

The assessment and accreditation of opinions and interpretations using ISO 17025:2017

PS 28

1) Purpose:

This policy sets out the requirements for assessment and accreditation of ISO 17025 accredited testing laboratories wishing to express opinions and interpretations within the accredited test reports. It does not apply to calibration laboratories.

2) Definitions:

'Opinion and interpretation' (O&I) is the process by which the applicability of a test may be extended. A technically qualified person assesses it and further inferences are made based on the result produced, using knowledge and professional judgement of the person in the area of testing being undertaken. The opinion and interpretation made should be technically sound and supported by definitive evidence.

3) References:

- ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories";
- EA-INF 4/23: The assessment and accreditation of opinions and interpretations using ISO/IEC 17025:2017;
- CRM user guide on making an application for accreditation of opinions and interpretations.

4) Policy:

Expression of opinions and interpretations relating to results is considered an inherent part of testing and so INAB will not accredit expression of opinions and interpretations as a separate or standalone activity. The laboratory shall be accredited for all testing for which it issues accredited opinions and interpretations.

Additional care shall be taken when reports contain opinions and interpretations, which rely on results obtained from tests performed by subcontractors and / or data provided by the supplier of the test item. The documented records for such reports should clearly identify the source of data used and the steps taken to establish their validity. Test results used in the formulation of any opinion / interpretation shall be accredited.

Similarly the opinions and interpretations expressed in test reports must be based on the test results obtained from the item tested. They shall not be used for the purposes of product certification. The laboratory must ensure it is clear to the user that the O&I given is based only on the results of the particular item tested. This shall be noted on any test reports.

Where an accredited laboratory reports a compliance / non-compliance statement along with the test result, this is not regarded as being part of opinions and interpretations. This is considered a general reporting activity as per ISO 17025:2017 Clause 7.8 (excluding 7.8.7)

It is the responsibility of each laboratory to decide whether to report opinions and interpretations in their test reports and whether to seek accreditation to include this activity. This shall be clearly defined in the quality system of each individual laboratory.

The scope of accreditation will clearly document the testing activities for which the laboratory is accredited for expression of opinions and interpretations.

If the laboratory is expressing opinions and interpretations not accredited by INAB they shall indicate clearly those that are not covered by INAB accreditation. The following statement shall be used in these instances:

'The opinions and interpretations indicated are outside the laboratory's scope of accreditation'

INAB will assess the system put in place by the laboratory for the purposes of making statements of opinions and interpretation. INAB does not accredit or otherwise endorse the individual statements themselves.

5) Application for accreditation

An ISO 17025 testing laboratory that is already accredited can apply to INAB for an extension to scope to cover expressions of Opinions and Interpretations. The applicant shall indicate the testing activities for which it seeks accreditation, in this area.

6) Assessment of laboratories

The initial assessment of opinions and interpretations will be an on-site visit which will be completed as part of a scheduled assessment / surveillance visit to allow input from the relevant technical assessors. The assessors shall report it clearly in the audit trail, when relevant.

Additional time for the lead assessor will be required for this initial assessment on site, depending on the extent of testing / activities for which the laboratory seeks accreditation for, in this area. This additional time will normally not exceed 0.5 assessor days.

Thereafter, assessment of the system for the expression of opinions and interpretations will be incorporated into the normal surveillance activities of INAB.

At the initial and surveillance visits the assessment team, when relevant, will consider the following areas at minimum:

a. **Documented procedures** reflecting the process that leads to the inclusion of Opinions and Interpretations in the test report.

b. **Contract review processes with customers**

The extent to which O&I are required by the customer should be clearly defined at the contract review stage. The contract review procedure shall confirm the following:

- Client's needs and wishes have been understood with respect to any statements of O&I.
- The laboratory's scope of accreditation covers O&I.
- The client has understood and accepted the implications of the O&I.
- The laboratory has the necessary professional competencies authorised to make such statements.
- That any legal requirements are understood and can be complied with.

- The extent to which the statements of O&I are based on test results of the item compared to information drawn from other sources, such as documentary research, previous experience, precedent. This process shall be clarified with the client.
- That the O&I given cannot be used for product certification in isolation and are based on the results of the items / products tested.
- The laboratory needs to maintain records of contract reviews in line with its general policies on record keeping.

c. Criteria for competence of personnel authorised to express O&I and the associated records of qualification, experience and training of those authorised personnel.

The qualifications, experience and training of staff that are involved in the formation of opinions and interpretations will vary from sector to sector, however the following are minimum requirements.

Please note that INAB may also seek advice from relevant professional bodies as to the level of qualifications, experience, training needed in particular sectors to qualify those responsible for expressing opinions and interpretations.

All personnel deemed competent to provide opinions and interpretations shall be identified as 'key personnel' and any changes notified to INAB as per normal procedures.

There will be specific qualification records available for those that are responsible for expressing O&I within the organisation and these records will include as a minimum:

- Full qualifications record detailing career to date
- Continuing professional development records (CPD) to demonstrate how the individual has kept up to date with changes in the particular sector for which opinions and interpretations are given.
- Details of experience in the required field of expertise.

d. Internal audit of the above process to ensure the laboratory itself is monitoring its effective implementation.

e. Risk assessment shall be completed and reviewed regularly on the process to provide opinions and interpretations and available for review by the INAB assessment teams.

7) Accreditation

The INAB team, as per the normal assessment process, may recommend award of accreditation for opinions and interpretations and this will be presented to the INAB manager or INAB Board for decision.

The INAB assessment manager will ensure the scope of accreditation for the laboratory is updated to indicate the areas in which accreditation for the expression of opinions and interpretations has been awarded. The statement below details as to how this is identified on the scope of accreditation. These notes shall be displayed at the end of the scope document for reference and used throughout to define where the accreditation of expression of Opinions and Interpretations has been awarded on a test / technique basis.

The statement '**The laboratory is accredited to provide opinions and interpretations for the tests identified as ***' will be included in each scope document as required.

8) Implementation

The policy applies from date of issue.

9) **Contact**

For further information please contact the assigned assessment manager or inab@inab.ie