



National Association of Testing Authorities, Australia

SISO Progress Report Supporting Information

Reporting Period

1 July 2020 to 31 December 2020

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

Meetings scheduled during the July - December 2020 period were conducted virtually or cancelled as a consequence of the ongoing COVID-19 pandemic. These are summarised on the spreadsheet 'NATA - activities'.

Dr Geoff Hogg, who was the Authorised Representative for NATA as a stakeholder member of ILAC and a member of the ILAC Laboratory Committee retired in October 2020. In light of Dr Hogg's retirement and following the publication of the revised ILAC Articles and By-laws, NATA reviewed its membership of ILAC and considered that it was no longer appropriate to hold membership as a stakeholder. Consequently, NATA discontinued its membership of ILAC as a stakeholder and, accordingly its membership of the ILAC Laboratory Committee at the end of 2020.

The face to face ILAC-IAF Mid-Term Meetings scheduled for March/April 2021 have been cancelled due to COVID-19 but individual committee and WG meetings will be scheduled on-line as required.

Accreditation: Supporting the implementation of SDGs with a case study to be included re the pandemic has been chosen as the theme for World Accreditation Day in 2021.

Executive Committee (EC)

As previously reported, the establishment of a single organisation for accreditation (ILAC + IAF) was approved in 2019 during the ILAC and IAF GAs and a Joint Steering Committee was established to progress this project. The JEC has received a proposal from the Steering Committee for the new body. The ILAC strategic plan (ILAC R3:12/2014 ILAC Strategic Plan 2015-2020) was originally presented for the period 2015 – 2020 inclusive. In light of the decision to establish of a single organisation for accreditation in the next 2 -3 years it was agreed in December 2020 that the time frame covered by this Strategic Plan be extended to include the period up until the development of the new organisation.

The recognition of the APAC MRA under the ILAC MRA has been extended in 2020 to include the accreditation of RMP using ISO 17034 following the extra-ordinary evaluation of APAC carried out in 2019/2020. With ILAC's recent recognition of APAC for reference materials producers (RMP), all signatories to the APAC MRA for RMP are now recognised by ILAC. This means that NATA's accredited reference materials producers are now recognised globally (not just in the Asia-pacific region).

The EC agreed to develop a brochure to explain how the ILAC MRA underpins the range of testing relevant to the COVID-19 pandemic. This will include pathology but also PPE, hand sanitiser, testing of surfaces, sewage, animals etc.

It was noted that the current ILAC brochure, which is aimed at Borderforce agencies (in particular those considering establishing traveller screening protocols), only specifies testing by laboratories accredited to ISO 15819 when ISO/IEC17025 could also be an acceptable standard. There was no agreement on modifying the current brochure to include a suitable reference to ISO/IEC17025, and it will not be withdrawn until the replacement is available.

Arrangement Management Committee (AMC)

The COVID-19 pandemic has caused issues due to requirements in documents for on-site witnessing (ILAC/IAF A1 and A2). ILAC/IAF were requested to define parameters for evaluations of regions based on risk based approach and a proposal was put to the JEC for JWG A- series to develop a framework by end of 2020 to be implemented in January 2021. Refer JWG A- series below.

Working Group 9 - Management of extraordinary events has a proposal to conduct a survey regarding pandemic impacts and activities conducted by ILAC signatories.

Joint Working Group A-Series Committee (JWGC)

A series of Frequently Asked Questions (FAQs) relating to the interpretation of ISO/IEC17011:2017 was published in August 2020 to ensure that IAF and ILAC harmonise responses and so that responses don't unintentionally add requirements beyond the intent of the standard.

The JWG A-series was tasked with developing a document, applicable for the duration of COVID-19 pandemic; that would enable evaluations of ILAC MRA (and IAF MLA) signatories to proceed with sufficient rigour in spite of the inability to perform on-site activities as required by IAF and ILAC procedures.

MRA evaluations are comprised of two elements. 'In-office' activities involve the evaluation team conducting a review of the AB's documented procedures, reviewing records including management system records (e.g. internal audits, management review, corrective actions, complaints etc.), AB personnel records (e.g. assessor training, competency etc.), and CAB files, and conducting interviews with key AB personnel. Witnessing is the evaluation team observing the AB actually conducting assessments.

The 'in-office' activities can be effectively conducted using technology such as Zoom so can be relatively easily transitioned from an on-site evaluation to a remote evaluation but the witnessing component of an evaluation cannot.

The JWG A-series has drafted a document that will:

- allow for the use of 'remote' evaluations to replace the 'in-office' activities; and
- allow for some exemptions to on-site witnessing but clarify when the requirements for on-site witnessing cannot be relaxed.

It is anticipated the document will be published by the end of 2020.

Accreditation Committee (AIC)

MU Sampling Position paper

Responses to a survey on measurement uncertainty requirements of sampling, and progress to date on the position paper on the topic, was provided by NATA's Technical Manager, Danielle Dicker. There is lack of consensus amongst ABs regarding the definition 'responsible for sampling' as covered by 17025:2017 and applicability of sampling measurement uncertainty.

A task force was reconvened to determine the way forward addressing the issues identified. A revised version of the position paper has been drafted and a workshop is proposed to be held at the next face-to-face meeting in an attempt to address the remaining issues identified.

Inspection Committee (IC)

A group has been established by the Inspection Committee to manage the "Q&A" section on the ILAC website relating to Inspection accreditation.

The Inspection Committee supported a proposal to establish a TFG, in view that 17020 is due for revision in 2022, to consider whether or not the next version of the standard should include requirements for sampling and what these should be (whether in a separate section or through out the standard). There was also agreement to prepare a log / listing of issues to address in anticipation of the revision of 17020.

ILAC-WADA Liaison Group

The membership and Terms of Reference will be updated once the 3rd ILAC-WADA Communique is finalised. A new International Standard for Laboratories (ISL) v.11.0 has been published and all technical documents and technical letters are being updated in view of the new ISL. There are about 30 assessors to be trained and face-to-face is preferred method. It will be subject to the lifting of restrictions due to the pandemic.

The impact of the COVID-19 pandemic on laboratory assessments has been discussed; Accredia classified all laboratories based on a risk profile when conducting remotes (risk = assessment history, organisation structure, complexity of testing, etc.). Lockdowns in many countries haven't been as severe as in Australia, thus in many economies on-site (to a certain extent) have continued to be possible. NATA's remote assessment process seems to be well advanced compared to the processes adopted by other ABs.

The possibility for accreditation/certification of WADA Laboratories' APMUs (Athlete Passport Management Units) was discussed and feedback from the group was that ISO 9001 may not be the right framework to provide reassurance for APMUs. ISO/IEC 17029 *Conformity assessment – General principles and requirements for validation and verification bodies* may be more appropriate. It was suggested that the processes and competencies for the APMU first be scoped by WADA and a technical document is currently being prepared.

UKAS has prepared a draft template (as part of its "Decision Maker Toolboxes" series) to serve as guidance for accreditation decision makers for the outcome of WADA assessments. The draft template covers all the main elements of the accreditation requirements (ISO std plus ISL).

NATA do not necessarily see that such a document would serve its decision process, but instead could serve benefit as an "assessment checklist" as do some other ABs. It was agreed to establish a WG to improve and finalise the document and NATA will be represented on this WG by the General Manager Operations and Technical, John Styzinski.

International Accreditation Forum (IAF)

Reports were received from various working groups and issues covered included verification and validation, fraud and counterfeit certificates. Counterfeiting is seen as different issue to fraud.

CertSearch is seeking to provide a centralized verification database allowing rapid global authentication of CA certs / claims with the aim of ultimately including testing and inspection certificates.

ILAC Publications

During the period July - December 2020 several publications were finalised and published or are awaiting publication. This includes both revisions of existing documents and new documents.

An updated IAF/ILAC Handbook published in August 2020 provides information on the global accreditation system; it is a handy educational tool as it provides good general information about ILAC's and IAF's structure and their roles.

ILAC published a brochure in relation to COVID-19 in August 2020 titled 'Specifying accreditation for COVID-19 testing'. ILAC and IAF also produced a video highlighting the role of accreditation, as one of the pillars of the quality infrastructure, in supporting sustainable development goals (SDGs) and in particular those dealing with the COVID-19 pandemic via the use of accredited conformity assessment services.

Revision of a number of other documents has been initiated and is in progress.

Refer spreadsheet 'NATA- Publications'.

2. Maintain membership and participate in meetings of the Asia Pacific

Accreditation Cooperation (APAC)

2.3 Maintain High Level Participation in Relevant APAC Committees

Meetings scheduled during the July - December 2020 period were conducted virtually or cancelled as a consequence of the ongoing COVID-19 pandemic. These are summarised on the spreadsheet 'NATA - activities'

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

Executive Committee and MRA Management Committee

APAC is considering a revised approach to MRA evaluations which establishes an 'evaluation program' for ABs covering the four year cycle. The aim is to spread the specific evaluation activities across the four years and to make better use of technology to conduct 'remote' evaluations.

The MRA MC considered the revised process and agreed that some flexibility was needed in the evaluation cycle in particular to accommodate smaller ABs for whom a rolling four year cycle may not work.

It was agreed that ABs would be able to opt for the 4 year 'rolling' evaluation cycle or have a full re-evaluation every four years with a 'surveillance' activity at the mid-point of the cycle.

The relevant procedures will now be revised to allow for these options and commenting rounds commenced in accordance with APAC procedures.

Ballots are currently underway for the expansion of the scope of the APAC MRA to include:

- ISO 20387:2018 *Biotechnology - Biobanking - General requirements for biobanking*
- ISO 22301:2012 *Societal security - Business continuity management systems - Requirements*

The APAC procedure for remote evaluations was finalised and training held for Lead Evaluators (LEs). Remote evaluations are already underway, effectively piloting the new documentation. The major concern about remote evaluations is that witnessing, which is a mandatory component of evaluations, is not possible. APAC noted that IAF and ILAC are jointly developing a position on witnessing activities as part of evaluation during the pandemic.

APMP/APAC Joint Proficiency Testing Working Group

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.

A number of PT schemes are under development, including:

- Covid-19 scheme. APMP CCQM are running a parallel study amongst NMIs for SARS-CoV-2;
- Genetically modified maize;
- Zearalenone in maize;
- Benzoic acid in fish sauce; and
- Trace elements (Sb, As, Cd, Pb) in mineral water.

There is good support from the NMIs for the testing community; however it is that the schemes undertaken are very much chemical metrology based, and that there is a need for more schemes to support physical, biological, medical and electrical testing.

APAC Publications

During the period July - December 2020 several publications were finalised and published or are awaiting publication. This includes both revisions of existing documents and new documents.

Refer spreadsheet 'NATA- Publications'

APAC Training Workshops

APAC workshop on remote assessment activities

The purpose of the workshop was to share experiences for conducting remote assessments by signatories to the APAC MRA. NATA's General Manager Compliance and Governance, Tony Vandenberg and Sector Manager Life Sciences, Neil Shepherd were primarily involved in presenting the webinar.

Much of the information presented was based on NATA's experience and processes. Participants also shared their experiences conducting remote assessments; it was evident that there were various levels of experience with remote assessment activities amongst the participants.

The webinar did not provide any new ideas /views for NATA, but instead confirmed that our processes are consistent with the practices of the more mature and experienced ABs.

The draft APAC guidance document for conducting remote assessments was also presented.

Refer spreadsheet 'NATA - activities'.

The planned APAC capacity building workshop for Reference Material Producers (RMPs) and ISO/IEC 17043 Proficiency Testing Providers (PTPs) has been postponed until 2021.

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

Due to the ongoing COVID-19 pandemic some evaluations postponed earlier in 2020 were conducted as virtual assessments, whilst others have been rescheduled to 2021. Refer spreadsheet 'NATA - activities'.

NATA's CEO, Jennifer Evans was involved as the Lead Evaluator in the evaluation of the Institute for Quality Management in Healthcare (IQMH) in Canada between 30 September and 4 October 2019 (as reported previously). Post-evaluation work continued during the latter half of 2020.

The evaluations of the Mongolian Agency for Standardization and Metrology, Accreditation Department (MNAS), with Jennifer Evans as Lead Evaluator, and the Korean Laboratory Accreditation Scheme (KOLAS), with NATA's General Manager Operations and Technical, John Styzinski as an evaluator, planned for the first half of 2020 were postponed due to the COVID-19 pandemic. Preparation for these evaluations which will be conducted virtually during 2021 has commenced.

The evaluation of KAN Indonesia was conducted virtually during November 2020 and NATA's Sector Manager Inspection, Julian Wilson was an Evaluator. The evaluation of AOSC, Vietnam was also conducted virtually during December 2020 and NATA's Sector Manager Calibration, Paul McMullen was an Evaluator.

NATA's General Manager Operations and Technical, John Styzinski participated on the Evaluation Review Panel (ERP) following the evaluation of AERSSC, Nepal.

Preparation has commenced for the evaluation of PJLA, USA which is scheduled to be conducted virtually in June 2021 with Julian Wilson as Lead Evaluator.

NATA's Evaluators attended an APAC training workshop conducted virtually in December on Evaluator Training - Remote Assessments.

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

Revision of ISO 15189 *Medical laboratories - Requirements for quality and competence*

The CD1 was very prescriptive and following extensive comments received has been paired back considerably with CD2 to be less prescriptive and more risk based. The drafting committee, which includes NATA's Sector Manager Legal and Clinical Services, Andrew Griffin, have worked to have CD 2 published by the end of 2020/ early 2021 in time for ballot and discussion at the TC 212 WG1 meeting planned for May 2021.

There are several other standards that are under review or have been proposed/ under development as supplementary documents for the revised ISO 15189.

ISO 20658 *Medical laboratories - Requirements for collection, transport, receipt and handling of samples*, which is undergoing review, will include much of the detail for Pre-analytical activities currently included in ISO 15189 and become a supplementary document to be read in conjunction with ISO 15189. ISO 20658 will address requirements for all pre-examination actions prior to samples arriving at the laboratory.

Andrew Griffin is the Project Leader for the review of this standard. The content will align with the revised ISO 15189 and be cross referenced to avoid duplication.

Development has commenced on a new guidance document ISO TR 23824 *Guidance on the application of ISO 15189 in anatomic pathology* and the content will cross reference the revised ISO 15189. Work will continue on this document once ISO 15189 progresses to the DIS stage.

ISO/TC212 and ISO TC276 have established a joint WG for development of a technical standard for the detection of SARS-CoV-2 by nucleic acid amplification methods.

4.2 Participate in Relevant ISO/CASCO Working Groups

ISO/CASCO Working Group 57 ISO/IEC 17043 revision

ISO/IEC 17043:2010 *Conformity assessment — General requirements for proficiency testing* is under revision to insert new CASCO common elements, the removal of Annexes B and C covering statistics in PTP and the use of PT respectively, and to include clarifications in technical requirements for PT in inspection and sampling.

NATA's Sector Manager Calibration, Paul McMullen participates on ISO/CASCO Working Group 57 that is responsible for the revision. It is anticipated to have a Committee Draft ready by December 2020 with the preparation of a DIS at the next WG meeting currently planned in March 2021. It is predicted that the new standard will be published by early 2022

The revision of the Standard will align it with the other 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.

It is noted however that the 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.

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

CODEX CCMAS Working Group

NATA's Sector Manager Life Science, Neil Shepherd participated in this meeting as it provided an opportunity to keep up with trade sensitive issues related to method development and actions undertaken by Standards Development Organisations. Current areas of focus include methods associated with cereals and grains, fats and oils, and dairy. Food sustainability and cooperation as good global citizens was also a common theme among delegates.

NATA's attendance at these meetings assists with maintaining a good working relationship with the Department of Agriculture, Water and the Environment (DAWE) and the National Measurement Institute (NMI) who make up the Australian CCMAS delegation.

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

The only activity for this reporting period has been associated with the role of Chair of the OECD Working Group which is held by NATA's GLP Program Advisor, Louise Calder.

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 had an informal meeting with the DISER Trade Facilitation team in August 2020 to discuss international engagement issues for the next 6-12 months. Updates on current activities and discuss future priorities were discussed, topics included:

- Ongoing FTA TBT Chapter negotiations (particularly with the EU, UK);
- EU MRA – key next steps for the ongoing EU MRA review; process for designating Australian CABs via the NANDO system;
- A read-out from the recent CPTPP TBT Committee meeting;
- APEC SCSC – projects of interest & confirmed timing for a remote second meeting (14-15 September);
- WTO TBT Committee – preparations for October 2020 and beyond; including any updates from NATA related to coal testing accreditation issues (ALS Newcastle);
- Pacific QI Initiative – Phase 2; and
- Any updates on NATA's ELMS for PPE labs.

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

- Provided inputs to the standards and conformance elements of the Australia-EU trade agreement negotiations;
- Comments on elements of negotiations of renewal of the Australia-EU Mutual Recognition Agreement;
- Provided clarification on the AU-UK MRA implementation checklist, to ensure everything was in place for the MRA to enter into force on 1 January 2021 should it be required when the Brexit transition period ceased;
- Commented on the APEC SCSC project proposal on "Understanding Conformity Requirements for Software Controlled Weight and Measuring Instruments for Sustainable Trade" (Malaysia); and
- Provided inputs into the CPTPP TBT Committee Information Exchange Template.

6.3 Cooperation between NATA and IANZ

NATA's Sector Managers did not participate in the IANZ Professional Advisory Committees (PAC) meetings that are held annually during this reporting period as they were cancelled due to the COVID-19 pandemic with the exception of the Inspection PAC that was conducted virtually.

NATA's Technical Manager liaised with IANZ and A2LA regarding provision of guidance on modifications to standard methods.

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

NATA's Sector Manager Life Sciences participated in the APEC FSCF PTIN Virtual Workshop on Pesticide Maximum Residue Limit (MRL) Harmonization.

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

7.1 Management of Deeds of Agreement

Information on MoUs and Deeds of Agreements, including those current, under negotiation or renegotiation is provided in the spreadsheet 'NATA- MoUs'. The current Deed with Medicare Australia (Services Australia) is of particular interest.

The Deed signed in 2016 was between NATA and Services Australia and remained in force until 31 December 2018. Interim extensions have been granted since that time as the Deed currently being negotiated is a Tripartite Deed between NATA, Services Australia and the Department of Health. This has resulted in extensive discussions between the various parties and significant delays in the negotiations occurred during 2020 as a consequence of the COVID-19 pandemic. The Deed negotiations are almost finalised and it is expected that the new Tripartite Deed will be signed in the near future.

7.2 Representation on Standards Australia Committees

Refer spreadsheet 'NATA- Committee Positions'.

Other activities

PTB DCC 2020 International Conference

PTB has developed an application for digital calibration certificates that supports the calibration sector by having a protocol for machine-readable digital certificates that allows for the mutual recognition of their validity. The digital calibration certificate contains the calibration information in a structure that is comprehensible for computers and can be secured with a digital seal. CIPM are also developing a protocol for the digital transfer of measurements called the Digital-SI.

NATA's Sector Manager Calibration, Paul McMullen attended this conference at the request of ARPANSA as this digital certificate protocol maybe adopted by all NMI's and their delegates around the world. NATA accreditation will need to give consideration to this digital information format in support of national infrastructure.

NATA will provide assistance to ARPANSA as required and ensure the accreditation requirements are maintained. NATA will investigate the need to implement systems in order to be compatible with digital certificates and/or training of assessors. This capability will be needed to support National Technical Infrastructure.

International Association for Food Protection (IAFP) 2020 Annual meeting

NATA's Sector Manager Life Sciences, Neil Shepherd attended this meeting to keep up to date with technical developments in food testing, and engaged with key stakeholders including the USDA and FDA.

Improvements in the technologies to detect, identify, and characterize foodborne pathogens have had wide ranging impacts on outbreak investigations, response, and retrospective analysis. These powerful tools are leading to the identification and investigation of more complicated outbreaks, such as those lasting multiple years and with multiple pathogens.

Availability of appropriate analytical methods is important for the control and monitoring of food safety hazards including chemical contaminants, microbiological contamination, and allergens. While each of these hazards has unique risk assessment and risk management considerations, the "absence" of these hazards is defined by the limitations of analytical methods. The definition of a safe amount of these hazards, that present no appreciable risk of adverse effects, informs the limits of quantitation for analytical methods in the development of ideal risk management strategies.