National Association of Testing Authorities, Australia

SISO Progress Report
Supporting Information

Reporting Period

1 January 2021 to 30 June 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 Mid-Term meetings scheduled during the January - June 2021 period and some previously cancelled meetings were conducted virtually as a consequence of the ongoing COVID-19 pandemic. These are summarised on the spreadsheet 'NATA - activities'. The annual meetings scheduled for October 2021 in Montréal, Canada will now be held virtually. No decision has been made on the mid-term meetings scheduled for April 2022.

World Accreditation Day was held on 9 June 2021 with the theme **Accreditation: Supporting the Implementation of the United Nations Sustainable Development Goals (SDGs)** for all people, the planet and prosperity. Each year we celebrate this global initiative to raise awareness of the importance and value of accreditation.

This year's theme focussed on the UN's Sustainable Development Agenda and promoting the many ways in which accreditation can help meet these goals and how accreditation may be applied to meet objectives such as increasing trade, addressing environment and health and safety concerns, and improving the general overall quality of output in an economy.

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

It was agreed that there will be no increase in ILAC membership fees for 2022.

Progress on the initiative to establish a single organisation for accreditation (ILAC + IAF) has been slow with significant consultation phases. It is difficult to see that the project will be concluded by the stated aim of the end of 2024. The project is being led by the Co-chairs of IAF and ILAC.

A contract between IAF, ILAC and the consultant engaged to manage the project has been signed and the agreed work plan commenced in March 2021. Thomas Facklam, ex-CEO of DAkkS, Germany has been engaged as the consultant to manage the project

The first phase is to determine eligibility for membership of the new organisation and the need for 'categories' of members. Currently, ILAC offers membership only to accreditation bodies whereas IAF offers membership to both accreditation bodies and stakeholders such as certification body associations. Allied to eligibility for membership of the organisation, is eligibility for committee membership and eligibility for election to office bearer positions. The other consideration related to membership and membership categories is voting rights and whether rights should differ based on membership category. It is noted that the European co-operation for Accreditation (EA) is also reactivating its crusade to allow only one member of the organisation from each economy.

These are contentious matters and there is currently no agreement at the steering committee with polarised positions held by some members on the fundamental question of membership eligibility.

Arrangement Committee (ARC)

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

<u>WG3 – MRA Users Group</u>

A new convenor is required for this WG to replace Llew Richards (IANZ) who retired in 2020 and Doug Leonard (ANAB) has volunteered for the role. It was noted that the records for the WG members are dated (2013) and it was agreed that a review and update of the WG ToR and membership is needed.

Concerns surrounding acceptance of the ILAC MRA by regulators was noted:

- United States Food & Drug Administration (FDA) –A proposed regulation relating to food testing by accredited laboratories, requires ILAC approved ABs and accredited laboratories (17025).

An additional regulation is to be introduced requiring accredited laboratories to send their food testing results and supporting information to the FDA for their review. The additional regulation also contains eligibility requirements for accreditation bodies to qualify for recognition, and requirements that accreditation bodies must meet once recognised, such as requirements related to competency and conflict of interest safeguards. The proposed regulation also contains eligibility requirements for laboratories to qualify for accreditation by a recognised accreditation body. The number of reports and the FDA review turn-around-times are unknown but there will be some disquiet if this drags out the process of analysing samples and releasing reports by laboratories, which in turn could delay food manufacturers from getting products to market.

It is anticipated that the new regulation will come into effect end towards the end of 2021 / early 2022 and it is not clear whether a transition period will be in place. It is understood that not all MRA signatories will be recognised and that ABs will have to apply to the FDA and that a fee is payable.

- India Telecom Engineering Centre (TEC) – Potential non-acceptance of EMI and EMC testing results from laboratories accredited by ILAC signatories related to MTCTE procedure. Current notification indicates that acceptance is extended until 20 June 2021 for "all requirements of essential requirements except safety requirement and EMI/EMC requirements". No further information was provided on this topic although requested from delegates from India.

The ARC Chair requested ABs to forward examples of where Regulations stipulate ILAC MRA as a prerequisite so that the information could be shared with ARC and Communications committees.

WG9 – Management of Extraordinary Events

A proposed document on management of extraordinary events is being developed to provide guidance on managing the assessment process that may be impacted by extraordinary events such as, natural disasters, disease outbreaks, or security concerns. The draft document has been reviewed and the objective of the document has been changed from guidance for both ABs and CABs to that for ABs only.

Several new sections are proposed:

- a section on investigation of the effect of an extraordinary event or circumstance and risk analysis;
- implementation of action plan; and
- communication with ILAC and the relevant regional cooperation group.

The draft document will be circulated within the ARC for a 30-day period. It was also raised that the JEC consider the document as an A series publication.

WG14 – Biobanking

A roadmap drafted for extending the ILAC MRA to include ISO 20387 *Biotechnology — Biobanking — General requirements for biobanking* has been circulated to the ARC for comment. Once approved, a subgroup of the ILAC Executive will draft the proposal to expand the MRA.

The proposal will be presented to the ILAC Executive together with supporting information and rationale. A decision is needed to ascertain if this constitutes a new Level 2 activity, or whether it could sit under an existing Level 2 activity (e.g. reference materials). There is strong stakeholder support to extend the MRA to include biobanking as some regions and a number of ABs are now accrediting to this standard or developing accreditation programs.

Once agreed, the proposal will be referred to other relevant committees for review. Results of the review and the recommendation from the ILAC Executive will be distributed to members for a decision to be made at the next ILAC General Assembly.

An ILAC committee will then draft and seek approval for inclusion of additional peer evaluation processes. 'On-site' evaluation will be needed for a new Level 2 activity for recognised regions as

stated in the Multi-Lateral Mutual Recognition Arrangements requirements documents IAF/ILAC-A1 and A2.

The extension to the MRA will become effective when:

- new or revised mandatory A series documents are adopted; and
- there is a positive vote of the evaluation of at least one recognised region by the ILAC Arrangement Council.

Accreditation Committee (AIC)

A position paper on the relationship between ISO 20387, ISO 17034 and ISO/IEC 17025 was to be presented at the meeting in December 2020; however, it has not been progressed.

A proposed 17025:2017 workshop has been put on hold until it can be held face-to-face.

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

ILAC Laboratory Committee (LC)

The LC raised the application of artificial intelligence in the laboratory with the AIC. It is noted that EUROLAB has developed a position paper on this subject.

Assessments in the time of COVID-19 were also discussed, in particular lack of harmonised practices on remote assessments, and the LC supports the development of a guidance document. Whilst the committee supports current actions taken with remote assessments in the current environment, there are concerns that this will set a precedent for future activities. The LC in general supports on-site assessments and feels that initial assessment should be on-site.

There was a specific concern raised over a regional document that had additional requirements that were seen as technical barriers to trade. One of the LC members took the action to discuss directly with the regional body as it was considered a potential threat to the ILAC MRA.

ISO TC 34/SC9

ILAC has met with the Chair and a couple of committee members of ISO TC 34/SC 9 (Food products – Microbiology) to discuss matters of mutual interest and to exchange information on recent developments and opportunities, including the recent issue of ISO 16140-3:2021 *Microbiology of the food chain - Method validation - Part 3: Protocol for the verification of reference methods and validated alternative methods in a single laboratory.*

A transition period has been developed by TC 34/SC9 for this to be implemented by 1st January 2028 and they are seeking ILAC's support for this to occur. ISO has no mandate to require this, and there is no current regulatory framework for the standard's roll-out or mandate other than the transition arrangement published by ISO TC 34/SC 9. Further discussion is required and a resolution is yet to be determined.

Liaison BIPM

The outcomes of the BIPM CIPM Mutual Recognition Arrangement (CIPM MRA)* are the internationally recognized (peer-reviewed and approved) Calibration and Measurement Capabilities (CMCs) of the participating institutes. Approved CMCs and supporting technical data are publicly available from the CIPM MRA database (the KCDB).

The KCDB database has been updated to version 2.0 and features of the new KCDB include:

- statistical reports - such as number of key comparisons by country, RMO and measurement type
- help on the KCDB - how to use, how to create a CMC, etc
- creates document control (versions) which was not the case before when excel files were used
- new improved intuitive search engine

- addition of an Application Programming Interface (xml coded query feature that can interact with digital calibration certificates)

* The CIPM MRA is the framework through which National Metrology Institutes demonstrate the international equivalence of their measurement standards and the calibration and measurement certificates they issue.

Liaison Eurachem

It was noted that The Eurachem General Assembly (GA) was held virtually in May 2021 and that revision on a few Eurochem documents that are of relevance to ILAC have been completed and development of others, including new ones is progressing. A listing of publications is available on the Eurochem website. https://www.eurachem.org/index.php/publications/

Liaison JCGM (Joint Committee for Guides in Metrology)

The first Committee Draft of the International Vocabulary of Metrology, VIM 4, has been prepared by a working group of the Joint Committee for Guides in Metrology (JCGM WG 2). It was revised to accommodate the new SI units and a new chapter (6) for nominal properties and examinations has been included. However, it is noted that some definitions in VIM 4 CD do not align completely with terminology used in e.g. ISO/IEC 17025 (method and measurement procedure) and ISO 15189 (examination result).

The document has been circulated amongst the eight member organisations (BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP, and OIML) for comment.

Liaison with OIML

An update was provided on the OIML CS (Certification System) and associated issues (former OIML MAA). The OIML-CS is a system for issuing, registering and using OIML Certificates and their associated OIML type evaluation/test reports for types of measuring instruments (including families of measuring instruments, modules, or families of modules), based on the requirements of OIML Recommendations.

The OIML CS will over the next 3 years develop from covering 2 OIML recommendations to 37 recommendations. Discussions are still ongoing whether the scheme will be recognised under 17020 or 17065

WG 5 - Accreditation of Sampling

The revised position statement addressing the two issues around measurement uncertainty (MU) that arose from sampling and decision rules raised at ILAC AIC in Mexico in April 2019 has been finalised. The AIC Chair reminded the AIC that a position paper is neither a guide nor a policy; and that there is no formal approval mechanism for it. The position paper is the result of discussions held to date and the issue remains a topic for a workshop to be held at the next face-to-face meeting.

Inspection Committee (IC)

The group established by the Inspection Committee in 2020 to maintain the Inspection Accreditation "Q&A" section on the ILAC website has been reviewing the information previously published. A number of "examples" removed from ILAC P15 *Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies* and previously published on the website have been revised and will be republished.

The Inspection Committee proposal supporting the establishment of a TFG to consider whether or not the requirements for sampling should be included in the next version of ISO/IEC 17020 (due for review in 2022) and what these should be (whether in a separate section or through out the standard) has not progressed.

A log of discrepancies and anomalies has been initiated to collate matters identified in ISO/IEC 17020. The purpose is to keep committee members informed of these and to compile for submission to CASCO for the next revision of the standard. It is proposed that the log be published on the members' page of ILAC.

The Grain and Feed Trade Association (GAFTA) required all inspection bodies in the profession of inspection of agricultural commodities and/or animal feedstuffs to be accredited to ISO/IEC

17020 and the latest GAFTA Standard for Supervision, Sampling and Weighing by 31 May 2021(transitioning from ISO 9000). ILAC was going to make contact with GAFTA to establish a channel of communication and to clarify their requirements.

ILAC-WADA Liaison Group

The MoU between ILAC and WADA was last signed in 2016 for a 5-year term and is due for review/renewal. A draft MoU will be presented to the ILAC Executive with the aim that it be reconfirmed later in 2021.

A proposal has been put forward that the Terms of Reference (ToR) for the ILAC-WADA Liaison Group be updated to allow ABs who accredit more than one WADA laboratory to be able to have two representatives attend meetings, i.e. A2LA = 2 labs; DAKKS = 2 labs; ENAC = 2 labs; NATA = 4 labs. Draft updated ToR to be circulated for comments.

Athlete Passport Management Units (APMU)

There are currently 16 APMUs and the liaison group has discussed how these can be accredited / recognised. All APMUs are hosted by WADA accredited laboratories. NATA's General Manager Operations and Technical is a member of the working group convened to scope the project.

Potential standards under consideration for accreditation/recognition are:

- ISO/IEC 17029 *General principles and requirements for validation and verification bodies*
- ISO/IEC 17020 *Conformity assessment — Requirements for the operation of various types of bodies performing inspection* **(preferred option)**
- ISO/IEC *17065 Conformity assessment — Requirements for bodies certifying products, processes and services*

APMUs analyse independently the results from the Athlete Biological Passport (ABP) laboratories and recommend actions including specific analyses, expert panel review, target testing, sample storage, and intelligence gathering. ABP laboratories are not accredited by WADA but instead "approved" for biological passport testing; currently there are 28 such laboratories.

ABP laboratories focus on biomarkers. Some substances are not easily detected, others are rapidly metabolised, and new substances are continuously being developed. Every athlete has different physiology and metabolism and personalised thresholds are based on athlete's own values. Modules for some analyses are well established whilst others are under development.

WADA provided an overview of a poorly performed validation study that resulted in a discussion on evaluation of method validation by accreditation bodies. WADA stressed the importance of reviewing validation; however, it also recognised that the accreditation process is a sampling exercise. There is no WADA document prescribing how validation must be performed, however, there is a Technical Note (TN) providing guidance. TNs are not made publically available on the WADA website. These are provided to laboratories and ABs may request a copy from WADA as necessary.

It was suggested that WADA could consider prescribing specific validation requirements, however, it is not keen on doing this as any non conformance with the WADA International Standards (ISL) or Technical Documents (TD) means that results can then be questioned.

TDs and Technical Letters (TL) are annexes to the ISL. Where there is any contradiction between the ISL and these publications, the latter takes precedent.

ILAC Publications

During the period January - June 2021 several publications were finalised and published or are awaiting publication. This includes both revisions of existing documents and new documents.

Revision of a number of other documents has been initiated and is 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 January - June 2021 period were conducted virtually or cancelled as a consequence of the ongoing COVID-19 pandemic. These are summarised on the spreadsheet 'NATA - activities'.

All future APAC meetings and activities scheduled for 2021 will be held virtually.

APAC General Assembly

The APAC MRA scope is to be extended to cover the new activities of Biobanking and Anti-Bribery Management Systems (ISO 37001) and APAC is seeking Evaluators for these new activities. The latter would be a sub-scope under ISO/IEC 17021-1 so would potentially be a JAS-ANZ accreditation activity.

Summaries were presented from several APAC committees and more detail is provided elsewhere in this report. The following topics of note were also covered:

- the first term of many of the APAC Executive Committee roles are up for election next year;
- spending has been less than budgeted as a result of travel restrictions;
- the challenges of performing the peer evaluations of APAC MRA Members as a remote activity were discussed;
- APAC is looking for volunteers to assist with the internal audit scheduled for next year;
- the Capacity Building Committee has been extremely productive over the past 12 months and learning tools maybe found at this link https://accreditation.teachable.com.;
- reports from liaisons to APAC, including IAF, ILAC, AFRAC, EA, IAAC, PASC, APLMF and ARAC were taken as read.

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

APAC's decision to be inclusive as a regional body means that the membership criteria are broad; essentially APAC is open to any organisation in the Asia Pacific region that is an accreditor of conformity assessment bodies. This has had the unintended consequence of enabling membership to organisations of questionable provenance and whose demonstrated behaviours may call into question issues of ethics. The Code of Conduct needs to be sufficiently robust to enable APAC to utilise its provisions to both exclude ABs from membership and to sanction members, where appropriate and necessary. The EC agreed to review the APAC Code of Conduct with a view to articulating the obligations more clearly.

The EC reviewed the fee model used to calculate the annual fee payable by each APAC member and agreed that no change is necessary.

The recent European Court of Justice ruling was discussed at the last EC meeting. It was noted that a number of European ABs have now contacted CABs in their economies that are accredited by ABs from another economy to advise them that they are operating outside the European Regulation 765/2008. There is concern that although the ambit of Reg 765 (and hence the recent ruling), is accreditation and conformity assessment subject to European regulation, National Accreditation Bodies (NABs) are extrapolating the application of Reg 765 to all conformity assessment i.e. so-called 'voluntary' conformity assessment. It is understood that some European economies may in fact have ABs, other than their NAB, that operate in these areas. This should mean that, subject to compliance with any ILAC and IAF requirements, ABs from other economies could also offer accreditation. There are a number of other issues, including the non-acceptance in the EU of conformity assessment reports from CABs not accredited by EA MLA signatory ABs. APAC has established a task force to investigate what, if any response, APAC can make to these issues/concerns.

The MRAMC discussed concerns raised by NATA's Chief Executive that MRA evaluation Team Leaders/Lead Evaluators would not, in many cases, be considered a true 'peer' of an accreditation body. Lead Evaluators should have AB management experience in order to be able to truly evaluate the clauses of ISO/IEC 17011 that relate to the overall functioning and management of an AB; however, there are no additional specific 'qualification' criteria for Lead Evaluators that would enable APAC to appoint only such persons as Lead Evaluators. This results in persons who are very capable, competent Lead Assessors in their own ABs ultimately being appointed as Lead Evaluators without necessarily having had experience in AB management. This calls into question a process that is intended to be a peer evaluation. Further discussion is required and a specific meeting of the MRAMC will be convened to progress the matter.

A complete review of evaluator training is also being undertaken based on feedback on evaluator performance, which has identified instances of poor performance. The transition to remote evaluations has led some evaluators to take a more compliance-based approach, possibly due to the constraints of virtual technologies. A number of training sessions have been identified as a priority including experience sharing in relation to remote evaluations for Lead Evaluators. It is essential that the rigour and focus of the evaluation process are maintained to enable on-going reliance on APAC MRA signatories and their accredited CABs.

It was also agreed that the proposed revised evaluation process should be managed via a specific meeting of the MRAMC as no progress has been made on this project.

The use of remote assessment techniques post the COVID-19 pandemic when ABs are able to revert to on-site assessments was discussed. Concern was raised that some ABs may see this as an opportunity to undertake their assessments remotely indefinitely; however, it was noted that Regulators and other stakeholders are unlikely to accept that scenario. Most members acknowledged that, in their own ABs, remote assessment techniques will be incorporated into their routine processes as another technique that can be utilised in prescribed circumstances. To that end, it was agreed that an information document should be prepared to assist ABs transitioning to post-COVID assessment processes. There was also discussion about the possibility of holding an on-line experience-sharing forum for APAC members.

NATA's Chief Executive Officer offered to host the APAC meetings in 2027 to coincide with NATA's 80th anniversary and this suggestion has been accepted with a suitable location to be determined closer to the time.

APAC Technical Committee 1 (TC)

NATA's Sector Manager Calibration, Paul McMullen participates on this committee as convener of the RMP Working Group (WG) and delivers the RMP WG report to the Technical Committee. The WG recommends APAC's guidance document on the accreditation of reference materials producers (TEC 008). It is under review and a draft copy was distributed to the WG participants.

The status of several publications of relevance to the Technical Committee was covered, including;

- ISO/CASCO revision of ISO/IEC 17043:2010 *Conformity assessment — General requirements for proficiency testing by ISO/CASCO WG 57.* This is detailed later in this document.
- ISO revision of ISO 15189:2012 *Medical laboratories — Requirements for quality and competence by ISO/TC 212 WG1.* This is detailed later in this document.
- ISO/CASCO clarifications in relation to ISO/IEC 17025:2017.
- ILAC/IAF FAQ's on ISO/IEC 17011 - https://ilacfaq.org/a-seriers-faqs/
- development of APAC TEC1-001 *Guidance on Scopes of Accreditation for Biobanks.*
- a guide on the using of current coils for metrological traceability is being drafted by the Calibration Working Group.

Several NATA APAC committee members attended a virtual seminar on Biobanking conducted by TC 1.

APAC Technical Committee 2 (TC)

Paul McMullen, NATA's Sector Manager Calibration participated in this meeting as an observer to keep abreast of activities being undertaken by TC 2.

An update was provided on the revision of several ISO Standards, including ISO/IEC 17065 and SO/IEC 17021. The change for the IAF certification of Medical Devices (MDQMS) to the ISO Standard ISO 13485:2016 from IAF publications and ISO 17065 was covered.

The IAF FAQs on ISO/IEC 17011 and COVID-19 were noted; and the following topics discussed:

- APAC document for Remote Assessments;
- paper on accredited conformity assessment of environmental footprints being prepared by the Sustainability Working Group;
- application of ISO/IEC 17029:2019 *Conformity assessment — General principles and requirements for validation and verification bodies*; and
- ISO 14020 series developed for the labelling of Environmental Footprints (including ISO 14024 *Environmental labels and declarations*

APAC CPC

APAC CPC has formed a number of working groups, including the Food Regulators WG to improve understanding and engagement with various industry groups. NATA's Sector Manager Life Sciences, Neil Shepherd is a member of the Food Regulators WG.

The Food Regulators WG surveyed ABs in the APAC region to better understand the relationships in place and identify where capacity building is needed. Capacity building support will include printed infographic materials and mentoring of ABs to improve engagement skills.

NATA's Sector Manager Life Sciences reported on progress of the WG including the number of survey responses received and presented a draft report on the results. A presentation to food regulators is being prepared for presentation in Q3 2021.

FSANZ is to be contacted by NATA's Sector Manager Life Sciences to discuss the possibility of the APAC forum for food regulators being held in conjunction with the APEC Senior Officials' Meeting in October 2021.

APAC/APMP Joint Proficiency Testing Working Group (PTWG)

The APMP Executive Committee has formally recognised the APAC/APMP PTWG which will exist under the Technical Committee Quality Management.

NATA's Sector Manager Calibration, Paul McMullen represents APAC as a member of this joint APMP/APAC working group that supports the availability of proficiency testing programs offered by the regional National Metrological Institutes. APMP sees these PT activities as an important capacity building exercise that supports the technical infrastructure for the region.

The PTWG was tasked with drafting recommendations on a possible update of the MOU between APAC and APMP. The updated MOU will be considered by the Executive Committees of APMP and APAC.

Possible recommendations may include an explicit expression of the APMP-APAC PTWG or the collaborative work of the 2 Specialist Regional Bodies (SRBs) on the organization of joint PTs. The PTWG will also explore how to work closer with APEC or the APEC Sub Committee on Standards and Conformance (SCSC) to raise recognition of the role of the PTWG in support of global trade.

In view of the possible extension of scope of the MOU covering physical measurements in the near future, the rule of 2 PTs a year was discussed. Some sort of flexibility to the rule was suggested to accommodate the expansion of scope and joint PTs of interest to both SRBs. The PTWG is also to investigate if there is likely to be any limitation due to a lack of funding or

resources. If funding support is identified as a concern, other sources of funding should be explored.

APAC Training Workshops

APAC Webinar Accreditation and Food Safety Schemes

NATA's Sector Manager Life Sciences, Neil Shepherd attended the webinar to improve knowledge on food scheme operations.

An update was provided in relation to progress on the revision of ISO 22003 *Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems* and development of supplementary requirements for bodies providing food system certification to be added to ISO 17065 *Conformity assessment - Requirements for bodies certifying products, processes and services*.

Concern was raised that 3rd party certification is giving unreliable results. Discussion covered:

- approaches to conduct of audits, namely Quality Management System and product/process-based audits;
- lack of harmonisation; it was also noted that multiple audits and overlap of schemes is a cost burden; and
- training of auditors using remote models.

In response to poor audit outcomes and loss of auditors, there has been an upturn in training and monitoring of food safety auditors. The Global Food Safety Initiative (GFSI) has proposed establishing a framework that includes benchmarking, continuous self monitoring, collaborative management and a recognised certification platform.

The proposed framework includes:

- Creation of a profession of FSA and that ISO 17024 be used to validate food safety auditors. Levels standard/expert/lead food safety auditors with CPD.
- Align the program with ISO 17011, ISO 17021 and ISO 22003.
- Collaborative management to try to deal with duplication and inefficiency. The IAF would coordinate collaboration and knowledge sharing.
- Audit findings shared rather than multiple audits of same processes.
- KPIs be developed.

APAC Workshop on ISO 17034 Reference Material Producers (RMPs) and ISO/IEC 17043 Proficiency Testing Providers (PTPs)

NATA's Sector Manager Calibration, Paul McMullen was a key facilitator/ presenter for this 4-day APAC training event held online due to the COVID-19 pandemic. It was a capacity building activity for the Asia Pacific region and was attended by more than 105 APAC Member accreditation managers and assessment personnel in the region.

It is an introductory/intermediate training course on the use of ISO/IEC 17043, *Conformity assessment - General requirements for proficiency testing* and ISO 17034, *General requirements for the competence of reference material producers*, to accredit bodies that undertake proficiency testing programmes or produce reference materials. There were four facilitators/presenters who provided insights on how this type of accreditation is conducted and participants were encouraged to share their experiences and ask questions. A report on the activity will be provided at APAC TC-1 in 2022.

APAC Publications

During the period January - June 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 have been conducted virtually during 2021. Refer spreadsheet 'NATA - activities'.

NATA's General Manager Operations and Technical, John Styzinski participated in the evaluation of the Korean Laboratory Accreditation Scheme (KOLAS) conducted virtually in February 2021.

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.

The evaluation of PJLA, USA was conducted virtually in May 2021 with NATA's Sector Manager Inspection, Julian Wilson as the Lead Evaluator.

NATA's General Manager Compliance and Governance, Tony Vandenberg participated in the evaluation of NSC Thailand conducted virtually in June 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.

NATA's General Manager Operations and Technical also participated on the Evaluation Review Panel (ERP) following the evaluation of BOA, Vietnam.

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

4.1 Participate in Relevant ISO Technical Committees

ISO/TC 212/WG 1

NATA's Sector Manager Legal and Clinical Services, Andrew Griffin represents NATA / Standards Australia and ILAC at the ISO TC 212 meeting where progress on the update of ISO 15189 *Medical laboratories - Requirements for quality and competence* and other WG1 documents are discussed.

ISO 15189 CD 2 was circulated in January 2021 to determine if it should progress to DIS with the overwhelming consensus being that it should. Following a review of the comments received on the CD2, the drafting committee, which includes NATA's Sector Manager Legal and Clinical Services agreed to propose to the ISO 212 secretariat that the document be progressed to DIS. The requirements of ISO 22870 (PoCT) have been included into the revision as an informative annex. Therefore ISO 22870 will be cancelled when the new version of ISO 15189 is published

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

- ISO 20658 *Medical laboratories — Requirements for collection and transport of samples.* NATA's Sector Manager Legal and Clinical Services is the project lead for revision of ISO TS 20658.
- 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*
- AWI 5798 *Quality Practice for detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by nucleic acid amplification methods*

ISO TC 34 SC 9: Microbiology

Standards Australia (Australia) has an obligation under the WTO technical barriers to trade agreement to harmonise testing standards globally with ISO and other relevant international standards. Consequently, participation at the ISO level allows Australia to have input into development of international standards for food microbiology which is a significant concern for Australian consumers.

NATA's Sector Manager Life Sciences, Neil Shepherd attends the ISO TC 34 SC 9 Food Microbiology Plenary and associated meetings, including the CEN Food Microbiology meeting as a member of Standards Australia's mirror committee FT-35 Food Microbiology. He is the incoming Chair of FT-35 and will be Australia's Head of Delegation at future ISO TC 34 SC9 meetings.

This Technical Committee SC9 is a very active committee with multiple working groups and a significant pipeline of new and revised standards.

Progress on the review and development of methods by the working groups was covered at the meeting with key outcomes provided. Work is proceeding to discontinue methods using an animal model to meet an ISO mandate. Future work under consideration was also mentioned along with discussion on standard methods that require periodic review.

A website has been launched for SC9 to provide information on projects in progress, including:

- Spreadsheets to assist with statistical analysis of verification data uploaded; and
- Guidance on the application of the ISO 16140 series of standards on microbiology of the food chain.

4.2 Participate in Relevant ISO/CASCO Working Groups

ISO/CASCO Committee on Conformity Assessment Mirror Committee (QR10)

NATA's Sector Manager Calibration, Paul McMullen participated on the Standards Australia mirror committee for ISO/CASCO in January 2021. The Committee reviewed the current ISO/CASCO work items and formulated Australia's position, as required, for the next ISO/CASCO Plenary and associated meetings conducted later that month.

There was considerable discussion relating to a complaint presented at the ISO/CASCO plenary in relation to an ILAC document, ILAC P15 *Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies* with concern centred on formulation of scopes of accreditation. It was agreed that the matter should be raised with ILAC.

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.

A Committee Draft (CD) was circulated in late 2020 and the outcome was to proceed straight to Draft International Standard (DIS) at the next Working Group meeting. The Working Group reviewed the CD comments received and clustered them (where relevant) under key topics and prepared the DIS for consideration. It is anticipated that the DIS will be sent out for ballot in mid 2021.

The revision of the Standard will align it with the other ISO/CASCO standards (e.g., ISO/IEC 17025 and ISO 17034) and related standards (e.g. ISO 13528 and ISO Guide 35). This will be beneficial for users who also operate testing and calibration laboratories and/or production of reference materials. The new standard is expected to be published by early 2022.

It is noted however that the ISO/CASCO document PROC33 (common elements) has undergone additional changes since the revision of ISO/IEC 17025 which will result in this Standard having a number of differences e.g. 'handling of appeals' will be included in ISO/IEC 17043.

ISO/REMCO Mirror Committee (CH-040)

ISO/REMCO has been disbanded and replaced with ISO TC-334 (Reference Materials). All projects under ISO/REMCO have been moved to the new committee and ISO/CASCO remains a liaison committee to TC-334. The Standards Australia committee CH-040 will be the mirror committee for ISO TC-334. NATA's Sector Manager Calibration, Paul McMullen has been nominated as the new chair of CH-040.

It is unclear at this stage whether ISO 17034 will remain with ISO/CASCO or be moved to ISO TC-334.

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

CODEX CCMAS

NATA's Sector Manager Life Sciences, Neil Shepherd participates in these meetings to provide advice to the Australian Delegation Head regarding matters under discussion, take notes and review the Australian delegation position on matters arising. There are representatives from the Department of Agriculture, Water and the Environment (DAWE) and the National Measurement Institute (NMI) in the Australian CCMAS delegation. The CCMAS meeting also provides an opportunity to keep abreast of trade sensitive issues related to method development and actions undertaken by Standards Development Organisations.

The focus of methods at this meeting included:

- Fats and Oils Workable Package (review of fats and oils methods); review has been completed.

- Fruits and Vegetables Workable Package (review of fruits and vegetables methods); a eWG has been established that will be led by USA.
- Dairy Workable Package (review of dairy methods)
- MU Guidance document (CXG54)
- Sampling Guidance document (CXG50) has progressed and a eWG led by NZ established to oversee work in the coming 12 months.
- CODEX Standard 234 *Additions and Clarification of Typing for methods of analysis*

AOAC Midyear Meeting

NATA's Sector Manager Life Sciences, Neil Shepherd attended the mid year meeting and several topics of discussion relevant to accreditation and the Australian industrial context were discussed:

- The need to collaborate across disciplines to share learnings and information has been recognised for One Health, the concept that recognises that the health of people, animals and the environment are interconnected.
- Method performance criteria for cannabinoids, microbiological and chemical contamination have been developed by the Cannabis Analytical Science Program.
- Technological advances are allowing the compilation and interrogation of very large databases. Such metadata analysis is providing information of global significance in tracking disease and predicting risk.
- In-silico analysis is proving to be a powerful tool in developing reference materials and validating assays for emerging diseases.
- Allergen science continues to evolve and novel allergens are emerging. NATA's Sector Manager Life Sciences is a member of the newly established AOAC Allergens WG.
- Heat generated acrylamide contamination is an emerging issue in Europe, however currently there is a lack of consensus on methods. This issue requires international collaboration.
- There is a major focus on food authenticity/provenance as international trade is being disrupted by counterfeit products which have health and economic consequences.
- There is an increasing impact of marine biotoxins on human health due to the increase in seafood consumption. Consequently, method development and the need for suitable reference materials have been identified.
- The Food Safety Modernisation Act (FSAMA) will come into affect in February 2022 and this will require test results for products exported to the US to be submitted to the US FDA. The FDA is also interested in documented sampling plans; the ILAC AIC Chair has been notified by A2LA.

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

The OECD Working Group on GLP held its annual meeting virtually in April 2021; the meeting is the major forum for discussion and development of policy and procedures relating to OECD GLP compliance monitoring. NATA's GLP Program Advisor, Louise Calder is currently the Chair of the GLP Working Party.

An optional session was held prior to the Working Group meeting to discuss:

- IT Inspections and Risk Assessment
- Technical Issues posted on the OECD Working Group webpage that could not be resolved. The summary and conclusion on these issues were then disseminated to the rest of the participants at the Working Group Meeting.

Activities and outcomes from the meeting included:

- Revision to the schedule for on-site evaluation (OSE) visits due to COVID delays.
- Discussion on the following draft documents still in development:
    - Revision to the current OECD Consensus Document Number 4: Quality Assurance and GLP; and
    - Cloud based Computer systems and GLP.
- A document regarding tools for Quality Improvement in GLP is to be developed.
- A webpage for inspectors to propose and informally discuss issues encountered with inspection of IT systems used for GLP studies is to be included on the OECD Clearspace site.
- Initial discussions on changes to the process used for Annual Overviews.
- Training for OSE inspectors; the next Inspectors Training course has been postponed to late 2022 due to COVID.

A closed session was held to discuss China's progress with becoming a provisional adherent to the OECD Mutual Acceptance of Data (MAD), a multilateral agreement which allows participating countries (including non members) to share the results of various non- clinical tests done on chemicals using OECD methods and principles.

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.

The NATA Stakeholder Team and the CEO met with key staff of the Trade Facilitation Branch to meet their new General Manager Alison Drury and discuss a range of topics including:

- Competition in accreditation (domestic, foreign accreditation bodies and implications);
- Pathology accreditation, the tripartite Deed (Department of Health and Services Australia) negotiations and the move to the ACSQHC;
- Fraud, as a consequence of the ALS Coal issue and other instances that have come to our attention. NATA is giving consideration to holding a Commonwealth and State/Territory agency workshop on this topic to engender cooperation with policy/regulatory/law enforcement agencies; and
- The Commonwealth/NATA MOU biennial performance review.

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

- Provision of comments on the proposed topics to be covered at the February 2021 meeting of the APEC Sub-Committee on Standards and Conformance;
- Discussion of shortcomings in the designation of a CAB from the EU to Australia under the Australia-EU MRA;
- Advice regarding an additional provision in the Australia-UK MRA requested by the UK which would appear to facilitate UKAS accreditation of Australian CABS;
- Advice regarding a US proposal to the WTO TBT Committee for a review of conformity assessment procedures in member countries that are signatories to the TBT Agreement; and
- Preliminary discussion on possible new trade initiatives regarding capacity building in conformity assessment in SE Asia and India

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.

NATA's Sector Managers did not participate in the most recent annual meetings of the IANZ Professional Advisory Committees (PAC) meetings scheduled during this reporting period as they were cancelled due to the COVID-19 pandemic, with the exception of the Inspection PAC.

<u>Inspection PAC</u>

This meeting was very low-key with no pre, or post discussions with any IANZ staff. It was the first face-to-face meeting of the Inspection PAC for 2 years and there were two new PAC members in attendance. The main focus of the meeting centred on the COVID-19 pandemic, use of remote assessments as a tool, assessment findings and regulation. Uncertainty in water regulations resulted in several withdrawals and there was negligible growth in accreditations (only 4 initial assessments).

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

NATA's Sector Manager Life Sciences participated in the APEC Food Safety Cooperation Forum (FSCF) Partnership Training Institute Network (PTIN) Workshop and Plenary held virtually in May 2021 on the Food Safety Risk Communication Framework. The APEC FSCF PTIN provides an opportunity for active collaboration with the Standards Trade Development Facility, Food Industry Asia, Codex Alimentarius Commission and the Australian Food and Grocery Council.

The Workshop and Plenary on the Food Safety Risk Communication Framework provided an insight into activities in the food regulatory space in the APEC region which is aligned with NATA's focus on food related activities, and included discussion on:

- strategies to promote the application of shared responsibility for the management of import and export food safety;
- enforcement of pesticide MRLs;
- work to enhance sustainable aquaculture practices in the region;
- application of WGS in the area of environmental sampling;
- development of SPS document digitalization and the need for future discussion on the application of this among member economies; and
- future work to include antimicrobial resistance.

There was mention of the number of guidelines that have been drafted by the Risk Communication eWG that will be circulated post the meeting.
It was noted that discussion with FSANZ may generate an opportunity under the APAC Food Regulators CPC WG to offer capacity building via a forum and follow up activities including mentoring.

At the review session attended by Malaysia, Indonesia, Hong Kong, Peoples Republic of China (PRC), Canada, United States of America and Australia the day after the plenary session held in May 2021, the PRC delegation attempted to alter the actions agreed to at the plenary session.

As a consequence, it was agreed that there is an urgent need to develop a ToR for the APEC FSCF PTIN and this will occur prior to the start of the third Senior Officials' Meeting (SOM3) in August 2021.

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:

- The new Tripartite Deed between NATA, Services Australia and the Department of Health was signed in March 2021. The new Deed places a lot more reporting responsibilities on NATA and now entails 2 governance meetings and 4 working group meetings per year.
- A new schedule has been added to the Department of Agriculture, Water and the Environment MOU to cover surveillance of environmental samples for a range of pests, pathogens and diseases as part of biosecurity arrangements (eDNA).
- The renewal of the MOU with the Australian Signals Directorate for the evaluation of ICT security products under the Australasian Information Security Evaluation Program ("AISEP") has progressed and should be signed in the near future.

7.2 Representation on Standards Australia Committees

Refer spreadsheet 'NATA- Committee Positions'.

Other activities

OIML Webinar 2021: Digital Transformation in Legal Metrology

NATA's Sector Manager Calibration, Paul McMullen and General Manage Stakeholder Relations, Sue Harry attended the OIML webinar that presented the current activities in transforming conformity assessment results into a uniform digital protocol and upload of results to cloud services (Metrology cloud). Key Speakers spoke to the following topics:

- Digital Transformation of Metrology - The View of the BIPM-OIML Joint Task Group;
- Law on Metrology - Barrier or Driver for Digital Transformation in Metrology;
- European Metrology Cloud: Establishing the European Metrology Network;
- Blockchain based Applications and Metrology.

The work by OIML is parallel to the Digital SI and Digital Certificate work being done by the BIPM, but is targeting the specific type testing activities performed on trade instruments, digital marking of the instrument certification and firmware updates of these instruments.

Presenters did acknowledge other applications of their work such as 'industrial' measurements and the calibration of these instruments.