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Accreditation of Reference Material Producers PS21

1) Purpose

This statement sets out the policy of the Irish National Accreditation Board with respect to the principles for the assessment and accreditation to ISO Guide 34 of reference material producers.

The ISO Guides concerning reference materials makes reference to Guides 30-35

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 34, General requirements for the competence of reference material producers
ISO Guide 35, Reference materials General and statistical principles for certification

2) References

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

ISO/IEC 17025:2005 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 Guide 34: "General requirements for the competence of Reference material producers".

Guide 34:2009 is intended for the use by reference material producers in the development and implementation of their management system for quality, administrative and technical operations.

Guide 34:2009 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) ISO Guide 35:2006 “Reference Materials – General and statistical principles for certification”

ISO Guide 35 gives examples of statistical principles to assist in application of valid methods to assign values to properties of a reference material, including the evaluation of their associated uncertainty. Reference Materials (RMs) that undergo all steps described in ISO Guide 35:2006 are usually accompanied by a certificate and called a certified reference material (CRM). However, ISO Guide 35:2006 is not exhaustive and INAB recognizes that there might also be other technically valid approaches to characterization and assignment of property values to reference materials.

2.4) International Laboratory Accreditation Cooperation (ILAC) has issued guidance G12 2000 "Guidelines for the Competence of Reference Materials Producers".

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 Guide 34 and ISO/IEC 17025 in combination. This means that 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 Reference Material Producer 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) This document is intended to provide explanation of the procedures and requirements for the accreditation of Reference Material Producers. The main issues addressed in this document are: general accreditation issues, an explanation of the specific requirements and the definition of scopes for accreditation of Reference Material Producers.

3.3) Guide (2009) give two definitions regarding reference materials:
Reference Material: Is a material, with sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process
Certified Reference Material: reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

In practice, a certified reference material must be prepared, characterised and documented in such a way to meet the full requirements of Guide 34. A non-certified reference material may be prepared, characterised and documented less rigorously provided that it can be demonstrated to be fit for its intended purpose.

ISO Guide 34 states that to fulfil the minimum requirements for a non-certified reference material, the following may not be necessary:

- Designing inter-laboratory exercises, assessing commutability, assigning property values and establishing uncertainty budgets
- Providing detailed information to users on the homogeneity study; however, information on the degree of homogeneity shall be provided
- Providing detailed information to users on the stability study; however, information on the degree of Stability shall be provided
- Characterization of the material
- Assignment of property values and their uncertainties
- Establishing metrological traceability of assigned values

To achieve accreditation by INAB for non-certified reference material production 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 a such a way as to meet the requirements of ISO 17025

4) General Requirements

In Oct 2012, the General Assembly of ILAC under Resolution GA 16.20 stated the following. As ISO Guide 34:2009 includes normative references to ISO/IEC 17025 and ISO 15189, the General Assembly resolves that accreditation of reference material producers is conducted in accordance with ISO Guide 34:2009 alone. This resolution rescinds ILAC resolution 8.12. In addition, ILAC-R6:02/2013 has been amended to reflect this decision.

4.1) The current view of INAB is that under accreditation a number of key tasks in producing a reference material shall not be performed by subcontractors. These tasks are given in italics:

- *Production planning*;
- Material preparation;
- *Homogeneity/Stability testing*;
- *Characterization of property values*; Where a network of qualified organisations is used to perform measurements on (candidate) reference materials following the concept given in ISO Guide 35, the Reference Material Producer has to be one of the participating laboratories.;
- *Assignment of and decision on property values*;

- *Authorization of property values (and issue of certificate for certified reference materials*);
- Handling and storage (including post certification testing);
- Distribution and post distribution service.

5.) Requirements ISO Guide 34 and ISO/IEC 17025

5.1) There are a number of different approaches a Reference Material Producer can use to generate and assign property values to its reference materials. Additionally a Reference Material Producer may choose to or need to (e.g. in the case of consensus values) use subcontractors to perform one or more of the tasks leading to the production of its reference materials. Whichever approach is taken, the Reference Material Producer is the organisation that is fully responsible for ensuring that all the activities leading to the production and the assignment of value(s) have been performed competently. Therefore INAB will assess the competence of the Reference Material Producer (and any subcontracting arrangements it uses) in accordance with ISO Guide 34 and the applicable clauses of ISO/IEC 17025.

5.2) Calibration/ testing laboratory already complying to the requirements of ISO/IEC 17025:2005 "*General requirements for the competence of testing and calibration laboratories*", shall adapt their management system in accordance with ISO Guide 34: 2009, "*General requirements for the competence of Reference Material Producers*". Laboratories should review ISO Guide 34 in order to understand the discrepancies between several ISO Guide 34 and ISO/IEC 17025 clauses, despite the fact that cross-references are given in this document.

Annex 1:- gives the cross reference table ISO Guide 34 2009 / ISO/IEC 17025

6.) Definition of Scope of accreditation

6.1) In the scope of a Reference Material Producer and for each individual activity four items shall be included:-

- The first column contains the sequence number of the activity.
- The second column specifies the matrix and or artefact for which property values have been established and is similar to a 'fixed scope'.
- The third column specifies the properties and/ or identity the species and/or characterisation ranges.
  For "synthetic" reference materials, e.g. calibration solutions and gas mixtures, it is desirable to accurately specify the identity of components in the matrix and the range of measurement. For "natural" reference materials it is important to specify the identity in generic terms as the composition way vary from source to source.
- The fourth column specifies one or more characterisation procedures which have been used in assigning property values to the reference material. These procedures are given in ISO Guide 35. The

characterisation procedures for assigning property values and the applied measurement methods (analytical methods) have to be assessed by INAB prior to accreditation.

Annex 2:- Outlines example of the scope of accreditation for Reference Material Producer.

Annex 1: Cross reference table (Guide 34 2009 / ISO/IEC 17025)

Activities directly or indirectly related to testing and/or calibration issues must always meet the applicable requirements of ISO/IEC 17025, these are given in *italics*.

no adequate cross-reference exists

ISO Guide 34	ISO/IEC 17025	Subject from ISO Guide 34
1	**1**	**Scope**
2	**2**	**Normative references**
3	**3**	**Terms and definitions**
4	**4**	**Organisation and management requirements**
4.1	**4.2**	**Management system requirements**
4.1.1	4.2.1	Scope of the management system and activities
4.1.2	4.2.2	Policies, objectives, commitments
4.1.3	4.2.1	Documented coverage of the management system
4.2	**4.2**	**Organisation and management**
4.2.1	4.1.1	Legal entity
4.2.2	4.1.2, 4.1.3, *4.1.4*	Responsibility of the Reference Material Producer
4.2.3	4.1.5	General requirements for Reference Material Producer
4.2.3 a	4.1.5.a	Availability of managerial and technical personnel
4.2.3 b	4.1.5.b	Undue pressure
4.2.3 c	4.1.5.c	Confidentiality proprietary rights
4.2.3 d	4.1.5.d	Undue activities
4.2.3 e	4.1.5.e	Organisation and management structure
4.2.3 f	4.1.5.f	Responsibilities and authorisation
4.2.3 g	4.1.5.h	Technical management
4.2.3 h	4.1.5.i	Quality manager
4.2.3 i	4.1.5.j	Deputies for personnel on key positions
4.3	**4.3**	**Document and information control**
4.3.1	4.3.1	Procedures to control all documents and information
4.3.2	**4.3.2**	**Document approval and issue**
4.3.2.1	4.3.2.1	Document control log
4.3.2.2 a	4.3.2.2.a	Availability of authorised documents
4.3.2.2 b	4.3.2.2.b	Periodic review and revision
4.3.2.2 c	4.3.2.2.c	Removal of invalid or obsolete documents
4.3.2.2 d	4.3.2.2.d	Identification of obsolete documents
4.3.3	**4.3.3**	**Document changes**

ISO Guide 34	ISO/IEC 17025	Subject from ISO Guide 34
4.3.3.1	4.3.3.1	Approval of changes
4.3.3.2	4.3.3.2	Identification on changes
4.3.3.3	4.3.3.3	Amendment of documents by hand
4.3.3.4	4.3.3.4	Changes of documents in computerised systems
4.4	**4.4**	**Request, tender and contract reviews**
4.4.1	4.4.1	Procedures for review of contracts
4.4.2	4.4.2	Records of reviews
4.4.3	4.4.3	Review of contracts including subcontracted work
4.5	***4.5***	***Use of subcontractors***
4.5.1	*4.5.1*	*Policy and procedures for selection of subcontractors*
4.5.2	*4.5.1*	*Selection and technical requirements for subcontractors*
4.5.3	*4.5.3*	*Assessment of competence of subcontractors*
4.5.4	*4.5.4*	*Register of subcontractors, including assessment records*
4.6	**4.6**	**Procurement of services and supplies**
4.6.1	4.6.1	Selection policy and procedures
4.6.2	4.6.2	Verification with standard specifications of requirements
4.6.3	#	Compliance with specified requirements for non-approved services and supplies
4.6.4	*4.6.2*	*Inspection of goods prior to use*
4.6.5	4.6.4	Records of main suppliers and subcontractors including evaluations
4.7	**4.7**	**Customer service**
4.7.1	4.7.1	Cooperation with customers
4.7.2	4.7.2	Feedback from customers
4.8	4.8	Complaints
4.9	**4.9**	**Control of non-conforming reference materials**
4.9.1	**4.9.1**	**Policy and procedures**
4.9.1 a	4.9.1.a	Management of non-conforming work
4.9.1 b	4.9.1.c	Implementation of corrective actions
4.9.1 c	4.9.1.b	Significance of non-conforming work
4.9.1 d	4.9.1.a	Halted work
4.9.1 e	4.9.1.c	Time management corrective actions
4.9.1 f	4.9.1.d	Recall of distributed reference materials
4.9.1 g	4.9.1.e	Resumption of work
4.9.2	4.9.2	Prevention for reoccurrence
4.10	**4.11**	**Corrective action**
4.10.1	4.11.1, 4.11.3	Policy and procedures
4.10.2	4.11.2	Cause analysis

ISO Guide 34	ISO/IEC 17025	Subject from ISO Guide 34
4.10.3	4.11.3	Selection and implementation of corrective actions
4.10.4	4.11.4	Monitoring of corrective actions
4.10.5	4.15.1	Additional audits
4.11	**4.12**	**Preventive action**
4.11.1	4.12.1	Identification and action plans
4.11.2	4.12.2	Monitoring effectiveness
4.12	4.10	Improvement
4.13	**4.13**	**Records**
4.13.1	**4.13.1**	**General**
4.13.1.1 a	4.13.1.1	Quality records
4.13.1.1 b	4.13.2.1	Technical records
4.13.1.2	4.13.1.2	Storage, recovery and retention times
4.13.1.3	4.13.2.3	Manual changes
4.13.1.4	4.13.1.3	Security and confidentiality
4.13.1.5	4.13.1.4	Back-up's, access to electronic records
4.13.2	4.13.2.1	Records and internal reports
4.14	**4.14**	**Internal audits**
4.14.1	4.14.1	Planning and schedule, auditor qualifications
4.14.2	4.14.2	Corrective actions
4.14.3	4.14.3	Reporting findings, time management corrective actions
4.14.4	4.14.4	Confirmation effectiveness of corrective actions
4.15	**4.15**	**Management reviews**
4.15.1	4.15.1	Planning and review items
4.15.2	4.15.2	Reports and actions
5	**5**	**Technical and production requirements**
5.1	**5.2**	**General**
5.1 a-f	#	Minimal requirements for non-certified reference materials
5.2.1	5.2.1	Production competence
5.2.2	5.2.2	Technical competence of personnel
5.2.3	5.2.3	Education and training
5.2.4	5.2.4	Job-descriptions
5.2.5	5.2.3	Contacts and supervision
5.2.6	5.2.5	Recording competence
5.3	**4.5**	**Subcontractors**
5.3.1	4.5.1	*Selection criteria*
5.3.2	4.5.4	*Demonstrable competence*
5.3.3	#	Compliance with Guide 34 and ISO 17025 for measurement, testing and calibration

ISO Guide 34	ISO/IEC 17025	Subject from ISO Guide 34
5.3.4	4.5.4	Records of methodology, procedures and results; register of subcontractors
5.4	**#**	**Production planning**
5.4.1	#	Selection of processes and use of technical standards
5.4.2	#	Mechanism for technical support
5.4.3 a-u	#	Specific procedures and facilities
5.5	#	Production control
5.6	**5.3**	**Accommodation and environmental conditions**
5.6.1	5.3.1, 5.3.2	Accommodation, facilities, prevention of contamination
5.6.2	5.3.1	Monitoring of environmental conditions
5.6.3	#	Health, safety and environmental protection
5.7	**5.8**	**Material handling and storage**
5.7.1	*5.8.1*	*Shielding and separation*
5.7.2	*5.8.4*	*Packing and storage facilities*
5.7.3	5.8.4	Monitoring of the condition of materials during storage
5.7.4	5.8.1	Packing and marking for transportation
5.7.5	5.8.2	Labelling of reference materials
5.7.6	5.8.4	Integrity during production (and delivery)
5.8	**#**	**Material processing**
5.8 a-h	*5.4.1*	*Specific procedures for material processing*
5.9	**5.4**	**Measurement methods**
5.9.1	*5.4*	*Methods in compliance with ISO 17025*
5.9.2	*5.4.5*	*Method validation*
5.9.3	*5.7.1*	*Sampling*
5.10	**5.4**	**Measuring equipment**
5.10.1	*5.4*	*Compliance with ISO 17025*
5.10.2	*5.5.7*	*Handling and labelling of non-performing equipment*
5.10.3	*5.5.8*	*Identification of calibration status*
5.10.4	*5.5.2, 5.5.10*	*Calibration and performance checks*
5.10.5	*5.6.1*	*Calibration programme to establish appropriate traceability*
5.11	**5.4.7**	**Data evaluation**
5.11.1	5.4.7.1	*Calculation and data transfers*
5.11.2	**5.4.7.2, 4.13.1.4**	**Computer systems**
5.11.2 a	5.4.7.2.a	Validation of (in-house developed) software
5.11.2 b	5.4.7.2.b	Procedure for the protection of data integrity
5.11.2 c	5.4.7.2.c	Environmental and operating conditions
5.11.2 d	5.5.11, 5.5.12	Procedures for data security (access, amendment of records, back-up's, hard copies)

ISO Guide 34	ISO/IEC 17025	Subject from ISO Guide 34
5.11.3	4.13.2.1	Archiving technical data (see also 4.13.2)
5.12	**5.6**	**Metrological traceability**
5.12.1	5.6.2.1	Documented evidence
5.12.2	5.6.2.1	State references for certified properties
5.12.3	#	Specific requirements for relative and absolute applications
5.13	**#**	**Assessment of homogeneity**
5.13.1	#	Quantification or limits for heterogeneity; ISO Guide 35
5.13.2	#	Design of homogeneity test; ISO Guide 35
5.13.3	#	Reporting minimum sample size
5.14	#	**Assessment of stability**
5.14.1	#	Establishment of required stability (fit for purpose)
5.14.2	#	Testing according to ISO 17025 criteria, design according to ISO Guide 35
5.14.3	#	Stability under transport conditions
5.14.4	#	Periodic confirmation of stability
5.14.5	#	Information on changes shelf-life
5.15	**5.4.2**	**Characterisation methods; ISO Guide 35**
5.16	**5.4.6**	**Assignment of property values and their uncertainties**
5.16.1	5.4.6.3	Procedures and statistical principles, expert team; ISO Guide 35
5.16.2	*5.4.6.1, 5.4.6.2*	*Method for assigning measurement uncertainty on property values; ISO Guide 35, GUM*
5.17	5.10	Certificates or documentation for users, ISO Guide 31
5.18	**#**	**Distribution service**
5.18.1	5.8.1	Conditions of transport and documents for customs clearance
5.18.2	#	Record of material sales or distribution
5.18.3	4.7.1	Guidance and technical support
5.18.4	4.9.1	Notification in case of changes in assigned value
5.18.5	#	Resale through authorized distributors
5.18.6	#	Resale by other organisations

Annex 2: Examples of scope definition

No.	Matrix / Artefact	Property Value(s) / Identity / Characterisation Ranges	Characterisation Procedure/ Technique
1	Ferrous Metals Steels, Irons and Ferro Alloys	Elements	Measurement by a network of qualified laboratories using a variety of measurement procedures of demonstrable accuracy.
2	Non-Ferrous Metals Aluminium Alloys, Chromium, Cobalt, Copper, Lead, Magnesium, Nickel, Tin, Titanium Zirconium Base Alloys	Elements	Measurement by a network of qualified laboratories using a variety of measurement procedures of demonstrable accuracy.
3	Cements, Clays and Related Products	Elements Metal oxides	Measurement by a network of qualified laboratories using a variety of measurement procedures of demonstrable accuracy.
4	Pure Organic Compounds Organic chemicals	Purity (% m/m)	Measurement by two or more independent reference measurement procedures. Methods selected from HPLC, GC-FID, GC-MS, titration Karl Fischer
5	Pure Organic Compounds Organic chemicals	Melting point (30-300°C)	Measurement by a single, primary, reference measurement procedure at an NMI laboratory by contact thermometry
6	Pure Organic Compounds Calibration solutions	Polychlorinated Biphenyls	Measurement by a single, primary, reference measurement procedure (GC-IDMS) and/ or measurement by a network of qualified laboratories using a variety of methods of demonstrable accuracy.
7	Petroleum Products Diesel and Gasoline	Sulphur (Trace to % Levels)	Measurement by a single, primary, reference measurement procedure (ICP-IDMS)
8	Foodstuffs Food supplements	Selenium (content and speciation)	Measurement by a single, primary, reference measurement procedure (HPLC -IDMS and GC-IDMS)

9	Soils, Sludge's and Sediments Soils, Sludge's, Sediments	Inorganics (Trace to % Levels)	Measurement by a single, primary, reference measurement procedure (ICP-IDMS) and/or measurement by a network of qualified laboratories using a variety of measurement procedures of demonstrable accuracy.
10	Analysed Gases Single and Multi Component Gas Mixtures	ppm to % Levels Carbon Monoxide/Nitrogen Carbon Dioxide/Nitrogen Nitric Oxide/Nitrogen Propane/Air Propane/Nitrogen Methane/Air	Measurement by two or more independent reference measurement procedures. Method selected from: NDIR, NDUV, GC-FID, GC-TCD or chemiluminescence.