2019 IANZ Assessment Cycle Changes

IANZ assessments of accredited organisations

The NZ mark of competence
Tohu Matatau Aotearoa

1. Purpose

To inform accredited organisations of the upcoming changes (nature and frequency) to the assessment cycle.

2. Scope

The changes apply to all IANZ accreditation programmes except the Building Consent Organisation (BCA) Accreditation Programme, the Gas Cylinder (GC) Testing Laboratory Accreditation Programme and the GLP Compliance Monitoring Programme, namely:

- All Testing Laboratory Accreditation Programmes (Applied Physics, Biological, Chemical, Electrical, Medical, Mechanical, MoH Drinking Water Laboratory programme, MPI Recognised Laboratory Programme, Wool);
- Metrology and Calibration Laboratory Accreditation Programme;
- Inspection Body Accreditation Programme;
- Proficiency Testing Provider Accreditation Programme;
- Medical Imaging Services Accreditation Programme;
- Reference Material Producer Accreditation Programme;
- Designated Conformity Assessment Body programme.

3. Background

At the present time the default accreditation cycle is three years (four years for Medical Testing Laboratories and Medical Imaging Services), comprising:

- A full reassessment of the scope of accreditation and revalidation of the management system every three (or four years) involving an IANZ Lead Assessor and one or more Technical Experts;
- Annual surveillance assessment in the intervening two (or three) years, generally involving only an IANZ Lead Assessor.

Variations to this default cycle are common e.g. a Technical Expert may be required at surveillance assessments when a requested extension to the scope of accreditation needs to be assessed. Or, for organisations with a large scope, the reassessments may be spread over the cycle with Technical Experts at each annual assessment. However, the intent remains that the full accreditation scope is assessed at least once over the cycle of three (or four) years.

This accreditation cycle was in full conformity with ISO/IEC 17011:2004 *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies* – the international standard to which IANZ has to conform, particularly to maintain its status as a Signatory to the international Mutual Recognition Agreements.

In late 2017, a revised and up-dated edition of ISO/IEC 17011 was published. In particular, one clause (7.9.3) now states (underlined for emphasis):

"…. A sample of the scope of accreditation shall be assessed every two years. The time between consecutive on-site assessments shall not exceed two years."

ISO/IEC 17011:2017 now effectively requires IANZ to bring a Technical Expert on-site at least every two years to assess a sample of the scope of accreditation.

4. Change

All accreditation programmes (except BCA, GC and GLP) will move to a default surveillance programme of:

- An on-site full reassessment of the scope of accreditation and revalidation of the management system every four years, involving an IANZ Lead Assessor and one or more Technical Experts;
- An on-site 'Technical Assessment' at two years within that cycle, involving an IANZ Lead Assessor and one or more Technical Experts to assess at least part of the scope of accreditation;
- An on-site surveillance assessment at years 1 and 3 in the four year cycle, generally involving an IANZ Lead Assessor only.

The objective is to technically assess the full scope of accreditation over the 4 year cycle (2 years + 2 years), and that the management system is fully assessed over the 4 year cycle.

The on-site surveillance assessment at year 1 will be mandatory in the first cycle following the granting of accreditation. For other surveillance assessments, the default will remain an on-site assessment but other options (e.g. remote assessment, review of documents, self-declarations, etc., down to the possibility of no assessment activity at all in years 1 and 3 of the cycle) may be considered based on an assessment of risk and how that risk can be managed.

In all cases where regulatory or other specifier requirements stipulate an assessment cycle, these will be implemented, provided the assessment cycle requested complies with the ISO/IEC 17011:2017 requirements.

5. Assessment of Risk

The most significant risk to all parties is that an accredited organisation will not comply with accreditation requirements and, in the worst case, issue incorrect or invalid results, and that IANZ has failed to identify this because of ineffective assessment activity.

The magnitude of the risk will be assessed based on many indicators such as any critical risk to the safety and wellbeing of society, the industry or sector sensitivities, previous compliance performance, recent changes to accreditation requirements, changes within the accredited organisation, the internal quality control programmes of the accredited organisation, etc.

Based on the magnitude of the risk, appropriate assessment activities will then be selected to be undertaken at the surveillance assessment.

In all cases, IANZ will still retain the right to assess an accredited organisation, with or without Technical Experts, at any time should there be due cause to do so.

6. Implications

Each accredited organisation will be considered on a case-by-case basis and on its own merits. The default option described above is just that; the default, and IANZ will require just cause to consider deviations from the default.

Some possible situations are described as follows:

1. Where the accredited organisation has a small or limited scope of accreditation, the technical assessment at 2 years is effectively going to cover the whole scope (100% sample). In such instances, a well performing accredited organisation may effectively end up on a 2 year reassessment cycle with no or limited surveillance in the years between.
2. For organisations with large scopes of accreditation, many are currently having parts of their scope technically assessed every year. Under the proposed cycle, there would be effectively no change.
3. Organisations that have a clearly defined separation in their scope of accreditation, possibly with two different Technical Experts required e.g. a chemical and biological testing laboratory or a mass and temperature calibration laboratory, the technical assessment may be split across the year 2 and year 4 assessments.

The impact on costs is not expected to be significant, with the major contribution coming from Technical Expert costs. For organisations that have current 3 yearly reassessment with more than one Technical Expert or over more than one day, there may be a cost saving with the Technical Expert resource split into two visits over 4

years, rather than the same resource once every 3 years. For organisations on a current 4 year reassessment, there would be no change but cost would be spread over the 4 years, rather than one spike every 4 years.

Organisations with a single day reassessment with one Technical Expert will now effectively get this every 2 years. However, this can be offset by savings at surveillance assessments for the well performing organisations.

7. Implementation

The new assessment cycle will be implemented as of the 1st January 2019, and organisations will be advised of the scope of the next assessment in the assessment notification communication prior to the planned on-site visit.

For testing laboratories currently working through the transition to the updated ISO/IEC 17025:2017 standard this may impact on when your updated management system is scheduled for review as part of the on-site assessment however IANZ will be in contact well in advance to ensure all laboratories are able to transition prior to the deadline of December 2020.

If you have any questions on the new assessment cycle and its planned implementation, please contact the relevant Programme Manager / Programme Specialist.