Frequently Asked Questions (FAQs) regarding ISO/IEC 17025:2017 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 29 November 2017.

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

   ISO standards are reviewed once every 5 years. The last review of ISO/IEC 17025 occurred in 2010 and a decision made then to not amend the Standard. Accordingly, the 2005 edition was the latest version prior to the 2017 version.

   The last significant change was in 1999, the year that ISO/IEC Guide 25 was replaced with ISO/IEC 17025.

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

   For more information, a brochure about ISO/IEC 17025 is available at: https://www.iso.org/publication/PUB100424.html

   As well, please refer to the ISO news at: https://www.iso.org/news/ref2250.html

   NATA has also published *General Accreditation Guidance ISO/IEC 17025:2017 Gap analysis* (between the 2005 and 2017 versions) on its website: https://www.nata.com.au/accreditation-information/accreditation-criteria-and-guidance/nata-accreditation-criteria-nac-packages/laboratory-accreditation-iso-iec-17025

   The presentation slides NATA delivered to Members and Technical Assessors throughout May 2018 are also available on the NATA website (https://www.nata.com.au/accreditation-information?id=101).

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/IEC 17025:2017 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 the SAI Global (https://infostore.saiglobal.com/en-au/Search/Standard/?productFamily=STANDARD) or directly from ISO (https://www.iso.org/standard/66912.html).

   The Australian version of the Standard is a direct adoption of the ISO version, however, it has a publication year of 2018. Both versions are identical.

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

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

   NATA will make the standard available to Technical Assessors once assessments commence against the new version of the Standard, from August 2018, 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?***

   Member and Technical Assessor information sessions, including webinars, on the requirements of the new version of the Standard and NATA's transition arrangements were held in May 2018. The presentation notes for these sessions are available on the NATA website (https://www.nata.com.au/accreditation-information?id=101).

   NATA's Training Services Group (TSG) also offers a one day course on understanding ISO/IEC 17025 requirements. The course examines the purpose and application of the requirements to assist participants in contributing to the implementation of these in their own laboratory. It is not intended for the course to provide a detailed learning/discussion on every specific clause of the Standard but rather to provide an overview of the requirements.

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.

Transition Questions

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

   From 1 August 2018, initial assessments and scheduled visits (surveillance visit or reassessment) will be against the new version of the Standard and no longer against the 2005 version.

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

   The *General Accreditation Guidance ISO/IEC 17025:2017 Gap analysis* and the *General Accreditation Criteria Transition Policy for the implementation of ISO/IEC 17025:2017* (which includes an Implementation Checklist) were published on the NATA website in April 2018 (https://www.nata.com.au/accreditation-information/accreditation-criteria-and-guidance/nata-accreditation-criteria-nac-packages/laboratory-accreditation-iso-iec-17025).

   The *Implementation Checklist* identifies the new requirements and those which have significantly changed that accredited facilities will need to address in order for their accreditation to be updated to the new version of the Standard.

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

   Accredited facilities will be required to complete the I*mplementation 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 or surveillance 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.

3. ***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 2019?***

   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 2018. This arrangement is detailed in the General Accreditation Criteria: Transition Policy for the implementation of ISO/IEC 17025:2017 and is to allow transition of each facility's accreditation in an orderly and considered fashion.

   Facilities should already be well on their way in meeting the new Standard. The Standard was published in November 2017 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 in January 2017.

4. ***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 29 November 2020, 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.

5. ***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 surveillance visit or reassessment from 1 August 2018 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.

6. ***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 surveillance visit or reassessment being conducted post 1 August 2018?***

   If a facilities wishes to transition to the new version of the Standard earlier than its next scheduled surveillance visit or reassessment, then this can be arranged as a chargeable visit as detailed in the General Accreditation Criteria: Transition Policy for the implementation of ISO/IEC 17025:2017.

   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. scheduled surveillance visit or reassessment post August 2018 has not as yet taken place), then the variation visit can be conducted against the 2005 version of the Standard.

7. ***How will corporate accreditations be handled?***

   Every facility will be assessed against the new version of the Standard after 1 August 2018. For organisations holding corporate accreditation, the first site, regardless whether it be the main

(core) site, will be assessed after August to the new version of the Standard. The remaining sites (which may include the core site) will be assessed to the new version of the Standard when their scheduled next visits fall due. Assessment of the corporate management system documentation will occur at the first site to fall due for a surveillance visit.

Where evidence is provided with the *Implementation Checklist* and is applicable to all sites (i.e. the evidence submitted is of a corporate nature such as a policy), then subsequent *Checklists* completed for remaining sites may make reference to the previous evidence provided.

If a corporate facility wishes to have all of its sites converted to the new version of the Standard at the same time, it will need to complete *Implementation Checklists* for each separate site where relevant.

Questions on New or Changed Requirements

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

The *General Accreditation Guidance: ISO/IEC 17025:2017 Gap analysis* has been created and is available from the NATA website. The document identifies the changes between the 2005 and 2017 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 2005 version than appears at first sight. There are structural changes in the document (e.g. mandatory ISO/CASCO structure and wording for a number of clauses), however, there are minimal significant changes in most of the previous elements of the 2005 version. In many cases, the 2017 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's in the same structure as ISO/IEC 17025:2017?"

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 a number of 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 ISO/IEC 17025 Standard Application Document (SAD) and associated Appendices and 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 meeting Option B of clause 8.

   The previous requirement to include the accreditation number on unendorsed reports covering results on activities covered by the scope of accreditation has also been removed. The *General Accreditation Criteria: Use of the NATA emblem, NATA endorsement and references to accreditation* covers the requirements for endorsing reports.

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

4. ***If a multi-site corporate accredited facility has some sites certified to ISO 9001 and some not, can it implement Option B across all sites?***

   One of the requirements for corporate accreditation is that the same management system be adopted across all sites. Further, NATA will only consider Option B if it is certified at each site (refer to the *General Accreditation Criteria: ISO/IEC 17025 Standard Application Document*).

5. ***The new version of the Standard requires the measurement uncertainty (MU) contributions of sampling to be considered. Is this still applicable if the facility is not accredited for sampling or is not responsible for sampling?***

   If the facility is responsible for sampling then it will be required to take into account the sampling contributions. This applies even if the facility is not specifically accredited for the sampling component. This is the case as the facility still maintains control. When determining the sampling contributions, facilities will need to consider what is reasonable and what contributions are significant.

   If the facility is not responsible for the sampling and does not have the required information, then samples accepted for testing or calibration are to be processed as received.

6. ***The new version of the Standard requires participation in external proficiency programs which was not previously stated in the 2005 version. Will the NATA requirements for proficiency testing participation and frequency change?***

   No. NATA's requirements remain unchanged as detailed in the *General Accreditation Criteria: Proficiency Testing*.

7. ***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 take into account any changes. This may occur, for example, during management review.

8. 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 deliver times).

9. 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.

10. What is a decision rule when making a statement of conformity?

Statements of Conformity were referred to as Compliance Statements in the 2005 version of the Standard.

The 2017 version of the Standard now clearly articulates such statements must take into account the decision rule to be applied when reporting a result as a pass or fail. The rule to be applied must be agreed with the customer at the contract review stage and must be stated in the final report (if not inherent in the specification or standard against which the statement is made).

A "decision rule" is a rule which describes how measurement uncertainty (MU) is used to report a numerical result simply as a pass or fail based on whether the result falls within the specification limits prescribed.

If a facility offers testing or calibration against a specification, however, it does not report the results as pass / fail or comply / not-comply, but instead issues the numerical values and the associated MU, then this is still acceptable. In such a case the facility is not actually determining whether the item tested or calibrated conforms (i.e. it is not making a statement of conformity), but instead is providing the result to the customer for them to determine compliance. It is important in such a circumstance that the facility also provide the MU so that the customer can make an informed decision especially if results fall around the specification cut-off limits.

11. 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*.

12. Are internal audits still to be completed every 12 months?

The previous version of NATA's *General Accreditation Criteria: ISO/IEC 17025 Standard Application Document* (SAD), stated that all the requirements of ISO/IEC 17025 must be covered and ideally within a twelve-month period. This requirement remains unchanged in the updated SAD irrespective of whether Option A or B of the management system requirements in the Standard are adopted.

13. 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 publically 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*.

14. Do reports need to include all the information stipulated in the 'reporting requirements' in the Standard if the reports are for internal customers only?

No. The Standard does allow for simplified reports so long as agreed with the customer and the information which is not included is readily available. This requirement has not changed from that which was in the previous version of the Standard.

15. 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.

16. What does the Standard now require with regard to 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 in order 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.*

17. Are test reports still able to include the statement "samples analysed as received" (or similar) if the facility is not responsible for the sampling i.e. the customer supplies the samples?

Yes. The Standard allows samples to be tested / calibrated as received with the mandatory statement included.

The Standard, however, now also requires that a disclaimer be included in reports when it is known that a sample received does not conform to specified requirements, or where information provided by the customer can affect the validity of results. Examples of concerns with samples may include, but not limited to, damage during collection or transport, insufficient sample for analysis, chemical preservation issues, inappropriate sample container, incorrect temperature on arrival, delays in sample transport etc.

Accordingly, the Standard now places more onus on the laboratory to ensure that samples received are appropriate for subsequent testing / calibration.

18. 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 2005 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.

Questions on Management System Options

1. ***If Option B 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) are able to offer certification.

2. ***How will Option A or B, for implementation of the management system requirements, be assessed by NATA?***

   ISO/IEC 17025:2017 requires the facility to implement a management system in accordance with either Option A or Option B.

   Option A requires clauses 8.2 to 8.9 of the Standard to be addressed.

   Option B requires that a management system be implemented in accordance with ISO 9001.

   If the management system established is in accordance with Option A, it 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 before a surveillance visit.

   If the management system established is in accordance with Option B, the assessment effort required while on-site to review the system may be reduced subject to the following:

   1) the management system is certified by a certification body (CB) accredited by JAS-ANZ, or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA);
   2) the CB’s accreditation covers ISO/IEC 17021-3 i.e. the CB can certify management systems to ISO 9001;
   3) copies of the most recent certification audit report(s) issued by the CB covering your facility’s management system in full is(are) provided to NATA;
   4) confirmation from the CB of the close out of any non-conformities raised during certification audits is provided to NATA;

5) the certification of the management system covers the laboratory activities proposed to be covered by your NATA scope of accreditation.

Evidence in support of 1) to 5) will be requested to be submitted with a copy of the facility's management system documentation. The latter is required to allow the assessment team to familiarise itself with the system. The assessment effort while on-site will be dependent on the extent of the evidence provided and the extent of the audits performed by the CB.

Should evidence supporting points 1) to 5) not be provided, NATA will assess the management system in accordance with Option A (i.e. clauses 8.2 to 8.9 of the Standard).

Assessment against Option A will follow the same process as assessment of clause 4 of the 2005 version of the Standard.

3. If a facility is currently in the process of having its certification transitioned from ISO 9001:2008 to ISO 9001:2015, can it still adopt Option B?

The version of ISO 9001 is not specified in ISO/IEC 17025:2017. NATA will accept certification to ISO 9001:2008 (in view that there is a current process for transition to the latest version of that standard) if the facility complies with the Option B requirements specified in the *General Accreditation Criteria ISO/IEC 17025 Standard Application Document*.

4. I hold Corporate accreditation but not all of my sites are covered by ISO 9001 only some are. Can I implement Option B for those sites covered by ISO 9001 certification and Option A for those that aren't?

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For corporate accreditation who maintain ISO 9001 which is certified, but does not cover all sites, that the assessment of each individual site will be based on either Option A or B dependent on whether the site is covered by the certification. This does not remove the requirement for corporate accreditation that the same management system must be adopted across all sites.

The management system documentation will still be reviewed once per cycle at the corporate site when it falls due against either Option dependent on whether certification to ISO 9001 is held. However, the implementation of the system at each site and review of records will either be Option A or B dependent on whether a given site it is covered by the certification.