



National Association of Testing Authorities, Australia

SISO Progress Report Supporting Information

Reporting Period

1 January 2024 to 30 April 2024

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

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 mid-term ILAC-IAF meetings were held virtually in April 2024.

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

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

PXX ILAC Policy for Cooperation between ILAC Arrangement Signatories

A task force group (TFG) was established following the ILAC meeting in November 2023 to review the comments received on the draft ILAC Policy for Cooperation between ILAC Arrangement Signatories. The TFG has two representatives from each region (AFRAC, ARAC, APAC, EA, IAAC, SADCA) and NATA's John Styzinski is one of the APAC representatives. 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. The TFG will develop proposed responses and next steps for submission to the ILAC EC for consideration.

World Trade Organization (WTO)

A presentation was given by the Head, Technical Barriers to Trade (TBT) Section, Trade and Environment Division, WTO. The WTO TBT Agreement recognises that WTO Members may require a positive assurance of conformity with technical regulations or standards to fulfil their legitimate objectives

- protection of human health or safety, or the environment; and national security requirements
- the Agreement has very little detail but does specify that any regulations should not be burdensome or a bloke to free trade while considering risk (nature and degree)

The WTO TBT Committee agreed to develop non-prescriptive practical guidelines to support regulators in the choice and design of appropriate and proportionate conformity assessment procedures and the G/TBT/54 guidelines on conformity assessment procedures were adopted at the meeting March 2024.

Accreditation Committee (AIC)

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

International Organisation of Vine and Wine (IOV)

Cooperation between ILAC and the OIV is still in an early phase. ILAC has been approached by OIV to participate in their symposium about wine analysis on 16-17 May 2024.

Liaison with the International Organization for Legal Metrology (OIML)

At the OIML meeting in March 2024 a document was introduced - OIML-CS_SC1_P1_N411 relating to IAF 'endorsement' of the OIML-Certification System (CS). There was considerable discussion relating to the implications of comments received from the IAF MLA committee in relation to the use of ISO/IEC 17020. The comments did not support 'endorsement' of the OIML-CS due to the use of peer assessment and use of ISO/IEC 17020 as an alternative to ISO/IEC 17065 by Issuing Authorities (IAs). It was proposed that ISO/IEC 17020 be removed from the

OIML-CS as it had been introduced to overcome problems that some IAs were having with ISO/IEC 17065, but it was confirmed that only one IA is using ISO/IEC 17020. There was broad support that it would be possible to remove ISO/IEC 17020 but not the option of peer assessment.

Forensics Working Group (WG 10)

Progress on ISO 21043 *Forensic Sciences* was discussed. Parts 3,4,5 are at the Draft International Standard (DIS) stage and went out for 12 week ballot in March 2024.:

- Part 3 - Analysis
- Part 4 - Interpretation
- Part 5 - Reporting

There is an upcoming meeting of ISO TC 272 Forensic Sciences in Brisbane, Australia on 14-18 Oct 2024.

Liaison with ISO/CASCO

There has been a change of leadership at ISO/CASCO for the 2024-2025 term with Caroline Outa, KEBS (Kenya) appointed as the Chair and Elias Rafoul, SCC (Canada) as the Vice Chair. A general update on activities within ISO/CASCO was provided including recently published conformity assessment standards.

Liaison Eurachem

A Task Force has been established to continue review and investigating practices for performance evaluation in qualitative and interpretative PT schemes. Two new leaflets are expected to be published shortly (Understanding PT Statistics; and Understanding PT Performance Assessment). A further leaflet on 'Basic instructions for participants in a Proficiency Testing scheme' is currently being developed.

An additional leaflet on 'Interlaboratory comparisons other than proficiency testing' is being developed on behalf of Eurachem by the EA-Eurolab-Eurachem (EEE) joint stakeholder working group on PT in accreditation

Work on producing draft guidance on the evaluation of uncertainty from in-house validation data to supplement QUAM:2012 is ongoing.

The revision of the 2nd edition of the 'Fitness for Purpose' Guide on method validation is still in progress.

Metrology issues

An update was provided on the draft Annex (guidance) for ILAC P10 *Policy on Metrological Traceability of Measurement Results* on CRMs not covered by P10 clauses:

- accredited CAB have to provide evidence of competence for non-accredited RMP to the accreditation body;
- list of competence requirements revised and shortened to be practicable for application;
- reference to ISO 17034 for competence requirements were kept; and
- there was discussion that the draft is too flexible.

The draft will be further updated and presented at the next meeting in Berlin.

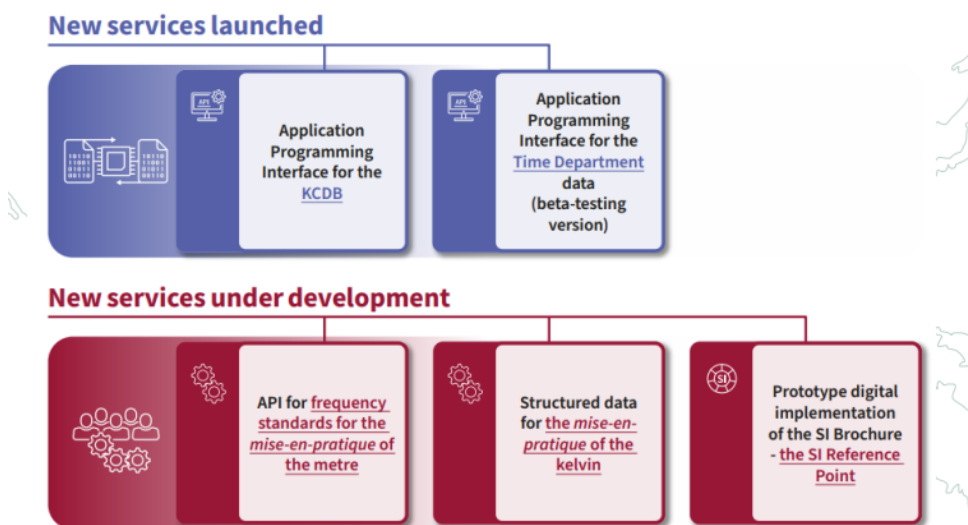
The Metrology WG is going to review and consider comments raised in relation to ILAC P14 section 5.3 by A2LA in relation to numerical value of expanded uncertainty.

Liaison with the Joint Committee for Guides in Metrology (JCGM) - (VIM and GUM WG).

The JCGM meeting was held December 2023 and an update on the VIM 4th edition CD2 was provided. The revision has been delayed and publication is not expected until 2025 - the project needs to be restarted as the 3-year revision deadline has passed.

Liaison BIPM

An update on Digital SI was provided:



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 15194 *In vitro diagnostic medical devices — Requirements for certified reference materials and the content of supporting documentation* are at Draft International Standard (closed for voting) and publication is expected in October 2024.

Total entries in the JCTLM database now includes 290 reference materials (mainly NMIs), 217 reference methods (accredited calibration labs), and 247 reference measurement services (accredited calibration labs). A gap analysis is being conducted to establish what is still not in the JCTLM database:

It is recognised that matrix CRMs are lacking for a number of medical testing analyses including total haemoglobin, ALT, Urea, Bilirubin (even purified RM), 25(OH)D3 commutable for immunoassays (even purified RM), Ion chromatography RMP for Chloride, AST, LDH and total protein.

Horse Racing Working Group (WG)

A Memorandum of Understanding (MoU) has been drafted and reviewed by the International Federation of Horseracing Authorities (IFHA) Executive Director and the ILAC Secretariat. The draft MoU has been circulated to the ILAC Executive Committee for comment.

Once the MoU is approved and signed by both parties, the revision of ILAC G7 *Accreditation Requirements and Operating Criteria for Horseracing Laboratories* will be undertaken by the Horse Racing WG. The WG needs to be re-constituted and it has been proposed that the accreditation specialist members of the WG should come from ILAC signatories with at least one accredited horseracing laboratory, and the horseracing chemist members should be appointed by the IFHA.

Inspection Committee (IC)

Minutes from the previous meeting were approved. These included feedback on the workshop which focused on revision of ISO/IEC 17020, and included discussions on personnel competency, skill demonstration, and the potential use of AI. It was emphasised that AI-related discussions should happen in a different forum; but highlighted that inspection bodies should still disclose any AI tools they use.

Members provided feedback on APAC's presentation on sampling and selection review.

Stakeholder engagement

Stakeholder updates were presented, including an overview from GAFTA which included a draft Memorandum of Understanding (MoU) between GAFTA and ILAC. The Inspection Committee has been asked to provide comments on the draft MoU to ILAC for consideration.

Updates from OIML were shared (refer AIC) and a report was presented on the TIC Council Industrial Life Cycle Services (ILCS).

An update on the work of the ISO CASCO Working Group 31 was provided in relation to the progress of the revision of ISO/IEC 17020. More detail is provided later in this document.

Update of the Regions:

IAAC - Working group updates were presented related to clarifying inspectors' technical competencies for specific activities and the implementation of ISO/IEC 17020 requirements concerning metrological aspects. It was agreed that the issues related to revising the ISO/IEC 17020 standard required further exploration. The region expressed interest in collaborating with GAFTA after identifying the instruments and equipment relevant to inspection activities.

APAC - An update was provided indicating that the group is currently concentrating on assisting WG31 by addressing questions related to the revision of ISO/IEC 17020. APAC conducted a survey of its members on key points to feed into the revision of ISO/IEC 17020 and the outcomes were discussed at the meeting. It has been recommended that there be a section on 'sampling' in the new standard similar to that in 17025.

EA - Update covered the discussions from meeting in March 2024, which focused on a range of topics. These included the application of ISO/IEC 17020 in crime scene investigation, the impact of ILAC-P9 *Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing* on inspection, the results from a workshop on flexible scopes, and new developments such as environmental technology verification and vehicle type approval.

AFRAC - Presentation covered topics encompassed memberships - including number of accredited CABs and AFRAC Inspection sub-committee meetings and MRA documents. The meeting focused on development of a guidance document for non-destructive testing, revision of ISO/IEC 17020 and the establishment of a criteria for flexible scopes.

ARAC - Shared information about their accredited inspection activities under the ARAC MLA, most of which involved engineering inspections. They also detailed training sessions focused on implementing ISO/IEC 17020 and ILAC Policy P15 *Application of ISOP/IEC 17020 for the Accreditation of Inspection Bodies*. Additionally, they raised some issues for consideration by the ILAC IC FAQ process.

IAF Meetings

NATA's Sector Manager Inspection attended the IAF Technical Committee (IAF TC) meeting and a couple of 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 Validation and Verification Working Group

The addition of climate change-related amendments to the ISO Management System Standards was noted. ISO and CASCO plan to include climate change-related changes, which are expansions of existing requirements, not new ones.

Results from the 2023 survey of IAF accreditation bodies on ISO/IEC 17029 *Conformity assessment — General principles and requirements for validation and verification bodies* and ISO

14065 *General principles and requirements for bodies validating and verifying environmental information* programs. The group discussed using the survey reports as a communications/ info paper from IAF in partnership with IAF communications.

ILAC Publications

During the period January-April 2024 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

The only APAC meetings scheduled during the January - April 2024 period are summarised on the spreadsheet 'NATA - activities'.

APAC Executive Committee

APAC will be nominating the following representatives to the APEC SCSC sub-fora:

- o Food Safety Cooperation Forum (FSCF)
Neil Shepherd (NATA), Kim Leighton (JASANZ)
- o Health Regulatory Harmonisation Steering Committee
Matt Pitt (JASANZ), representative from Standards Malaysia

APAC MRA Management Committee (MRAMC)

The APAC MRA has been extended to include ISO/IEC 42006 *Information technology - Artificial intelligence - Requirements for bodies providing audit and certification of artificial intelligence management systems* and ISO/IEC 42001:2023 *Information technology — Artificial intelligence — Management system as a new sub-scope under the main scope of Certification - Management Systems*.

Further work will now be undertaken to identify and train suitable evaluators prior to acceptance of applications from accreditation bodies (ABs).

With the number of sub-scopes (level 4 standards) covered by the MRA increasing, making evaluations increasingly difficult to manage / conduct (i.e. size of teams, duration etc), APAC has established a working group to:

- o further develop the sub-scope sampling arrangements;
- o develop a risk-based approach to sub-scope sampling taking into account other regional procedures and have this circulated for discussion amongst Lead Evaluators;
- o consider options for long-term arrangements for evaluation planning, including the possibility of a centralised administrative activity; and
- o propose additions to the APAC MRA extension procedure to provide greater clarity when extensions should be approved and applications accepted.

APAC is experiencing difficulties evaluating accreditation bodies in Iran and Russia. Many evaluators are unable to travel to these economies for a variety of reasons. Assistance is being sought from other regional cooperations, in particular, the Arab Regional Accreditation Cooperation (ARAC).

APAC Publications

During the period January - April 2024 several publications were finalised and published. Refer spreadsheet 'NATA- Publications'.

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

No NATA staff have participated on MRA evaluations during this period. A couple have been involved in preparations for evaluations to be conducted in coming months.

Refer spreadsheet 'NATA - activities'.

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

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

ISO/IEC 17020 is a standard used by NATA and other accreditation bodies to accredit inspection bodies. The working group experts play an important role in the review process by addressing the reasons for the review, considering ISO/CASCO's direction, and collaborating with the WG to achieve consensus. The expertise ensures that the standard is current and reflects best practices in inspection activities.

Following the September 2023 WG meeting, the ISO/IEC 17020 working draft (WD) was circulated amongst committee members for consultation. The substantial feedback received was incorporated into the meeting documents.

At the meeting, Committee members were divided into three breakout groups to concurrently address proposed changes based on received comments. One group focused on clause 4 and annex A (impartiality and independence), another on clauses 5 and 7 (structure and process), and the third on clause 6 (resources).

The breakout groups concentrated on their designated sections, discussing the received comments in preparation for subsequently presenting their findings to the entire WG.

The results from the breakout groups were presented and discussed. It was decided to transition the meeting into plenary mode, facilitating a comprehensive group discussion on the proposed changes to the document.

The participants mainly deliberated on requirements pertaining to impartiality and independence, leading to modifications in clause 4. Extensive discussions on independence, prompted by numerous comments, explored potential resolutions, including narrowing independence to two types (Type A and all others) or introducing a new type alongside existing types A, B, and C. Despite prolonged deliberations, consensus remained elusive. Another proposal to eliminate types and Annex A generated diverse opinions. After several hours, the decision was made to postpone further discussion on the topic.

Discussed technical management responsibility and appointment, considering the absence of similar requirements in other standards. After a detailed explanation from the technical manager, the decision was made to retain and enhance the requirements.

The requirement for operational control of inspection activities conducted by branch offices, agents, etc was also discussed. Divergent opinions emerged, with some advocating for the clause to enhance control, while others expressed concerns it would exacerbate issues. Failing to reach a consensus, the clause was ultimately removed.

The WG made progress on the document, but certain sections and a notable portion of comments were left unaddressed. Emphasis was on clauses 4, 5, and 6, leaving the introduction, clauses 1, 3, and 7, and only partially covering clause 8. The consensus was that additional work is required before progressing to the Committee Draft (CD) stage.

The decision was made to reestablish task groups that operated between the 1st and 2nd meetings. These groups will focus on various sections, propose changes, and an additional WG meeting was scheduled for a comprehensive review in plenary mode.

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

AOAC Mid-Year Meeting

NATA's Sector Manager Life Sciences attended the AOAC mid-year meeting held in the USA in March 2024.

Analytical Science Forum

- FSIS program to reduce incidence of Salmonella food poisoning outbreaks. Proposal to make Salmonella an adulterant in raw products if exceeding 1g/CFU.
- Change to cloth sampling for carcass surfaces in 2023. This may impact the export meat program where sponges are used currently.
- New joint work program on cell cultured meats between FDA and USDA. Currently only 3 restaurants licensed to sell these products but gearing up for an uptake as consumer attitudes adjust.
- Developing methods for detection of PFAS in foods. Surveillance program established.
- New AOAC programs for PFAS migration to food from packaging, Ethylene Oxide in foods and packaging, Novel foods (cell based, plant based, insect based)
- New PT programs for cannabis in foods.
- Cyanide in cassava. NMI have been working on this as part of the pacific islands development program. Inter lab program to be run to look at variation in methods.
- WG to look at developing in vitro methods to phase out animal testing.
- Impact of AI and data analysis on testing needs to be investigated.

Cannabis Analytical Science Program (CASP)

- AOAC PT program now accredited by A2LA for Cannabis PT program. Can ship interstate and internationally.
- Current issues with cannabis testing non cannabis additives in cannabis products, shelf life and expiration data lacking, safety thresholds for contaminants impacted by mode of consumption data needed on this, lack of reference labs at the state level.
- Pesticide Standard Method Performance Criteria (SMPR) developed in 2018 no methods have been submitted for review. Is the SMPR fit for purpose a review is needed.
- Suggestion now is to develop a step by step method that is achievable by commercial labs.
- Moisture in cannabis still an issue with cost and complexity of different methods adding to the problem. Reliable moisture data is need to determine THC levels and levels of contaminants.
- Sampling variation needs to be addressed. Guidance document to be considered.
- Method validation for micro methods has been completed and included in AOAC Appendix J.

Contaminants Working Group

- Call for methods for alkaloids
- Call for methods for PFAS in foods and packaging materials. Short chain molecules are bale to migrate from packaging. Various rules on inclusion around the world. Very low levels will be a problem for detection 1-4 ng/Kg.
- US has voluntary removal of PFAS from packaging all manufacturers have now ceased use.
- Ethylene Oxide difficult to analyse as it evaporates over time. Use 2-chloroethanol as a substitute. No PT or Reference materials available. Makes method development challenging.

Novel Foods WG

- USDA has invested 37M in alternative proteins research since 2021. Covers cell based, plant based and fermentation. New food additives or additives used for a new use have to be approved. Onus is on the manufacturer to compile data. Data must be in the public domain and accepted by the majority of subject matter experts. Allergens carried over from fermentation are of concern. Nitrogen is used as the proxy for protein and conversion factors introduce bias. Conversion factors will need to be developed for novel proteins.

Gluten and food allergens

- Validation guidelines for allergen test kit developers have been submitted for review by Official Methods Board. Anticipated that publication in AOAC Appendix M will occur in March 2024.
- Gluten test kit guidelines are nearing completion. Split into 2 parts qualitative which is ready for OMB vote and Quantitative which is still has comments under review by WG.
- End use guidance on verification is next project. Will cover method verification, sampling and results and data interpretation. At the meeting it was suggested that automation and use of incurred materials be included. Proposal to model guidance on ISO 16140-3. WG to produce preliminary document for discussion at the August 2024 AOAC meeting.

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

The ISBER annual meeting and exhibits was held in Melbourne, Australia in April 2024. Australia is leading the way when it comes to the foundational elements of the emerging biobanking industry. This was the feedback from many at the International Society for Biological and Environmental Repositories' (ISBER) annual conference. The participation of NATA representatives reviewing and developing standards on ISO committees, including the Biobanking Standard ISO 20387, has contributed to Australia punching above its weight globally in biobanking, along with Australia's strong infrastructure to support these standards.

Biobanking Victoria was confirmed as the first NATA-accredited biobank in Australia back in 2022 which makes it fitting that the 25th edition of ISBER's Conference was held in Victoria for the first time. 350 of the world's foremost authorities on biobanking descended on Melbourne's Convention and Exhibition Centre in April. Over the four days of discussion into the future of biobanking, connections were established within Asia, Europe and the US, as well as strengthening those that have been made through the ISO committee working on the review of ISO 20387.

Precision medicine is growing in importance and the vital role biobanks play in this field was highlighted throughout the conference. High standards and best practices of biobanking are the first steps for successful precision medicine clinical trials. Ultimately, biobanking creates the link between the patients themselves and the ability to deliver precision medicine.

NATA's lead accreditation specialist in biobanking, Brodie Quine, chaired one of the roundtable events during ISBER's four days in Melbourne, focusing on the role accreditation plays in the industry. Helen Tsimiklis, from Biobanking Victoria noted: "Biobanking accreditation gives us confidence in our practices".

Representatives from international and domestic biobanks were well-represented throughout the roundtable discussions, including delegates from USA, UK and Asia. It was noted that other jurisdictions are starting to introduce requirements for biobanks to become accredited for funding, however Australia has not reached this point yet.

NATA remains one of only two Accreditation Bodies globally that is recognised for having biobanking on its Mutual Recognition Agreement (MRA). While there is still education needed about the value of accreditation for biobanks, it's clear that those that have moved first, like Cornell Veterinary Biobank and Biobanking Victoria, have seen a massive competitive advantage; particularly with ensuring standardised outcomes and collaborations.

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 attended the OECD Working Group on GLP annual meeting (38th Meeting) in April 2024. The meeting is the major forum for discussion and development of policy and procedures relating to OECD GLP compliance monitoring. NATA's GLP Program Advisor attended on behalf of the Australian GLP compliance monitoring authority (NATA).

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

A2LA

In February NATA hosted a delegation from A2LA that discussed a range of topics including accreditation practices, areas of new program growth and development, trade considerations between the countries and other synergies that enhance the relationship between our organizations.

UKAS

NATA has been involved in a benchmarking project with representatives from UKAS since early February with several virtual meetings held. UKAS and NATA have been reviewing our respective forensic science accreditation programs recognising the differences in the forensic landscape between the two economies.

All aspects of the accreditation programs have been covered, with focus on new technologies including the move to digital forensics, and discussing similarities, differences, and the challenges that we both encounter as accreditation bodies.

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 the new MOU was signed on 27 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 and expansion to include other cancer screening programs is being considered..

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.

7.2 Representation on Standards Australia Committees

Refer spreadsheet 'NATA- Committee Positions'.