric vehicle supply equipment (EVSE)*, and the OIML Certification System (CS). There are 40 categories of measuring instruments in the OIML-CS

- 39 in Scheme A (accreditation or peer assessment); and
- R111:2004 *Weight* now in Scheme B (self-declaration with transition to Scheme A after 2 years).

A need for experts was identified to act as management system specialists for peer assessments. Currently OIML CS has 13 Issuing Authorities, 27 Test Laboratories, and 36 Utilisers and Associates.

A strategic Digitalisation Task Group (DTG) has been established by OIML (includes a sub-committee for SMART OIML Documents) that will exchange with the IEC Strategic Group 12.

A new liaison has been appointed for OIML by the ILAC Executive and the deputy liaison remains NATA's John Styzinski.

### Liaison ISO/CASCO

General overview of ISO/CASCO activities was presented, including timeline for the review of ISO/IEC 17020 that is being the responsibility of WG31. A report on the activities of WG31 is available in Section 4 of this document.

### Liaison Eurachem

An update was provided by Eurochem on documents that are draft, under review or revised that are used by laboratories, and of relevance to accreditation bodies:

- The 2nd edition of the Eurachem Guide '*Terminology in Analytical Measurement: Introduction to VIM 3*' has now been published and is available on the Eurachem website.
- Measurement Uncertainty (MU) - Drafting of a guidance on the evaluation of uncertainty from in-house validation data to supplement QUAM:2012 is progressing.
- Method Validation - The revision of the 2nd edition of the '*Fitness for Purpose*' Guide is making good progress, with the 3rd edition of the Guide currently undergoing an extensive editorial review.
- A new publication is being planned on the role of uncertainty from sampling within Acceptance Sampling.

### International Organisation of Vine and Wine (OIV)

Cooperation between ILAC and OIV is still in the early phase and is expected to continue and be developed.

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

- Revision of ISO 15193 *In vitro diagnostic medical devices - Requirements for reference measurement procedures* and ISO 15194 *In vitro diagnostic medical devices - Requirements for certified reference materials and the content of supporting documentation* are at the draft international standard (DIS) stage and publication of the revised standards is expected in 10/2024.
- The JCTLM database currently has listed 290 Reference materials (mainly national measurement institutes (NMIs)), 217 Reference methods (accredited calibration laboratories), and 247 Reference measurement services (accredited calibration laboratories)

### Revised ISO 15189 issues

There was discussion on feedback received regarding implementation of ISO 15189:2022 and whether there is a need for harmonisation.

The WG will perform a review of the documents referenced in ISO 15189 (e.g. ISO 15190, ISO 22367, ISO/TS 20658) or with which ISO 15189 is aligned, and determine which ones require circulation within the AIC (e.g. ISO/DIS 5649, ISO/CD TS 22376, ISO/CD TS 23824). There was also discussion regarding the extent to which ILAC be involved in reviewing and providing feedback on revisions.

### **Inspection Committee (IC)**

#### Feedback from the Regions:

APAC - In June 2023, the group, now representing eight accreditation bodies, reconvened with a specific focus on concentrating efforts to revise ISO/IEC 17020, with a particular interest in sampling.

EA - Discussions primarily focused on European regulations, exploring scoping considerations such as flexible scopes, location assessments, and IT technology evaluations. The agenda also included revising ISO/IEC 17020 and addressing GAFTA-related matters in alignment with other regions. Furthermore, the group addressed the implementation of ILAC P15 in areas lacking sufficient guidance, particularly into the frequency of internal audits, defining subcontractors, and considering proficiency testing activities.

IAAC - Discussion covered documents clarifying inspectors' technical competencies for specific activities and the implementation of ISO/IEC 17020 requirements related to metrological aspects. It was deemed necessary to discuss the issues relating to the review of the ISO/IEC 17020 standard.

#### ISO/ CASCO Update - Working Group 31 Revision of ISO/IEC 17020

Ninety-four experts, including two from ILAC are participating in the working group. Discussion is focused on current and future planning for the revision, with an emphasis on information sessions during ballots. Working group conveners will present key elements, address changes, and respond to questions from participants during these information sessions. The first session is scheduled for the draft stage in the first half of 2024, with an option to invite stakeholders for clarification. Further detail under Section 4 of this document.

A workshop was conducted during this Inspection Committee meeting with an aim to discuss several proposals from the Working Group, requiring vital feedback from members especially as no definitive decisions have been reached at this stage.

Task group updates were presented by leaders covering definitions, risk, and the remaining aspects of the standard. The discussion revolved around maintaining consistency with references to types A, B, and C Inspection bodies as outlined in other documents. Additionally, the conversation delved into the handling of professional judgment, both internal and external personnel, as well as considerations related to clients and customers.

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

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

Regular meetings are held for the Marketing and Communications professionals to discuss the latest updates.

#### **Marketing and Communications Committee (MCC)**

NATA's Head of Marketing and Communications attended the meeting of MCC that is responsible for ILAC's internal and external marketing and communication. MCC is involved with the promotion of ILAC's objectives, and the publication of ILAC documents, newsletters and other information.

This year the theme for World Accreditation Day is *Accreditation: Empowering Tomorrow and Shaping the Future*.

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

The meeting took place in two parts and the first part included a combined hybrid session for the ILAC-WADA Liaison Group Members (present in-person in Montreal) and ISL trained assessors (joined virtually). NATA has 2 representatives on the ILAC-WADA Liaison Group as NATA has multiple WADA accredited laboratories.

An update on the current network of WADA laboratories, the Accreditation Bodies involved in the accreditation/assessments of WADA laboratories and the existing pool of ISL trained assessors was provided. There are currently 34 trained WADA assessors; and the global network of WADA laboratories comprises:

- 30 WADA-accredited laboratories
- 1 probationary laboratory
- 4 candidate laboratories
- 3 ABP\* laboratories

- 2 ABP Candidate laboratories

*\*ABP laboratory: A laboratory not otherwise accredited by WADA, which is approved by WADA to apply Analytical Methods and processes in support of the haematological module of the Athlete Biological Passport (ABP) program and in accordance with the criteria for approval of non-accredited labs for ABP.*

The ILAC WADA Liaison Group members and ISL trained assessors were informed that as part of the global review and update process of WADA's World Anti-Doping Code, all of WADA's International Standards, including the ISL, will soon undergo a revision process. The target date for the final draft of the revised ISL is November 2025 and the revised ISL will become effective on 1 January 2027. Accreditation Bodies will be invited to provide comments as part of the review process.

The second part of the meeting was the 24<sup>th</sup> ILAC WADA Liaison Group Meeting and only involved members of the WADA Liaison Group.

A discussion was had concerning the use of expired reference materials: and the critical considerations:

- an assessment of the material quality - physical state, chemical stability and potential degradation using techniques such as spectroscopy, chromatography, MS
- quantitative versus qualitative properties - for quantitative, expired RMs might significantly impact accuracy due to changes in conc and degradation of compounds. For qualitative, where identification or classification is the primary objective, the impact of expired materials might be less severe
- regulatory compliance and mitigation - compliance with ISO/IEC 17025, records justifying use of expired RMs, consider traceability
- alternative sources or remediation

UKAS' Toolbox for Decision Maker to be made available / shared on a needs basis with the group

## **WG ISO 17034**

### ISO 17034 Reference Materials

The liaison report for the 4<sup>th</sup> ISO TC 334 meeting was presented that reviewed the progress of the transformation of the guidance documents (Guides) into international standards. The ISO guidance documents support the implementation of ISO 17034. It was noted that other approaches may be used as long as the requirements of ISO 17034 are fulfilled.

ILAC AIC has formed a small taskforce group to look at the use of non-accredited CRMs (USP standards) for pharmaceutical analysis following a report around issues of interpretation of some clauses in ILAC's Policy P10.

## **IAF Meetings**

NATA's Sector Manager Inspection attended the IAF Technical Committee (IAF TC) meeting and several IAF working group meetings to keep abreast of certification programs and undertakings that are associated with testing and inspection activities accredited or that may require accreditation by NATA. The working group meetings attended included:

- IAF Management Systems Certification Working Group
- IAF Digital Working Group - covers information communication technology and data security
- IAF Validation and Verification Working Group
- IAF Food Working Group - scope extends beyond food safety to encompass all matters related to food and feed

## **ILAC Publications**

During the period July-December 2023 several publications were finalised and published.

Revision of a several 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 2023 period were conducted in association with the ILAC meetings in Montreal. These are summarised on the spreadsheet 'NATA - activities'.

#### **APAC Executive Committee**

APAC has revised its Constitution to align with the New Zealand *Incorporated Societies Act 2022*, noting APAC is incorporated in New Zealand.

APAC has also taken the opportunity to reconsider its membership criteria on the basis of the experience with applications over the five years since its establishment. The major changes result in 'raising the bar' for accreditation bodies to gain membership of APAC, including Associate Membership, and also to gain signatory status to the APAC MRA. This is aimed at ensuring that accreditation bodies have a sufficient history of accreditation to support decision making around compliance with membership criteria.

The other major change is that Full Members whose signatory status is terminated or Associate Members who do not achieve signatory status after an evaluation, will have membership terminated and will be unable to reapply for a period of 3 years.

APAC is also establishing a succession planning strategy for positions within APAC and for positions within IAF and ILAC.

Evaluation procedures for the APAC MRA are going to be reviewed to allow sampling of scopes and sub-scopes.

#### **APAC Training Workshops**

[APAC Training on ISO/IEC General requirements for the competence of testing and calibration laboratories](#)

NATA's Sector Manager Calibration, who is also Chair of the APAC TC1 Reference Materials WG assisted APAC as one of two facilitators of the 17025 Calibration Training available for all APAC participants in Vietnam. This training served as a capacity building activity for the Asia Pacific region.

Outcomes of the Training will be utilised by NATA for internal training of Lead Assessors.

#### **APAC Publications**

During the period July - December 2023 several publications were finalised and published. Refer spreadsheet 'NATA- Publications'.

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

NATA's General Manager Operations and Technical, John Styzinski participated on the Evaluation Review Panel (ERP) for the evaluation of SAAC, Saudi Arabia. This activity was conducted virtually.

Refer spreadsheet 'NATA - activities'.

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

### 4.1 Participate in Relevant ISO Technical Committees

#### ISO/TC 212

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 22583 *Guidance for supervisors and operators of POCT devices*.

He was the project lead for revision of ISO TS 20658 *Medical laboratories - Requirements for the collection, transport, receipt and handling of samples* which has now been published and continues as a project member for NWIs In-house IVDs, and Validation/Verification and Competence in the medical laboratory drafting committees.

There was concern raised within TC 212 regarding a proposal of ISO TC 304 Healthcare organisation management to create a new WG Clinical Pathology Management to draft a standard titled: Blood Banks General requirements for quality and competence of blood bank activities.

The issues were that TC 212 is the expert group for producing standardisation in Medical Laboratories and that this new proposed document could potentially "compete" with ISO 15189 in this space. The Chair of TC 212 is seeking a meeting with the Chair of TC 304 to discuss.

#### Plenary

It was agreed at the Plenary that the Scope of ISO/TC 212 be revised as follows:

*'Standardization and guidance in the field of medical laboratories laboratory medicine and in vitro diagnostic test systems.'* This includes, for example, quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems and quality assurance.

The title of TC 212 will also be changed to

*Clinical laboratory testing - Medical laboratories and in vitro diagnostic test systems.*

At the Plenary, attendees were advised of resolutions passed since the last Plenary and current and potential work items were reviewed. Each working group provided an update on their activities and points of relevance to Australia are noted.

#### WG1 Quality and competence in the medical laboratory

- ISO 5649 *Medical laboratories - Concepts and specifications for the design, development, implementation and use of laboratory-developed tests*  
Recommendation to move to DIS ballot.
- ISO 22583 *Guidance for supervisors and operators of POCT devices*  
This document was confirmed for another three years; however it was approved for some minor editorial changes to be made, most of which were made to align with ISO15189:2022
- ISO/PWI 21385 *Guidance for emerging technologies intended for medical laboratory use*  
Draft text for a working draft (WD) document will be prepared and shared with the project team early in 2024.
- ISO/PWI/TS 24069 *Medical laboratories - Guidance on personnel training and competence*  
A draft document outline was presented in preparation for drafting a WD.

- ISO/DTS 23824 *Guidance for the application of ISO15189 in anatomic pathology*  
Comments received had been reviewed and resolved by the project team and it was recommended for it to proceed for publication
- ISO/TS 20914 *Medical laboratories – Practical guide for the estimation of measurement uncertainty: 2019*  
Recommendation to confirm the document for a further three years.
- ISO/PWI 17849 *Guidance on the validation and verification of quantitative and qualitative methods*  
Clarified scope and document objectives, agreeing that the document needs to focus on the user and complement other documents.
- ISO/PWI 24051-1 *Medical laboratories – Part 1: General principles for the application of AI in medical laboratories*  
This new project is complementary to ISO/PWI 24051-2 Digital pathology and AI based image analysis from WG4,

#### ISO/TC212 WG2 Reference Systems

- ISO 15193 *Requirements for content and presentation of reference measurement procedures*  
Document is ready to register for DIS by 14 October 2023

- ISO 15194 *Requirements for certified reference materials and the content of supporting documentation*

Document is ready to register for DIS by 14 October 2023

- ISO/TS 20914:2019 *Practical guidance for the estimation of measurement uncertainty*  
Decision to confirm the document at this time, next periodical review scheduled for April 2026

#### ISO/TC212 WG 3 In-Vitro Diagnostic Products

Recommendations from WG:

- ISO 23640:2011 *In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents, to be revised.*
- ISO TS 16766 *Manufacturer's consideration for in vitro diagnostic medical devices in a public health emergency to move to the second CD ballot – Recommend extending the limit date for ISO TS 16766*

#### ISO/TC212 WG4 Microbiology and Molecular Diagnostics

- ISO/NP 24051-2: *Medical laboratories — Part 2: Digital pathology and artificial intelligence (AI)-based image analysis*  
Liaising with TC 212/WG1
- ISO/AWI 21474-4: *In vitro diagnostic medical devices – Multiplex molecular testing for nucleic acids – Part 4: Detection of pathogens*
- ISO/AWI TS 7552 (3 Parts): *Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood – Part 1: Isolated RNA. . . Part 2: Isolated DNA. . . Part 3: Preparations for analytical CTC staining*  
Initiate registration of DTS
- ISO/NP 18704: *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for urine and other body fluids — Isolated cell free DNA*  
Recommendation: Initiation of CD review and commenting

- *ISO/AWI TS 18702: Specifications for pre-examination processes for exosomes and other extracellular vesicles in venous whole blood - DNA, RNA, and protein*
- *ISO/NP 18703: Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Isolated circulating cell free RNA from plasma*
- *ISO/AWI TS 18701: Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for human specimens — Isolated microbiome DNA*
- *NEW Proposal: Standard on design and workflow requirements for NGS oncology panel somatic or germline variants detection technique*

Agreement that this is a worthwhile document.

## **4.2 Participate in Relevant ISO/CASCO Working Groups**

### **WG31 Revision of ISO/IEC 17020 Conformity Assessment - Requirements for the operation of various types of bodies performing inspection**

NATA's General Manager Compliance and Governance, Tony Vandenberg has been appointed by ISO/CASCO as a Co-convenor and NATA's Sector Manager Inspection has been appointed as a Member of this WG that is revising the ISO/IEC 17020 standard..

ISO/IEC 17020 is the conformity assessment standard which contains requirements for the operation of various types of inspection bodies performing inspections. During the initial meeting held from April 4-6, 2023, via Zoom, various areas requiring revision were identified. Task groups were established, with each group tasked with reviewing specific sections of the standard and proposing suggestions for discussion at this meeting in Geneva in September 2023.

Task Group 1 - Risk; Intensive discussions brought up diverse issues, but consensus remained elusive on the topic of risk, with recurring focus on impartiality and independence requirements (Annex A). But agreed on the below statements:

- Uniform impartiality requirements apply to all inspection bodies, regardless of their inspection types, and independence from involved parties can affect how these requirements are fulfilled.
- In specific markets, ISO/IEC 17020 Annex A's independence requirements define certain types of inspection bodies, but these requirements do not affect competence, consistency, or impartiality, warranting their inclusion in the standard in a separate context.
- Discussions highlighted the need for introducing certain definitions and suggested drawing from ISO/IEC 17025 for risk introduction, considering inspections' susceptibility to external influences.

Task Group 2 - Definitions; Presented work in three sections: revised definitions, new ones like "item," "client," and "independence," and additional definitions to be incorporated - appeal.

Task Group 3 - Structural requirements; Discussion included CASCO inquiries, alignment with ILAC P15, ISO/IEC 17029, and ISO/IEC 17025. Added positions for inspection oversight (Technical manager) and operational control.

Task Group 4 - Resource requirements; Review of resource needs, encompassing contracting and subcontracting (including reporting prerequisites for subcontracting).

Task Group 5 - Process Requirements; Validating non-standard methods (consider aligning with ISO/IEC 17025), considering technological advancements which may minimize human factors including professional judgement and review G27's guidance on testing under ISO/IEC 17020.

Following the work presented by the task groups, the working group reviewed all sections of the standard with proposed changes, gathering comments that helped shape the working draft of the standard.

A finalised version of the working draft of the standard is being prepared based on proposals from the task groups in response to feedback received, and further editorial review by convenors, secretariat, and task group chairs.

The finalised draft of the standard and the WG consultation comments will be discussed at the next face to face meeting being held from 6-8 February 2024 at the ISO Central Secretariat, Geneva, Switzerland.

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

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

NATA's Sector Manager and Deputy Sector Manager Life Sciences attended the AOAC annual meeting and exposition held in the USA in August 2023. This meeting attracted a global audience of participants and technical developments in food testing including allergens, gluten testing and cannabis testing were discussed.

#### Stakeholder Program on Agent Detection Assays (SPADA) Meeting

SPADA has developed two next generation sequencing (NGS) standards and are working on drafting standard method performance requirements and validation guidance for amplicon sequencing biothreat agent detection methods.

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

The meeting featured updates from ISO/TC 34/SC 5 (Milk and milk products), the International Dairy Federation on aligned methods and activities, and the latest on Codex activities.

#### Gluten and Food Allergens (GFA) Program Meeting and Food Allergens Community Meeting

The WG Chairs provided an update on the development of the validation guidelines documents for both gluten and food allergens. There was discussion on the scope for the end-user guidance document.

#### Analytical Solutions Forum (ASF): Emerging Topics and AOAC Sections Update

The ASF provided updates on important activities in AOAC sections, followed up on topics discussed during the AOAC mid-year meeting, highlighted new emerging issues, and needs, and solicited input from the audience.

#### Validation and Verification of Methods, and the Proper Use of Reference Materials

The ISO/IEC 17025 standard requires both 'selection and verification of methods' and 'validation of methods' but understanding of the key differences between these requirements has been problematic for laboratories. A roundtable discussion was held that showcased examples of methods being validated or verified, summarised the key differences between the requirements, and provided ideas for implementation that could be applied to quality systems.

#### TDRM Help Desk on Reference Materials (RMs) and Demo of Free on-line Course on Measurement Uncertainty (MU) and RMs

The Technical Division on Reference Materials (TDRM) is continuously providing knowledge about the use and sourcing of RM to the worldwide AOAC community. As a service to the AOAC community, the division conducted a 'helpdesk on RM' session at this year's annual meeting. The session provided answers to questions and problems based on queries sent in beforehand via a functional mailbox. This allowed the chairpersons to develop practical, succinct, and accurate answers to the discussion points.

For the long-term sustainability of spreading more in-depth knowledge about RM, MU, and metrological traceability, a demo of a free on-line course on RM and MU that was recently made available by the European Commission's Research Centre was presented. It consists of eight separate modules all related to RM, MU, and method validation.

#### Microbiology Community Meeting

This committee provided an overview of the current micro projects within AOAC, highlighted upcoming initiatives, and introduced hot topics for discussion (Alignment of Matrix Categories; Alignment of Test Portion Sizes; Alignment of Validation Guidance; Consensus Validation Schemes and Revisions to Appendix J).

Keynote addresses covered the AOACs role on the topics of food fraud prevention and pesticide residue challenges.

The US Department of Agriculture provided an overview of metagenomics with respect to big data, data driven life science and smart farming. They reviewed the future of this data and artificial intelligence.

#### FAO/WHO/Codex Guidance on Food Allergens and the Impact on Methods for the Detection of Allergen Residues in Foods

Food allergies have become a global public health priority in recent years. Avoidance of the offending food(s) has been the primary preventive approach. Over the past 20 years, analytical methods have been developed for the detection of allergenic food residues as a tool for the food industry to evaluate allergen control measures in mixed-use manufacturing facilities. The Codex Alimentarius Commission (CAC) first provided guidance to global public health authorities in 1999 with the recognition of 8 foods/food groups as the leading global causes of food allergy. In 2020, the Food & Agriculture Organisation (FAO) and the World Health Organisation (WHO) organised an ad hoc Joint Expert Consultation on Risk Assessment of Food Allergens under the auspices of the Codex Committee on Food Labelling (CCFL). Between 2020 – 2022, this expert panel developed recommendations for consideration by CCFL and CAC on the global priority list of allergenic foods, thresholds or reference doses, labelling strategies, and assessment of the allergenicity of ingredients derived from priority allergenic sources. Simultaneously, the Codex Committee on Food Hygiene (CCFH) developed new guidance on a code of practice for food allergen management.

This session summarised the recommendations made to CCFL and CCFH, the scientific basis for those recommendations, and the timeline for CAC consideration/adoption. The impact on global regulatory considerations and harmonisation was discussed with a focus on the impacts of these FAO/WHO recommendations on the needed sensitivity, specificity, and robustness of methods for the detection of allergen residues.

#### Risk Assessment and Risk Management: Current Issues in Sampling and Analysis

Risk assessment is classically described as a four-step process involving hazard identification, exposure-response, exposure assessment, and risk characterisation. Based on risk characterisation and risk tolerance factors, risk management decisions are made to either accept the risk, moderate factors affecting the risk, or to consider the risk as unreasonable.

This session explored risk assessment and risk management, and issues associated with the processes in the context of sampling for food contamination and asbestos in trace concentrations.

#### Food Allergen and Gluten Method Development: Approaches to Solve Quantification and Specificity Challenges

Food allergens and gluten remain crucial food safety concerns for industry, regulators, and allergic consumers. Evaluation of allergen and gluten controls, monitoring of regulatory compliance, and investigation of incidents often rely heavily on analytical tools. Over the past several decades, the availability of methods to detect and quantify food allergens and gluten in

foods has increased dramatically. As methods have been used more widely and in a variety of circumstances, method limitations and shortcomings have been identified.

This session featured presentations on approaches to solving critical analytical challenges and provided insights into state-of-the-art food allergen and gluten methodology and highlighted remaining research and standards development needs.

#### Psilocybin-Producing Mushrooms: Cultivation, Medicinal Uses, Regulatory Landscape, and Analytical Challenges

Psilocybin is a naturally occurring prodrug produced by over 200 species of mushrooms that grow naturally throughout the world. Many psilocybin mushrooms are in the genus *Psilocybe*, but species across several other genera contain psilocybin. In vivo, psilocybin is rapidly converted to psilocin, which is the compound that acts on serotonin receptors in the brain causing mind-altering effects.

These mushrooms are used for spiritual and ceremonial purposes by many indigenous peoples, but also have recognised therapeutic uses. Oregon was the first state to legalise a regulatory framework for production of psilocybin and the provision of psilocybin services through the Oregon Psilocybin Services Act and began accepting applications for various types of licenses on January 2, 2023. Since the passage of the Oregon Psilocybin Services Act, other states have worked on policies to legalise and/or decriminalise the possession and/or use of psilocybin mushrooms.

This symposium explored the cultivation, chemical profiles, and therapeutic uses of *Psilocybe* mushrooms, as well as the evolving regulatory landscape, analytical challenges of potency and safety testing, and the development of analytical standards and certified reference materials.

#### AOAC PFAS Initiative Updates

AOAC PFAS Initiative Updates, an overview of the draft SMPR for determination of PFAS in selected food commodities was presented.

#### Cannabis Analytical Science Program (CASP) Meeting

The Cannabis Analytical Science Program (CASP) was launched in 2019 and members of CASP lead the scientific community in cannabis standards development for regulatory and private sector laboratories, validation guidance, and training and education. This session included updates on the AOAC Cannabis Proficiency Testing Program, discussions around pesticides in cannabis, and presentations on a variety of topics related to the cannabis industry,

#### Machine Learning and Analytical Methods for Leaner and Greener Chemistry

The last decade has seen the emergence of analytical challenges for dietary supplements and cannabis. These have been compounded by the need to reduce chemical waste, carbon footprint, and analytical costs. Advances in computing power has provided solutions in the form of tools for targeted and non-targeted evaluation of large and heterogeneous datasets. Applications range from botanical authentication to adulteration detection to determination of hazardous contaminants. New methods must be accurate, precise, fit for purpose, and reproducible.

This session provided examples and case studies of the application of machine learning approaches to these challenges.

#### Recent Advances in 3rd Generation Sequencing for Food Safety

The U.S. Centre for Disease Control and Prevention estimates that unspecified agents cause 38.4 million episodes of foodborne illness in the United States alone each year. In addition to the public health risk associated with foodborne pathogens, it also imposes significant economic burden on governments and the food industry. Microbial contamination of food can occur anywhere within the supply chain, so faster and more accurate confirmation and tracking methods are needed to improve control measures in the food industry. Traditional methods for



identifying and tracking foodborne pathogens and spoilage microbes can be time-consuming and may require well-trained personnel to visually distinguish closely related species. New microbial detection approaches such as next generation sequencing (NGS) are being increasingly applied for tracing microbial contaminants entering the food chain. The food industry can directly benefit from these powerful new approaches which allow for the rapid identification of all microbial pathogens in food and environmental samples, thereby reducing the cost and turnaround time from the many different detection assays. With recent advances in third generation sequencing technologies along with its portability and declining costs, it has enabled development of new industry tools to rapidly detect, identify, and predict microbial contamination risks in real-time.

This session discussed the application of the latest industry tools for food and environmental surveillance and risk assessment during incident investigations.

### Novel Foods and Alternative Protein Sources: Trends, Challenges and Opportunities

Research, development, and marketing of proteins and foods produced from new and alternative pathways are on the rise. Increased access to financing by investors who are committed to sustainability, circular economy, and rise in “flexitarianism” are poised to accelerate these industrial endeavors. Projections expect the global alternative protein business to reach 200 billion dollars by 2030.

While insect, plant-based and fermented products are available in many parts of the world, only Singapore and United States have given permission to sell cell-cultured meat products. The speed at which these products are debuted, and the amount of stakeholder focus on early market entry creates unique challenges to the safety, acceptability, and quality of these products. As these products are intended to replace some traditional foods, they must not differ in a way that the consumption of the novel food would be nutritionally disadvantageous to the customer. Currently, there are gaps in chemical and microbiological tests that validate the safety, quality, and acceptability of these products. Tests developed by manufacturers are also hard to verify due to a lack of proficient methods and reference materials.

The goal of this session was to bring together leaderships from industry, regulatory agencies, laboratories, and academia to explore solutions to the challenges faced by this novel industry.

### Return on Investment (ROI) of Compliance and Automation in the Modern Laboratory

The key to achieving efficient and accurate laboratory results lies within a seamless integration between standards, like ISO/IEC 17025, and laboratory systems. Laboratories can leverage ISO/IEC 17025 recommendations to develop and implement action plans that will address various risks and possibilities, enhance the efficacy of the management system, prevent negative implications, and accomplish better results.

This presentation explored how guidelines from the ISO/IEC 17025 standard can be used to foster collaboration within existing laboratory environments and enhance information exchange with key stakeholders while simultaneously integrating other standards and protocols alongside ISO standards. While a part of this presentation discussed the application of ISO/IEC 17025 in the Cannabis testing world, another part discussed elements of laboratory accreditation for analysis of food (FDA).

Ways to improve the efficacy of the management system, get positive and negative feedback from customers, and suggestions from personnel utilising ISO standards, was explored. Additionally, the review of operational protocols, existing policies, audit results, corrective actions, assessment of risks, data analysis, proficiency test results along with reporting and storing of data was discussed.

From preparation to risk management to testing and reporting, this presentation uncovered how to achieve conformity and replicability so results can be widely accepted by peers in various countries. This presentation was relevant to regulatory officials, laboratory customers, accreditation bodies, and agencies that rely on peer assessment.

### Challenges for Natural Occurring Contaminants in Agriculture Community: Mycotoxins and Beyond

Accurately measuring naturally occurring toxins presents significant challenges for food industry regulations and food safety. Over the last decade, the agriculture community has made significant progress toward overcoming the challenges.

This session discussed the risks for new food consumption trends, unexpected foods and potential contaminants. The session also introduced the new portable mass spectrometry technology applications for point-of-sampling mycotoxins, and the collective efforts to establish a community-based efficiency testing program in distillers dried grains (DDGS). The need to standardise data reporting and interpretation was also presented.

A roundtable discussion on sampling, sample extraction, sample preparation and other issues involving mycotoxin analysis concluded the session.

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

### **OECD Working Party on GLP**

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

#### Evaluation of the Australian GLP Compliance Monitoring Program

On-site evaluation (OSE) visits increase confidence in the mutual acceptance of data (MAD) agreement and builds trust between compliance monitoring authorities (CMAs) and hence regulators.

The on-site evaluation visit of the Australian GLP compliance monitoring program was conducted between 14-18 August 2023 in the NATA Adelaide office. The team for the OSE comprised of a Lead Evaluator from the UK Medicines and Health Care products Regulatory Agency (MHRA) and a co-evaluator from Entidad Mexicana de Acreditación (EMA).

A meeting was held on Day 1 to provide an overview of the Australian GLP compliance monitoring program and to clarify issues in the draft report of the OSE that was provided to the team six months prior to the visit. Representatives from NATA, including our GLP Program Adviser and an Accreditation Specialist, GLP Program, were present and Receiving Authorities (Therapeutic Goods Administration (TGA) and Australian Pesticides and Veterinary Medicines Authority (APVMA)) were in attendance virtually.

On days 2 - 4 the team observed NATA staff conduct a GLP assessment of an Australian test facility located in Adelaide.

On Day 5 a summary of the evaluation was provided to NATA representatives at a final meeting by the evaluation team. The draft report and any issues arising from the observation of the assessment were discussed.

The following summary was provided by the Lead evaluator by email on 18 August 2023

*'Overall the GLP monitoring program of NATA follows the OECD guidelines and the OECD GLP requirements had been implemented. An adequate number of trained GLP inspectors with appropriate expertise and scientific knowledge to understand and inspect the studies were available.*

*The inspectors observed were professional, and well-prepared for the inspection. They examined the study plan and audited raw data to reconstruct the study. They followed up on issues raised appropriately and communicated well within the team and with the test facility.*

*No deviations were found.*

*The evaluation team concludes that the National GLP Compliance Monitoring Programme of NATA adheres to Documents Nos. 2, 3, 9 of the OECD Series on the Principles of GLP and Compliance Monitoring'*

The next OSE of Australia will be scheduled for 2033

## **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**

### **6.1 Provide technical support for Government FTAs and Mutual Recognition Arrangements**

Engagement with the DISR Trade Facilitation Section has continued with discussions 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

### **6.2 Bilateral Cooperation between NATA and Foreign Accreditation Bodies**

#### Taiwan Accreditation Foundation (TAF)

NATA's CEO attended the celebration for the 20<sup>th</sup> anniversary of the establishment of the Taiwan Accreditation Foundation (TAF) in Taipei on 26 October 2023 in her capacity as NATA CEO and APAC Chair. NATA has had a long association with TAF and its predecessor organisations, CNLA and CNAB, having hosted a number of attachment trainees.

NATA's CEO gave the keynote presentation at the formal celebration which was focussed on how accreditation supports sustainability initiatives. The formal celebration was attended by the TAF President, President-elect, TAF CEO, and all TAF staff. A number of senior personnel (Directors-General) from Government Departments were also in attendance.

There was also an opportunity on the previous day to spend time with TAF personnel to share knowledge on accreditation practices in particular in relation to biobanking, point-of-care testing and validation & verification (not a NATA accreditation activity) and on NATA's approach to government relations and our uplift in marketing & communications.

### **6.3 Cooperation between NATA and IANZ**

#### IANZ meetings

The NATA Chair, David Turner and CEO, Jennifer Evans attended the meetings of the IANZ Accreditation Advisory Committee and Council (Board of Directors) on 29 & 30 August 2023 respectively. There are no specific outcomes, it is part of the reciprocal attendance at meetings of Boards of Directors by the respective Chairs and CEOs. It was, however, interesting to note the similarity in the challenges being faced by both organisations such as increasing business costs affecting profitability, limited opportunity for growth in traditional business areas, understanding of accreditation by key government and business decision makers.

NATA looks forward to hosting the IANZ Chair, Ms Nicole Anderson and CEO, Dr Brian Young in 2024.

With much overlap of accreditations between Australia and New Zealand who have joint AS/NZS standards, attendance at the technical committees helps ensure uniformity of accreditation criteria for these AS/NZS publications.

#### Metrology and Calibration PAC (MCPAC)

MCPAC covers metrology and calibration laboratories, applied physics testing laboratories and electrical testing laboratories.

NATA's Deputy Sector Manager Calibration attended the MCPAC meeting

The IANZ CEO's report was provided, and the following points of interest were noted:

- Office relocation -they are now settled into their new offices.
- COVID 19 and extreme weather events (flood, cyclone and then flooding again) has impacted on the overdue surveillance.
- The framework for a simplified form of accreditation called Te Paerewa Recognition is now established and will initially focus on point of care testing.

- IANZ are exploring technology options for improving the efficiency and client/assessor experience of remote assessments
- IANZ strategies:
  - customer service, partnership and consistency
  - information systems transformation
  - developing our people

The Chief Metrologist of New Zealand presented a report detailing significant changes in New Zealand's technical infrastructure which included:

- MSL published its new 5-year strategy at the end of 2023 covering
  - Enhance MSL's role as a world class National Metrology Institute
  - Build MSL's leadership and influence in the national quality infrastructure and the science ecosystem
  - Contribute to the evolution of metrology.
- Research includes a long term project to build a Kibble Balance, maintain research efforts in quantum technologies, low humidity measurement, digital transformation of metrology, and light scattering. They have also received an optical frequency comb and the atomic force microscope.
- PT programs are limited but mostly in temperature and less in length and electrical.

The Program Manager presented their report detailing the nonconformities from their APAC evaluation, current technical matters, PT program types undertaken by facilities (to ensure sufficient participation by facilities and to identify gaps), and information on non-conformances raised and under which clauses of ISO 17025.

NATA's Deputy Sector Calibration presented a report on NATA's activities of relevance to the MCPAC which generated good technical discussions.

#### Medical Testing PAC (MTPAC)

The following was noted in the IANZ chairman's report:

*'IANZ currently accredits medical testing laboratories and medical imaging services within the public and private sectors, but there is no guarantee that our public service healthcare accreditations will continue.*

*We are currently engaging broadly with the Te Whatu Ora (Health NZ) to ensure the continuity of our existing healthcare accreditation activities, and to identify other areas of healthcare where accreditation can assist with improving the quality and consistency of service delivery across Aotearoa New Zealand.*

*The forthcoming election could affect these reforms, but they are possibly too advanced at this stage for a new Government to reverse them in their entirety.'*

There are serious issues with public pathology in NZ which have been growing for some time - the main issues appear to include inadequate staffing and lack of investment in infrastructure. There are insufficient pathologists,; hence NZ does not meet the NPAAC requirements for supervision.) IANZ has clear oversight of this and there is real concern they may lose this part of the programme.

IANZ has reported the issues to the government who are now reacting.

IANZ have changed the focus of their assessments, concentrating more on the high-level issues that affect providers abilities to do their jobs. As part of the response and to mitigate risk, IANZ (as a whole) will no longer differentiate between Major and Minor Non-conformances there will just be non-conformities. This has been driven from the issues experienced in medical testing. The Program Manager indicated that there was unanimous agreement at the meeting that IANZ accreditation for the profession is not negotiable and the members were in support of the proposed changes.

There is concern that healthcare accreditation (eg, pathology) may not continue to be mandatory. IANZ have recently established a framework for a simplified form of accreditation covering facilities such as POCT, and similar narrow-scope simple-test situations and for whom full accreditation is not necessary. This will have distinct branding and be presented on a separate website to avoid confusing the Te Paerewa Recognition Programme with actual accreditation.

The programme includes an on-site assessment every 4 years, a lot of self-evaluation and a management system that is appropriate, risk based, and outcome focused.

It was noted that IANZ is working on adopting some of the Royal College of Pathologists of Australasia (RCPA) requirements and some from US for structured cancer reporting.

In 2022 the government introduced the “Therapeutic Products Bill” into parliament. The Bill would “regulate how therapeutic products are manufactured, tested, imported, promoted, supplied and exported. The purpose of the Bill is to protect, promote, and improve the health of all New Zealanders by providing for the: acceptable safety, quality, and efficacy of medicines”. This appears to be similar in intent to the TGA requirements already in place in Australia.

#### Physical Sciences PAC (PSPAC)

PSPAC are seeking to engage with engineering professional bodies and are getting little traction – NATA has previously had similar experience with Australian engineering bodies.

There was a discussion of method deviations and what is permissible, and what can be reported - IANZ has the same position as NATA on method deviations.

IANZ no longer accredit the Inspection of water supplies, but they do continue to accredit testing of the water supply. This is in response to a change in their regulations.

Late in 2022 IANZ commissioned an international benchmarking study to explore the accreditation programmes of ‘like-minded’ international ABs to identify gaps and opportunities. IANZ stated that they would share this report with NATA.

Accredited sampling, ‘tested as received’ and non-accredited sampling by an accredited laboratory was discussed. Nothing that we are not seeing at NATA, and no new insights.

Staff retention is a major issue for NZ laboratories, in keeping with what we see in Australia.

The steel industry is currently running independent third party checks on imported steel products for construction. They are getting mixed results – with some serious concerns uncovered.

## 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 covering all NATA's accreditation activities and GLP has been re-negotiated and agreed and is awaiting sign-off. The existing MOU has been extended until the end February 2024.

##### Services Australia and Department of Health

The tripartite Deed of Agreement between NATA, the Department of Health and Services Australia is under re-negotiation and is currently being reviewed by the departments' legal teams. An extension for the current tripartite Deed is in place until the end June 2024. Governance and working group meetings are continuing as scheduled.

Quarterly informal meetings are held with Services Australia to address operational issues that arise in the pathology accreditation program.

##### Department of Health and Aged Care

The MOU for the National Cervical Screening Program for medical laboratories undertaking cervical screening and confirmatory testing is under re-negotiation.

##### Department of Agriculture, Fisheries and Forestry (DAFF)

The MOU with DAFF for microbiological and chemical analysis has been reviewed and re-negotiated to reflect the current needs of both parties.

In support of areas covered by the Deed of Agreement and Memorandum of Understanding, NATA's Sector Manager Life Sciences attended the 3rd Australian Authorised Officers (AAO) Annual Meeting and provided an update on NATA's accreditation activities covered by the Deed, including changes to the meat inspection program. Attendees included all organisations that provide Authorised Officers.

The Sector Manager Life Sciences also attended a meeting hosted by DAFF of NATA accredited facilities approved by DAFF to test imported food samples. Information was provided by DAFF on changes to the surveillance and risk foods program and feedback sought.

#### State and Territory

##### Health MOUs

The MOU with Northern Territory Department of Health that covers medical testing, food testing, water testing, medical imaging and sleep disorder services has been re-negotiated.

The MOU with NSW Health Pathology covering medical testing has been re-negotiated.

#### Professional Bodies

##### Thoracic Society of Australia and New Zealand (TSANZ)

An MOU has been signed with TSANZ for the development and operation of a respiratory function laboratory accreditation program.

## 7.2 Representation on Standards Australia Committees

Refer spreadsheet 'NATA- Committee Positions'.

### Other activities

#### National Measurement Institute

NATA's Deputy Sector Manager Calibration, Judy Smart has attended the OIML R126 Committee meeting that is finalising the calibration method for evidential breath analysers.

#### Australian Building Codes Board (ABCB) WaterMark Technical Advisory Committee (WMTAC)

NATA's Sector Manager, Materials, Assets and Products (MAP), Diane Hobday is a member of WMTAC; and reviews, provides feedback, and addresses queries on a range of standards and WMTS specifications (refer below) for plumbing and drainage products for compliance with the WaterMark Certification Scheme in accordance with the Plumbing Code of Australia (Volume 3 of the National Construction Code).

WaterMark Technical Specifications (WMTS) are published by the Australian Building Codes Board (ABCB), as part of their role in managing and administering the scheme.

#### Australian Building Codes Board (ABCB) Lead Free Certification Procedures Working Group

NATA's Sector Manager MAP participates on this working group that includes representatives from three WaterMark Conformity Assessment Bodies, NATA, JAS-ANZ and ABCB. A meeting was convened to discuss the issues around laboratory capacity for testing for lead in any plumbing product containing copper alloy and intended for use in contact with drinking water. Many of these products are imported.

#### Australian Institute for Non-Destructive Testing (AINDT) NDE 4.0 Committee

Nick Di Cresce, Deputy Sector Manager MAP attends the committee meetings that discuss national and global aspects of NDE 4.0 and also attends the meetings of the international working group ICNDT SIG..