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Technical Note

What is Accreditation?

Laboratories around the world process and analyze hundreds of thousands of samples each day. Without an assurance of competency and accuracy, those results could be called into question, risking the world's health, safety and economy. Since the 1940s, the International Organization for Standardization (ISO) has become one of the world's largest developers of voluntary international standards from all manners of manufactured, agricultural and technological products and services. In the 1990s, ISO began creating standards for laboratories to standardize procedures and ensure competency and accuracy. Through the years, laboratories and reference material providers have pursued ISO accreditation for their facilities as a mark of quality and reliability. Recently, laboratory and reference material standards have been expanded or rewritten. Many established accredited laboratories are now wondering how these recent changes will affect their business. New unaccredited industries and laboratories are trying to understand the standards and the accreditation process in order to prove their own competency and value. In this note, we will look at the most common questions regarding ISO accreditation and how the new changes apply to laboratories and reference material suppliers.

What is accreditation?

Accreditation is the confirmation of the competence of a testing or calibration laboratory or reference material (RM) producer by an unbiased independent third party accreditation body to an ISO international standard.

What are the accreditation bodies?

Each nation usually has several organizations which are considered to be accreditation bodies. There is cooperation between international organizations with a goal to provide international agreement between accreditation bodies. Accreditation bodies give an unbiased evaluation of the competence of a laboratory to meet the requirements of the international standard.

What is the procedure to become an accredited laboratory or reference material producer?

A laboratory or company can become accredited to a particular ISO standard by applying to a third party accreditation body. The laboratory or company will enter into an agreement with the third party accreditation body to perform the necessary evaluations of their competency to become accredited under a particular ISO international standard. This evaluation of their competency will involve a technical review of their procedures and periodic on-site audits. A proficiency testing program is also used to determine competency. An assessment report will be created by the auditors listing any deficiencies that were noted in the audit. These deficiencies or non-conformances must be corrected before the company can receive accreditation to a particular ISO standard.

What is ISO/IEC 17025?

ISO/IEC 17025 is the standard for the 'General requirements for the competence of testing and calibration laboratories'. This standard is used by testing and calibration laboratories worldwide to demonstrate their technical competence. The standard was originally issued in 1999 and was followed by a second release in 2005. The 2005 version contained five elements: Scope, Normative References, Terms and Definitions, Management Requirements, and Technical Requirements. The main sections of the standard are: Management Requirements and Technical Requirements.

The management requirement section was comprised of documents mainly relating to the quality management system of the laboratory. The technical requirements section related to all the factors relating to the reliability of a laboratory or product including: accuracy, precision, stability, homogeneity, traceability, and uncertainty of the tests, products and calibrations performed in the laboratory.

The standard ISO/IEC 17025:2005 was revised again in 2017 to ISO/IEC 17025:2017.

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What exactly are accuracy, precision, stability, homogeneity, traceability, and uncertainty?

Accuracy is the degree in which a result or measurement correlated to the 'true value' while **precision** is how close measurements or results are to one another. High precision is often associated with reproducibility, while high accuracy is associated with close correlation to the target or true value.

Stability is the state of being non-reactive during normal use. A reference material or reference standard retains it properties in the expected timescale in the presence of expected conditions of the application. An unstable material is one which will corrode, decompose, polymerize, burn, or explode under normal conditions and applications.

Homogeneity is the state of being of uniform composition or character. Reference materials can have two types of homogeneity: in-bottle homogeneity or between-bottle (or lot) homogeneity. In-bottle homogeneity means there is no precipitation or stratification of the material that cannot be rectified by following instructions for use. Some reference materials can settle out of solutions but are still considered homogeneous if they can be re-dissolved into the solution by following the instructions for use (i.e. sonicate, heat, shake, etc.). Between-bottle or lot homogeneity is the homogeneity found between separate packaging units,

Traceability is the ability to trace a product or service from the point of origin through the manufacturing or service process through to final analysis, delivery and receipt. Reference material producers must ensure that the material can be traced back to a primary standard. A primary standard is a standard of the highest metrological value that is accepted without reference to another standard of the same quality. Secondary standards are standards that are assigned a value by comparison of the same quantity of a primary standard.

Uncertainty is the estimate attached to a certified value that characterizes the range of values where the 'true value' lies within a stated confidence level. Uncertainty can encompass random effects such as changes in temperature, humidity, drift accounted for by corrections, and variability in performance of an instrument or analyst. Uncertainty also includes the contributions from within-unit and between-unit homogeneity, changes due to storage and transportation conditions, and any uncertainties arising from the manufacture or testing of the reference material. Uncertainty, however, is not error or mistakes. Error is the difference between the stated measurement and the true value of the measurand. Error causes values to differ when a measurement is repeated.

Both the earlier ISO/IEC 17025 standard and the newly implemented 2017 version address the issues of documenting, calculating and verifying the parameters of uncertainty, stability, traceability, and homogeneity to improve accuracy and precision.

What is ISO 17034?

ISO 17034, and its predecessor ISO Guide 34, refers to a document called 'General requirements for the competence of reference material producers' which was originally drafted by ISO/REMCO in 1991 and published in 1996. An update was published in 2009 and in 2016 was changed from a guide to an actual standard called ISO 10734.

This standard was published to allow the transfer of results between testing, analytical and measurement laboratories by using certified reference materials produced by certified manufacturers. These materials would be used for the calibration of measurement equipment and evaluation or validation of measurement procedures. For the certified reference material producers, ISO 17034 requires demonstrations of scientific and technical competence. It also requires certified values and supplementary information be provided about reference materials including traceability, uncertainty, preparation, methods of measure, etc.

ISO 17034 also includes references to several other documents including ISO/IEC 17025 (previously discussed), ISO Guide 31: Reference Materials - General and statistical principles for certification, and ISO/TR 16476: Establishing and expressing meterological traceability of quantity values assigned to reference materials.

Some of the major points for reference material users are the requirements for RM producers to:

- Verify the identity of the reference material
- Provide necessary advice on the storage and use of the material in order to maintain stability
- Record secondary parameters (such as temperature, humidity, etc.) that can have influence on a reference material's certified value (or its uncertainty) for traceability
- Assess the effect of repeated use or sampling of a reference material (under the instructions for use) for stability of the material and provide guidance for maintaining material stability
- Identify uncertainty contributions for a reference material which are included in the assigned uncertainty of certified values

What is a 'Scope of Accreditation'?

The scope of accreditation for a reference material producer or laboratory is the detailed statement of all the activities, tests, analyses, compounds, instruments, equipment, etc. for which the laboratory or company is accredited. The accreditation body ensures that the laboratory or provider has the competence to provide the products or services defined within the scope. The scope provides both the areas of competence and details on any calibrations or certifications covered by the scope.

How do you read a Scope of Accreditation?

A scope of accreditation for products or materials with numerical values are part of the calibration and measurement capabilities of an organization, laboratory or manufacturer that represents the uncertainty assigned to that measured or certified value. These values (expressed as either a number of formula) are the values assessed by the accreditation body of the laboratory or manufacturer taking into consideration their personnel, equipment and processes.

The format of a scope usually has tables of information and values which are often divided up by parameters. For example, for reference material producers, the table may contain a list of uncertainty sources with their corresponding calculation or values. These calculations of uncertainty can vary in complexity with the type of uncertainty.

What are the different types of uncertainty and what do they mean?

There are two basic classifications for types of uncertainty: type A and type B uncertainty. Type A uncertainty is associated with repeated measurements and the statistical analysis of the series of observations. Type A uncertainty is calculated from the measurement's standard deviation divided by the square root of the number of replicates.

Type B uncertainty is based on scientific judgment made from previous experience and manufacturer's specifications. There are three common models for type B uncertainty: rectangular, triangular and normal. Rectangular distribution is used when a certificate or other specification is provided and gives limits without specifying a confidence level. Triangular distribution is used when the measurement distribution is symmetrical and when values are close to the target value and not near the boundaries. This distribution is commonly associated with volumetric glassware. The final distribution is normal distribution which is used when an estimate is made from repeated observations of a randomly varying process and an uncertainty is associated with a certain confidence interval. This type of uncertainty distribution is often found with a calibration certificate with a stated confidence level. Reference material providers accredited by ISO/IEC 17025 and ISO 17034 provide certificates using combined and expanded uncertainties within a normal distribution. These certificates contain stated values and the uncertainty associated with that value as well as the contributions to those uncertainties.