ISO Guide 34 Accredited Manufacturers—Do You Know What You Are Getting?

Accreditation to ISO Guide 34 "General Requirements for the Competence of Reference Material Producers" is designed to ensure competency in the manufacture of reference materials and assurance that international guidelines are followed in the production and assignment of material property values. Accreditation to ISO Guide 34 not only involves technical competence and good quality management practices but also adds verification of critical production management specific to reference material producers. A Certified Reference Material (CRM), according to ISO Guide 34, is a "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." (1)

Originally, accreditation to ISO Guide 34 meant the manufacturer was producing CRMs. When the third edition was published, two separate designations were provided: CRMs and Noncertified Reference Materials (1). How do these designations impact laboratories and their analytical results? Requirements for Noncertified Reference Materials are less stringent and lack many of the critical aspects of data reporting under the CRM designation, including characterization of the material, stability reporting, assignment of property values and their uncertainties, and establishment of metrological traceability. The purpose of this article is to highlight the importance of these elements to the analytical laboratory when considering a suitable reference material.

Section 4.1.1 of ISO Guide 34 states that a reference material needs to be characterized to the level of accuracy required for its intended purpose (1). The decision falls to the manufacturer to determine what level of accuracy is appropriate for material characterization. If the manufacturer is offering a Noncertified Reference Material, characterization is not required. Full characterization will provide a laboratory with confidence in identity and purity of the material and provide values to calculate a proper weighing adjustment. With limited to no characterization, a laboratory cannot have confidence in the quality or accuracy of the material or its suitability for the laboratory's intended use (2). Insufficiently certified materials can lead to misidentification and inaccurate preparation of calibrators and controls which can result in erroneous data. To prevent this, a laboratory would need to perform its own testing to properly characterize the material.

Stability reporting, another critical CRM requirement under ISO Guide 34, is also not mandated for a Noncertified Reference Material. Reporting of stability information provides the laboratory assurance in product integrity during transport and normal laboratory use, as well as stability for long-term storage or in case of accidental excursions. FDA and other regulatory bodies, as well as ISO and other accrediting organizations, may require stability information to support test result integrity (2, 3). If not available, the laboratory could experience a compliance issue during an audit (4).

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Assignment of property values and their uncertainties is a required component of multiple ISO accreditations from ISO/IEC 17025 to Guide 34 (5, 6). A statement of the measurement uncertainty is mandatory under Guide 34 for certified property values (7). For noncertified property values, reporting the measurement uncertainty is not required. Property values assigned to Noncertified Reference Materials are for information purposes only which limits use of the material. Guide 34 highly recommends reporting measurement uncertainty of a Noncertified Reference Material to improve its use (7).

How does use of a Noncertified Reference Material without measurement uncertainty impact laboratory compliance? In Driving Under the Influence (DUI) cases, some state courts require a statement of measurement uncertainty on a test result. In the district court of Michigan's Mason County, for example, a judge dismissed blood sample evidence in a DUI case as unreliable, because uncertainty had not been defined. In the judge's opinion, the absence of measurement uncertainty implies an absolute value. If the same sample was run multiple times, according to the judge, test results would likely be different each time (8). In order to decide whether a result indicates compliance or noncompliance to a specification, the

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laboratory must take into account the measurement uncertainty associated with the result (9).

ISO Guide 34, in section 5.12.1, states that reference material manufacturers "... shall provide documentary evidence on the metrological traceability of the measurement results to a stated reference" (10). Traceability can be achieved through an unbroken chain of calibrations, all having stated uncertainties (10). The concept of traceability allows laboratories to establish a common point of reference which ensures accuracy of results and international comparability in measurement (11,12). Without a common point of reference for comparison, the result is meaningless (12). Test results are metrologically traceable through CRMs if using a reference method. However, establishment of metrological traceability is not required for Noncertified Reference Materials (1).

Accuracy—of the method, reference material, and ultimately the test result—is critical to measurement, value assignment, and critical decision making. If an analytical laboratory uses either research-grade or Noncertified Reference Materials that have values assigned without traceability to SI or an accredited calibration laboratory, then they cannot demonstrate a chain of traceability. Lack of traceability can infer the inability to assure accuracy.

For many years accreditation to ISO Guide 34 has been associated with providers of CRMs. Today this is no longer true. Having the option of less stringent requirements has allowed providers of Noncertified Reference Materials to become accredited to ISO Guide 34. With this change, it is critical for analytical laboratories to be aware that Guide 34-accredited suppliers may not be manufacturing CRMs. Laboratories should evaluate their suppliers to ensure the level of quality meets their needs for intended use. ■

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The opinions expressed in the article are those of the authors and do not necessarily represent those of any organization listed.

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Looking to the Future

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has been challenged by the BOD to consider many alternatives to the "way we have always done things." Not only have they responded to the requests made by the BOD, but they have also brought forth many of their own initiatives that will help and strengthen AOAC in the future. We have repeatedly challenged the OMB to look at new ways of doing things, but to never sacrifice the quality of the AOAC brand, and they have done all that was asked of them and more.

I want to also thank the members that took their personal time this year to contact me to ask questions, challenge directions, or just bounce ideas off of me for improvements to AOAC. I greatly appreciated each and every one of these contacts.

Have a great meeting in Chicago, continue to increase your involvement with AOAC, and if there is ever anything I can do to help you, please don't hesitate to ask.

It has been a pleasure to serve as president of AOAC. Thank you for the opportunity. ■

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