Frequently Asked Questions (FAQs) regarding ISO 15189:2022 and the transition of accreditation from the previous version of the standard

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General Questions

1. ***When was the new version of the Standard published?***

   The Standard was published by ISO on 8 December 2022.

2. ***When was the Standard last reviewed and revised?***

   ISO standards are reviewed once every 5 years. The last review of ISO 15189 occurred in 2017 and a decision made then to not amend the Standard. Accordingly, the 2012 edition was the latest version published prior to the 2022 version.

3. ***Where can I obtain more information on the changes to the standard?***

   For more information, a brochure about ISO 15189 is available at:
   https://ilac.org/?ddownload=120819

   As well, please refer to the ISO news at:

   https://ilac.org/latest_ilac_news/iso-151892022-for-medical-labs-published/

   NATA has also published *Specific Accreditation Guidance: ISO 15189:2022 Gap analysis* (between the 2012 and 2022 versions) on its website.

   A video presentation describing the changes to the Standard and the transition process is/will be available on the NATA website.

4. ***Are facilities required to purchase a copy of the new standard?***

   Yes. The requirement for facilities to maintain a full copy of the NATA Accreditation Criteria, of which the Standard is a part of, has not changed.

5. ***From where can a copy of ISO 15189:2022 be obtained? And what is the difference between the Australian (AS) and ISO versions?***

   Facilities can purchase the ISO or AS version of the new Standard from standards producing bodies and their distribution partners, some of which are listed below:

   ISO

   Standards Australia

   SAI Global

   Techstreet

   The Australian version of the Standard is a direct adoption of the ISO version, however, it has a publication year of 2023. The versions are otherwise identical.

   NATA always references the ISO version in its documentation and in the scope of accreditation of accredited facilities.

6. ***When will Technical Assessors be provided with a copy of the Standard?***

NATA will make an electronic version of the standard available to Technical Assessors once assessments commence against the new version of the Standard, from August 2023, and when an assessor is next used from that date.

7. ***Will training for the new version of the Standard be provided to facilities by NATA?***

   A video has/will be produced which describes the requirements of the new version of the Standard and NATA's transition arrangements. This video is/will be available on the NATA website.

   NATA's Education team also offers a two-day course on Understanding ISO 15189 requirements. This course examines the purpose and application of the requirements to assist participants in contributing to the implementation of these in their own laboratory. Please note that this comprehensive course covers all aspects of the recently revised Standard and is not intended to identify or focus on the differences between the old and revised versions of ISO 15189.

8. ***Considering the new version is less prescriptive on document requirements can I use flow diagrams to describe my processes?***

   Yes, as is currently the case. Documentation should be to the extent necessary to allow the consistent fulfilment of the requirements of the Standard.

9. ***How will NATA determine whether process are in place given that the new Standard does not insist on documentation?***

   The Standard requires documentation to be as extensive as necessary without being prescriptive on what must be documented. Labs decide what they will document and how to do this (e.g. detailed procedure v flowchart). It is up to the lab to demonstrate how they manage the risks and achieve consistency for those processes which are not documented/contain little detail.

10. ***Staff who conduct internal audits in our laboratory have been trained to ISO 15189:2012 and have the training certificate. Now that ISO 15189 has been updated, is it necessary for staff to attend the new training of ISO 15189:2022?***

    Laboratories need to be clear about the skill set required, and training must be provided. Staff need to be authorised to undertake audit activities. The standard does not require that training be undertaken externally.

11. ***Why should we be accredited to ISO 15189 and what advantage does ISO 15189 accreditation give my laboratory?***

    ISO 15189 is a globally recognised standard for pathology, allowing results from accredited pathology laboratories to be recognised in different jurisdictions. The recent pandemic brought this into focus, whereby some jurisdictions required COVID tests to be undertaken in an accredited laboratory for these results to be accepted. Australian laboratories risk being left behind if they choose to ignore or disregard ISO standards.

    The TGA also require accreditation to ISO 15189, as well as NPAAC IVD document, for any laboratories that are undertaking in-house testing.

12. ***I am trying to set up a new laboratory. Do we have to undertake different assessments to NPAAC and ISO 15189? Are there additional costs?***

    ISO 15189 and NPAAC are complimentary standards. ISO is more broad-based and provides the over-arching management framework, and NPAAC provides the detail in the Australian context.

Assessments are conducted against both the ISO and NPAAC standards concurrently. There is no additional cost.

Transition Questions

1. When is the start date for transition of accreditation to the new version of the Standard?

From 1 August 2023, initial assessments, and scheduled visits (reassessments) will be conducted against the new version of the Standard. Specific arrangements are in place for Networked laboratories which hold multi-site accreditation and are detailed in the *Specific Accreditation Criteria: Transition Policy for the implementation of ISO 15189:2022.* Also see Q8 below.

2. How will assessment against the new version of the Standard occur?

The *Specific Accreditation Guidance: ISO 15189:2022 Gap analysis* and the *Specific Accreditation Criteria: Transition Policy for the implementation of ISO 15189:2022* were published on the NATA website in March 2023).

An *Implementation Checklist* will shortly be published which will identify the requirements which are new or that have significantly changed in the new version of ISO 15189. Accredited facilities will need to address these requirements for their accreditation to be updated to the new version of the Standard.

Accredited facilities will be required to complete the *Implementation Checklist* and supply evidence (policies, procedures, and records as necessary) demonstrating compliance with the new Standard as part of the routine preliminary arrangements prior to an on-site visit.

Any areas of non-compliance identified at a scheduled NATA visit (reassessment visit) will be detailed in the report on assessment as conditions as per the current NATA process. Facilities will need to respond to these in the usual manner prior to accreditation being continued and granted to the new version of the Standard.

As accreditation to the new version of the Standard involves a change to the scope of accreditation, facilities will need to provide evidence of the close-out of all minor conditions ('M's) raised against the new version as is the normal practice for major conditions ('C's). These Ms will be specifically identified in the report on assessment.

The scope of accreditation will be updated to reference the new Standard following confirmation of the close-out of all Cs and Ms.

Initial assessments (for applicant facilities) will occur as per current NATA procedures.

3. If the transition is part of the routine reassessment, will it take more time?

Depending on the size and scope of the facility, more time on-site may be required to complete a routine reassessment and cover the transition to the new version of the Standard. This will be conveyed to the relevant laboratories during the pre-assessment communications.

There will not be any additional charges to the laboratory where the transition is covered during a routine assessment.

Once the laboratory (or laboratory network) has transitioned to the new standard, future assessment should not require additional time.

4. ***The transition period set by ILAC for conversion to the new Standard is 3 years from its publication date. Will NATA allow facilities 3 years to comply with the new version of the Standard even if their next scheduled visit is due in 2024 or 2025?***

   The 3-year period specified by ILAC (International Laboratory Accreditation Cooperation) is for signatory accreditation bodies, such as NATA. In order for NATA to meet its ILAC obligations, accredited facilities will be assessed against the new Standard at the time of their next scheduled visit from August 2023. This arrangement is detailed in the Specific Accreditation Criteria: Transition Policy for the implementation of ISO 15189:2022 and is to allow transition of each facility's accreditation in an orderly and considered fashion.

   Facilities should already be well on their way to meeting the new Standard. The Standard was published in December 2022 and NATA has provided updates on the revision process over the last three years. The Standard, while at the Draft International Standard (DIS), was also made available to all NATA members for their information, review, and comments.

5. ***If facilities are not transitioned prior to the cut-off date, what is/are the implications?***

   If a facility is not accredited to the new Standard by 8 December 2025, it will not be recognised under the ILAC MRA.

   As part of its ILAC obligations, NATA's Transition Policy has been developed to allow all accreditations to the new version of the Standard to be achieved within the three-year period specified by ILAC. The cooperation of NATA's members and their obligation to comply with all accreditation criteria is requested to allow successful transition of all existing accredited facilities.

6. ***Because a 3-year transition plan has been stipulated by ILAC, do facilities have 3 years to close out any conditions raised at their assessment against the new version of the Standard?***

   No. The close out of conditions raised at a facility's reassessment from 1 August 2023 will need to be addressed in accordance with the current NATA process, i.e. within 4 weeks from receiving the confirmed report on assessment. This timeframe is achievable where facilities have endeavoured to prepare against the new version of the Standard. Further, it is not considered that the new or changed requirements in the new version of the Standard necessitate significant input or effort to address and comply with.

7. ***What about desktop variations and on-site variation visits? Will NATA require facilities to comply with the new version of the Standard if such visits are conducted prior to a reassessment being conducted post 1 August 2023?***

   If a facility wishes to transition to the new version of the Standard earlier than its next scheduled reassessment, then this can be arranged as a chargeable visit as detailed in the *Specific Accreditation Criteria: Transition Policy for the implementation of ISO 15189:2022*.

   If a request is made for an extension to a facility's scope of accreditation and the facility has not transitioned yet to the new version of the Standard (i.e. reassessment post August 2023 has not yet taken place), then the variation visit can be conducted against the 2012 version of the Standard.

8. ***Will the Checklist and other required documents be sent to us with the initial paperwork for NATA assessments?***

Stand-alone laboratories will be sent a copy of the implementation checklist along with your pre-assessment paperwork and AID.

Where a facility is recognised as a pathology network (has a single governance structure and centrally managed management system) it is expected that the transition will occur for the entire network. Networked laboratories will be sent a copy of the implementation checklist when the main laboratory is due for its next assessment.

Compliance with 15189:2022 will be assessed at the next scheduled NATA reassessment of the primary site (e.g. GX/S laboratory) and transition will occur for the entire facility, including all associated sites (e.g. B laboratories). For network transition to occur, the facility must be able to demonstrate all sites within its network have been included in the implementation of ISO 15189:2022. Where this cannot be demonstrated the facility will no longer be recognised as a network with wider implications, including each site being individually assessed for compliance against ISO 15189:2022 and transitioned accordingly.

A copy of the implementation checklist and other resources are available to download from the NATA website at any time.

Questions on New or Changed Requirements

1. Is NATA providing further information on the new version of the Standard?

The *Specific Accreditation Guidance: ISO 15189:2022 Gap analysis* has been created and is available from the NATA website. The document identifies the changes between the 2012 and 2022 versions of the Standard and indicates these as either editorial, minor, or major, or new requirements.

Some changes to the Standard are straight forward, such as a change in clause number, while other changes may require a more in-depth look at the application in the context of the new wording.

The new Standard differs much less from the 2012 version than appears at first sight. There are structural changes in the document (e.g. mandatory ISO/CASCO structure and wording for several clauses), however, there are minimal significant changes in most of the previous elements of the 2012 version. In many cases, the 2022 version clarifies (and in some cases expands) on the previous requirements.

The changes in the management system requirements, risk-based thinking and process orientation should leave facilities with more flexibility in implementing the Standard.

Having said the above, some of the requirements are new and application or interpretation may evolve as experience is gained through the assessment / accreditation process.

2. Does a facility have to re-write its quality manual, so that it is in the same structure as ISO 15189:2022?"

No, this will not be necessary. With the previous version of the Standard, there was no requirement that that management system documentation needed to follow the same structure and clause numbers as the Standard.

Having said the above, there may be several procedures which may need to be updated and/or expanded depended on the facility's current document content.

Note, that the management system documentation, apart from meeting the Standard, should be established to reflect the facility's needs.

It should also be noted that the new Standard does not specifically require a quality manual per se. NATA's approach has always been to allow facilities to structure and document their management systems as they saw fit without necessarily creating one quality manual (however named).

3. What changes will there be in NATA's accreditation criteria i.e. Application Documents?

The *General Accreditation Criteria: ISO 15189 Standard Application Document (SAD)* and associated Annexes have / will be updated to align with the new clause numbers of the Standard.

Requirements previously included in the documents which are now included in the Standard have / will be removed. Further, the SAD describes the new process and requirements for the fulfilment of the Certified Quality Management System criteria.

Other than the above, the updated documents will not include additional requirements compared to the previous versions.

4. If a multi-site accredited facility has some sites with a certified quality management system and some not, can it implement a certified quality management system across all sites?

One of the requirements for multi-site accreditation is that the same quality management system be adopted across all sites.

Further, NATA will only consider certified quality management systems if it is certified at each site (refer to the *General Accreditation Criteria: ISO 15189 Standard Application Document*).

5. Could NATA provide some examples of how impartiality can be reviewed on an ongoing basis?

The requirements for impartiality are not new.

The facility needs to identify risks to its impartiality. The Standard does not prescribe how this is to be achieved but does require risks arising from the activities it undertakes, relationships with other bodies and the relationships of personnel to be considered. Safeguarding impartiality could be facilitated by clearly documenting the identified risks and from where these may arise and periodically reviewing these to consider any changes. This may occur, for example, during management review.

6. Is an external provider (subcontractor) who is NATA accredited deemed appropriate?

The facility's requirements for selecting external providers (previously referred to as subcontractors) must be communicated to the provider and a means of determining that these requirements are satisfied must be established. If a facility, for example, requires that a "subcontractor" be NATA accredited, then confirming the accreditation status for the tests / calibrations required should suffice, so long as the facility has not prescribed any additional requirements (e.g. service delivery times).

7. When reporting subcontracted results, the facility previously included the subcontractor's accreditation number in the report. Since NATA no longer requires that unendorsed reports include the facility's accreditation number, does this also apply to the subcontractor's accreditation number?

Regardless of whether a facility includes the accreditation number on its reports on results covered by its scope of accreditation, the Standard still requires that results provided by external providers be clearly identified. Hence, the requirement for identifying "subcontracted" results remains unchanged. Refer to the *General Accreditation Criteria: Use of the NATA emblem, NATA endorsement and references to accreditation.*

8. Have the requirements for metrological traceability changed?

No. The requirements in the new version of the Standard remain unchanged. Also refer to NATA's *General Accreditation Criteria: Metrological Traceability*.

9. Can a facility still perform its own in-house calibrations?

In-house calibrations are those a facility conducts for its own purposes and does not offer this service externally. In such cases, the facility's publicly available scope of accreditation does not identify that it can perform its own calibration (i.e. accreditation is not held for offering calibration services to external customers).

The new version of the Standard does not change a facility's ability to perform in-house calibrations. NATA's process for reviewing this activity remains unchanged. Refer to *General Accreditation Criteria Equipment assurance, in-house calibration, and equipment verification*.

10. Does the new version of the Standard preclude the top-down approach for determining measurement uncertainty?

No. The Standard does not prescribe or preclude how measurement uncertainty is to be determined.

11. What does the Standard now require regarding the frequency of checks on calibrated equipment and/or recalibration periods?

As with the previous version of the Standard, the new version does not prescribe frequency or periods and it is for the facility to determine what is necessary to maintain confidence in the status of its calibrations. For further information, refer to the *General Accreditation Criteria Equipment assurance, in-house calibration, and equipment verification.*

12. Are facilities required to implement a formal risk management process now that the new version of the Standard requires actions to be taken to address risks and opportunities?

The Standard does not require that a formal risk management process to be implemented.

The word "risk" appears numerous times in the Standard, compared to the 2012 version. This reflects a shift, that is, the Standard acknowledges that "risk-based thinking" should be inherent in all processes adopted to ensure good laboratory practice. Risks and opportunities may arise with any process, including but not limited to, impartiality, personnel, contract review, equipment, quality control, when reporting statements of conformity, etc.

Facilities should already be taking risks and opportunities into account in their current processes.

The new version of the Standard now requires that actions to address risks and opportunities must be planned and implemented into the management system and their effectiveness evaluated. The actions taken must be proportional to the potential impact and reflected in the records maintained by the facility.

Two key changes in relation to risks and opportunities is that these need to be updated, as necessary, when a nonconformity occurs, and management review is now to consider the results of risk identification.

13. ***How will NATA determine whether process are in place given that the new Standard does not insist on documentation?***

    The standard requires documentation to be as extensive as necessary without being prescriptive on what must be documented. Labs decide what they will document and how to do this (e.g. detailed procedure v flowchart). It is up to the lab to demonstrate how they manage risks and achieve consistency for those processes which are not documented/contain little detail.

14. ***Under 7.4.1.6 requirements for reports, is it required that the information of 7.4.1.6 a) should print on each page of the result report?***

    The requirement as stated in the Standard is:
    Each report shall include the following information, unless the laboratory has documented reasons for omitting any items:

    a) unique patient identification, the date of the primary sample collection and the date of issue of the report, on each page of the report.

    The answer is yes - all of the information listed under 7.4.1.6 a) is required to be included on each page of the report, unless the laboratory has documented reasons for omitting any items.

15. ***With the changes with governance in the POCT section, does this cover POCT testing such as iStat and ROTEM?***

    Appendix A of ISO 15189:2022 covers all POCT devices that are included under your scope of accreditation, regardless of the type of POCT device.

16. ***5.2.1 is broad in lab director competence whereas NPAAC supervision S1.1 states medical practitioner how will this be handled at assessment?***

    As laboratories need to comply with both ISO 15189 and the NPAAC requirements, the highest requirement will be applied. In this scenario, the NPAAC supervision requirements are more detailed and will be applied.

17. ***What is the expectation in relation to clauses 4.2.1 (Management of information), 4.2.2 (Release of information) and 4.2.3 (Personnel responsibility)?***

    4.2.1 Management of information. It is now expected that patients and other users are made aware of how their private information may be used prior to the sample being collected. It is up to the laboratory to determine how to do this, but some examples could include information available on your website, a pamphlet for a patient to read, a discussion with the collector etc.

    4.2.2 Release of information. The intent of this clause is that the patient is made aware up front of what information will be disclosed to third parties under mandatory reporting arrangements (such as disease registries). This is a proactive approach, rather than a reactive approach. It is up to the laboratory to determine how to do this, but some examples could include information available on your website, a pamphlet for a patient to read, a section on the referral form, a discussion with the collector etc.

    4.2.3 Personnel responsibility. It is already expected that staff follow your privacy policy, however, the laboratory must ensure that other personnel who have access to patient information, such as

IT staff, equipment maintenance staff and NATA assessors, are also aware of, and abide by, your privacy policy.

18. ***I am an assessor. What should I be looking at with respect to risk-based assessments?***

NATA has had an increased focus on risk and patient outcomes, rather than compliance, for the last few years.

A risk-based approach allows laboratories to determine the outcomes they want to achieve and how they want to get to these outcomes. Assessors need to look at the risks associated with the activities undertaken, and where these risks are managed, acknowledge that there is more than one pathway to achieving the desired result.

The NPAAC RMPS document, there are 13 risk points in Appendix A for laboratories to consider. These risk points may help guide your conversations at assessment.

Looking back at past assessments has highlighted several areas of high-risk areas in pathology labs, such as:
- new areas of testing,
- results with high patient risk attached,
- new staff (especially senior staff), or high staff turnover,
- previous issues with performance (e.g. assessment findings, QA/QC issues)
- complex manual tasks
- low frequency testing,
- areas not meeting the labs own quality indicators, such as turn-around-time.

19. ***How can my laboratory incorporate risk-based thinking into my management system as opposed to a compliance-based management system?***

This will be different for every organisation. Think about the definition of a risk-based approach, which includes identifying the highest compliance risk to the organisation and highest patient risk to the organisation and make these a priority for your organisation's compliance controls. Once these risks are reduced to acceptable levels, move onto other risks. This is a continuous process, and your risks will change over time. e.g. changing technology, changes to processes.

ISO 15189 identifies that the lab shall have a process for identifying risks of harm to patients, and opportunities for improved patient care. Outcomes must be at the forefront, with improved patient outcomes being of the highest priority for all laboratories.

Questions on Management System Requirements

1. ***If a Certified Quality Management System is adopted to implement the management system requirements, is NATA able to offer certification to ISO 9001?***

Accreditation bodies are not able offer certification.

Only certification bodies accredited to ISO/IEC 17021-3 by an accreditation body signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA) can offer certification.

2. ***How will the different options for implementation of the management system requirements be assessed by NATA?***

ISO 15189:2022 requires the facility to implement a management system, which can be either a Certified Quality Management System, or a Non-certified Quality management System.

Non-certified Quality Management Systems require clauses 8.2 to 8.9 of the Standard to be addressed. The Quality Management System will be assessed in full against clauses 8.2 to 8.9 of the Standard and a document review of the management system documentation will be conducted by NATA prior to the next visit as per the transition policy.

Certified Quality Management Systems require that a management system be implemented in accordance with recognised Quality Management System Standards, e.g. ISO 9001.

If the management system established is in accordance with a recognised Quality Management System Standard, the Quality Management System may not be assessed by NATA in full subject to all the following:

- the quality management system being certified by a certification body accredited by JAS-ANZ, or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA). The certification body must be accredited to certify QMS schemes (e.g. to ISO 9001). NATA will request the facility to provide evidence that the certification body's scope of accreditation covers the applicable standard; and
- copies of the most recent certification audit reports being made available to NATA for review, including confirmation from the certification body of the close out of any non-conformities raised; and
- evidence the QMS satisfies the requirements of ISO 15189, clause 8.1.2; and
- the management system supports and demonstrates the consistent fulfilment of the requirements of ISO 15189 for the activities covered (or proposed to be covered) by the NATA scope of accreditation.

The required extent of assessment will depend on the evidence provided.

Where nonconformities are identified with the management system, these will be reported against the relevant clause (i.e. 8.2 to 8.9).

The facility shall notify NATA within 14 days when a change occurs in its QMS certification status.

Evidence in support of the above points will be requested to be submitted with a copy of the facility's management system documentation prior to the next visit.

The facility's management system documentation is required to allow the assessment team to familiarise itself with the system.

3. Our network holds multi-site accreditation but not all my sites are covered by a Certified Quality Management System, only some are. Can I implement a Certified Quality Management System for some sites and a Non-Certified Quality Management System for others?

No. Where a facility is recognised as a pathology network, it must have a single governance structure and a centrally managed quality management system (either certified or non-certified) that covers all sites.