

Why become an Accredited Reference Material Producer



When Reference Materials are needed

Laboratories use reference materials for a variety of purposes. They include:

- *Establishment of metrological traceability of measurement results.* For most measurements, their objective is to compare the results with a prescribed value or with results obtained by other laboratories. Without metrological traceability, measurement results will not be comparable and hence unable to achieve this objective. ISO/IEC 17025 acknowledges that certain calibrations currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as the use of certified reference materials (CRMs) produced by a competent producer to give a reliable physical or chemical characterization of a material. This requirement is also applicable to testing where traceability of measurement to SI units is not possible and/or relevant.
- *Validation of Test Method.* Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. CRMs offer a most effective means to assess the trueness and precision of a measurement process.
- *Quality control.* Reference materials (RMs) provide one of the most effective ways of assessing and demonstrating that the measurement process is in statistical control because the homogeneity and stability of RMs have been confirmed to be suitable to be used as quality control materials.



Why Reference Materials Produced by Accredited Producers are used

For whatever purposes, to ensure the quality of RMs, it is desirable to use RMs that are produced by competent producers. Accreditation is a means of determining the technical competence of RMPs to produce specific RMs. It also provides formal recognition to competent RMPs, thus providing a ready means for RMs users to identify and select the most suitable RMs that meet their needs. This recognition of competence relates to the properties of the reference materials the accredited RMP produces, and may include, if applicable, the ranges of the assigned values and their associated uncertainties. It may also include the RMPs involvement in the performance of testing, calibration and measurements in relation to homogeneity, stability and characterisation assessments and their use of subcontractors in these tasks. These are the factors that RM users need to know and consider when selecting RMs.

Accredited RMPs are required to issue a certificate for CRMs, and provide appropriate documentation for non-certified RMs in the form of a statement or product information sheet howsoever named, according to the requirements given in ISO Guide 34 and ISO Guide 31, and the certificate / statement / product information sheet can bear the accreditation body's accreditation symbol. This ensures that the certificates / statements / product information sheets include all necessary information, and the endorsement with the accreditation body's accreditation symbol indicates the accreditation status of the RMP.

According to the ILAC policy in regard to metrological traceability provided by RMPs, the values assigned to CRMs produced by an accredited RMP under its scope of accreditation to ISO Guide 34 are considered to have established valid metrological traceability. When RMs produced by non-accredited RMPs are used, these are considered as critical consumables and the laboratory is required to demonstrate that each RM is suitable for its intended use. The use of RMs produced by accredited RMPs save laboratories the task of verifying the RMs as critical consumables.



Benefits of becoming accredited

- Accreditation is recognition of competence. The accreditation criteria for RMP is ISO Guide 34 *General requirements for the competence of reference material producers*. This Guide specifies the general requirements in accordance with which a RMP has to demonstrate that it operates, if it is to be recognized as competent to carry out the production of RMs. Accreditation means that the RMP meets the requirements of ISO Guide 34. This ISO Guide covers the production of RMs considered as a “family term”, including certified and non-certified RMs.

(Note: ISO has decided to change ISO Guide 34 to an ISO standard. Once published, this ISO standard replacing ISO Guide 34 will be used as the accreditation criteria for RMPs)

- Accreditation provides RMPs with a benchmark for maintaining competence. To maintain this recognition, RMPs are re-assessed periodically by the accreditation body to ensure their continued compliance with requirements, and to check that their standard of operation is being maintained. Proficiency testing can be used to monitor the on-going competence of the testing and calibration activities done by the RMPs.
- A regular assessment by an accreditation body checks all aspects of a RMP's operations related to consistently producing reliable RMs. Areas for improvement are identified and discussed, and a detailed report provided at the end of each visit. Where necessary, follow-up action is monitored by the accreditation body so the RMP is confident that it has taken the appropriate corrective action.
- Accreditation is an effective marketing tool for RMPs. It provides assurance that the accredited RMPs are competent to produce the RMs as listed in the scope of accreditation. It provides confidence to RM users that the reference materials (RMs), and certified reference materials (CRMs) in particular, are produced according to technically valid and internationally recognized principles, and fitted for the intended uses. These uses include the assessment of precision and trueness of measurement methods, quality control, assigning values to materials, calibration, and the establishment of conventional scales. This eliminates the needs of the users to evaluate the quality of the RMs themselves.
- RM users usually check with the RMP as to what specific category and/or subcategory of RM (including the matrix), the property(ies) characterized; ranges of assigned values



Benefits of becoming accredited *continued*

and associated uncertainties (if applicable); and the characterization technique(s) they are used for the production of the RMs. This information is usually available in the RMP's scope of accreditation issued by the accreditation body, and the scope also includes the RMP's contact details. The scope of accreditation facilitates RM users in identifying the RMs they needed. This is an effective means to disseminate the necessary information to RM users.

- RMs are used globally. Many economies around the world have accreditation bodies offering accreditation to RMPs. These accreditation bodies have adopted ISO Guide 34 as the criteria for RMP accreditation. This has helped economies to adopt a uniform approach to determining RMP competence. This uniform approach allows accreditation bodies in different economies to establish arrangements among themselves, based on mutual evaluation and acceptance of each other's RMP accreditation systems. ILAC is in the process of establishing a mutual recognition arrangement (MRA) for RMP accreditation but at present, the ILAC MRA does not cover the accreditation of RMPs. At the regional level, APLAC operates an MRA for RMPs and a number of economies operate systems for the accreditation of RMPs, and the number of accredited RMPs is increasing. The use of CRMs produced by accredited RMPs is recognized by ILAC as providing valid metrological traceability. Therefore, being accredited will assist the acceptance of the RMs produced globally.



How do Reference Material Producers become accredited?

RMPs can have either all or part of their RM produced accredited. The accreditation process involves the use of technical specialists who assess the specific types of RMs being produced. The accreditation criteria are based on ISO Guide 34: *General requirements for the competence of reference material producers*, which is used for assessing RMP throughout the world. RMP accreditation bodies use this international guide specifically to assess factors relevant to a RMP's competence to produce RMs, including the:

- Operation of a management system
- Technical competence of staff
- Appropriateness of production plan
- RMs produced are sufficiently homogenous and stable
- Certified values are metrological traceable to a reference
- Suitability of RMs distribution process

At the end of the assessment a detailed report on the assessment is presented to the RMP, highlighting any areas that require attention and corrective action before the RMP can be recommended for accreditation.

Once accredited, the RMP is regularly re-assessed to ensure its continued compliance with requirements, and to check that its standard of operation is being maintained.

All these factors contribute to a RMP being formally recognized as technically competent to produce specific RMs.

For more information, you will need to contact your ILAC recognised accreditation body. Visit the ILAC website at www.ilac.org and use the directory of accreditation bodies available on this website.



About ILAC

ILAC facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement – the ILAC Arrangement – among Accreditation Bodies (ABs) in order that the data and test results issued by laboratories and inspection bodies, collectively known as Conformity Assessment Bodies (CABs), accredited by ILAC Accreditation Body members are accepted globally. Thereby, technical barriers to trade, such as the re-testing of products each time they enter a new economy is reduced, in support of realising the free-trade goal of “*accredited once, accepted everywhere*”.

In addition, accreditation reduces risk for business and its customers by assuring that accredited CABs are competent to carry out the work they undertake within their scope of accreditation.

Further, the results from accredited facilities are used extensively by regulators for the public benefit in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services.

ABs that are members of ILAC and the CABs they accredit are required to comply with appropriate international standards and the applicable ILAC application documents for the consistent application of those standards.

ILAC is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

It is a representative organisation that is involved with:

- the development of accreditation practices and procedures,
- the promotion of accreditation as a trade facilitation tool,
- supporting the provision of local and national services,
- the assistance of developing accreditation systems,
- the recognition of competent testing (including medical) and calibration laboratories, inspection bodies, proficiency testing providers and reference material producers around the world.

ILAC actively cooperates with other relevant international organisations in pursuing these aims.

ABs having signed the ILAC Arrangement are subject to peer evaluation via formally established and recognised regional cooperation bodies using ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.



The ILAC website provides a range of information on topics covering accreditation, conformity assessment, trade facilitation, as well as the contact details of members. Further information to illustrate the value of accredited conformity assessment to regulators and the public sector through case studies and independent research can also be found at:

www.publicsectorassurance.org.

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