

1) Purpose

This statement sets out the policy of the Irish National Accreditation Board with respect to the principles for the assessment and accreditation of reference material producers to ISO 17034.

2) References

2.1) ISO/IEC 17025: “General requirements for the competence of calibration and testing laboratories”.

ISO/IEC 17025:2017 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.

It is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.

2.2) ISO 17034: “General requirements for the competence of reference material producers”.

ISO 17034 is intended for the use by reference material producers in the development and implementation of their management system for quality, administrative and technical operations. It covers the production of certified and non-certified reference materials. For non-certified reference materials, certain requirements are less stringent than for certified reference materials.

2.3) There are several ISO guides relevant to RMP and which are referred to in ISO 17034 – these are considered useful by INAB in the assessment of RMP.

- ISO Guide 30, Terms and definitions used in connection with reference materials;
- ISO Guide 31, Reference materials - Contents of certificates and labels;
- ISO Guide 32, Calibration in analytical chemistry and use of certified reference materials;
- ISO Guide 33, Uses of certified reference materials;
- ISO Guide 35, Reference materials – General and statistical principles for certification.

2.4) Any applicable EA or ILAC guidance/mandatory documents.

3) Assessment Criteria

3.1) INAB assesses and accredits technically competent bodies producing reference materials with assigned property values. These assessments are conducted against harmonized criteria based on ISO 17034. Any testing and/or calibration activity that takes place as part of the production process must always meet the applicable requirements of ISO/IEC 17025, even in the case of subcontracting. In practice, the RMP may already have an accreditation for specific calibration/ testing activities under a fixed or flexible scope. For these activities other INAB documents apply.

3.2) To achieve accreditation by INAB for production of non-certified reference materials the following minimum requirements must be met:

- A reference material must be accompanied by a clear statement of intended purpose.
- The homogeneity and stability of the materials must be determined and shown suitable for the intended purpose.
- The property values and their uncertainties must be determined using methods that are relevant and suitable for the intended purpose.
- Metrological traceability of assigned values must be determined where that is necessary for the intended purpose.
- Test methods used to establish homogeneity, stability and assigned values must

be operated in such a way as to meet the requirements of ISO 17025.

- 3.3) The system for management, evaluation and monitoring of any subcontracted activities performed by the RMP will be assessed by INAB. This may include witnessing of the RMP evaluation/audit of the subcontractor.
- 3.4) Where the RMP selects option B to demonstrate conformity with management system requirements, INAB shall assess the system to satisfy itself that all management systems elements are in place and effective.

4.) Definition of Scope of accreditation

INAB scopes of accreditation for RMP are in compliance with ISO 17011:2017 and are outlined in ST15CRM “Reference Material Producers Classification” scope description document available on the INAB website.