NEMC Draft Paper

ISO Guide 34 and Second Source

Most “second source”, as well as primary source, materials are obtained from a reference material producer (RMP). Due to the reliance on these materials in testing activities to establish traceability, set calibration curves, establish uncertainty statements, etc. the industry has demanded an evaluation of these organizations’ competence to produce these standards. This in part led to the development of the standard ISO Guide 34 which establishes the general requirements for a RMP to meet to ensure competent operation and production of reference materials. ISO Guide 31 which details the requirements of the certificates and labels issued by a RMP even address the idea of “second source” material by stating “Certifying bodies should always avoid the situation where failure to disclose relevant information about the source may result in the CRM being used to validate an analytical method applied to the same batch of material as the CRM.”

Per the International Organization for Standardization (ISO), ISO Guide 34:2009 - General Requirements for the Competence of Reference Material Producers“is intended for the use by reference material producers in the development and implementation of their management system for quality, administrative and technical operations. Reference material customers, regulatory authorities and accreditation bodies may also use it in confirming and recognizing the competence of reference material producers.” Unlike other international standards like ISO 9001 which only addresses and organization’s quality management system, ISO Guide 34 is specific to the activities that a RMP undertakes in the production of its reference materials and there are requirements that the RMP conducts those activities competently. Areas of additional specific requirements include production planning, production control, material handling and storage, material processing, data evaluation, metrological traceability, assessment of homogeneity, assessment of stability, characterization, assignment of property values and their uncertainties, certificates and documentation for users, and distribution services. All of these additional areas are critical to production of a quality reference material which can be relied upon.

ISO Guide 34 also requires that a reference material producer meets the applicable requirements of ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories for any testing and calibration activities in which I partakes in the production of the reference materials. It is critical that the RMP is competently performing the testing activities that support their production as these activities will support the final assigned values and uncertainties of the reference material.

A RMP can create and implement a management system that meets the requirements of the standard and assess themselves to the requirements and make an attestation of such. However, many organizations have chosen to also pursue accreditation from a third party accreditation body for the reference materials that they produce. This third party attestation that the RMP meets the requirements of the standard allows increased confidence in the users of their products and often grants them increased recognition in many markets. It is important that the accreditation body is also competent to perform the assessment of the RMP. It is recommended that the accreditation body is part of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement as they have been evaluated and deemed competent to perform those assessments. For more information <https://www.ilac.org/ilacarrangement.html>.

A RMP that has been accredited will be issued a scope of accreditation that details the types of reference materials that it is competent to produce. These categories are typically based upon the guidance in ILAC G12 Appendix B (<https://www.ilac.org/guidanceseries.html>). Currently there are limited requirements to dictate the information that an accreditation body must include on the scope of accreditation for a RMP. The scope may not detail things such as testing method used by the RMP to determine the assigned values, specific concentration ranges or uncertainties, each specific analyte that could be included in a reference material, etc. However, this information will generally be included on the certificate provided by the RMP if it is a certified reference material. A RMP is required to meet the requirements of ISO Guide 31 for the certificates and labels that are issued. If there is ever a question regarding the acceptability of a reference material for your use it is suggested that you request an example certificate to verify it is fit for your intended purpose.

So, there are internationally recognized requirements and an assessment processes for the evaluation of RMPs in which the competence to produce a reference material is determined. There are similar requirements for the testing and calibration laboratories that are the users of the reference materials some of which may be these second source materials. However, in many cases there are no requirements for the manufacturers of the starting materials (chemicals, pesticides, etc.) from which the reference materials are being produced. The manufacturers of these starting materials are not typically in the business of producing a product with the intent of it being used as a starting product for a reference material. However industry, government, regulators, etc. have demanded that the material they produce be tested for its presence in things like waste water, soil, toys, etc. This has essentially made the manufacturer of a product, a supplier of a starting material for a RMP in their production of reference materials.

An ISO Guide 34 accredited/compliant RMP is required to evaluate their suppliers of critical consumables, services, and supplies which include these starting materials. The challenge in evaluating suppliers in many instances is that the manufacturer does not maintain accreditation for testing or reference material production but they may be registered to another standard such as ISO 9001. ISO 9001 registration gives the RMP assurance that the manufacturer has implemented a quality management system that meets the requirements of ISO 9001, however ISO 9001 registration does not include evaluation of the technical competency of the manufacturer to produce a “quality” product which would include the testing and production processes. These causes concerns when evaluating a potential supplier especially when the supplier is providing a test report and/or certificate that contain data that the RMP would need to rely upon when producing their reference materials. This situation is further complicated by the fact that in many instances the RMP may not have another option for the supplier of the starting material as that manufacturer may be the sole source or possible the only “second source” available.

ISO Guide 34 addresses the production of reference materials including the processing of the starting material. However, when the starting material is being provided by a manufacturer or perhaps a third party supplier that is not accredited to ISO Guide 34 or comparable standard it will likely cause the RMP to conduct additional testing and to have increased uncertainty associated with the final product. This will result in a reference material that will likely be more costly and, due to the higher uncertainty, may not be ideal for its intended purpose as a second source material. However, it may be the only option available.