

ISO Guide 34

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ACCREDITED
ISO GUIDE 34
BY A2LA

INORGANIC VENTURES
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ISO Guide 34 Certified Reference Materials (CRMs)

A Brief History of Guide 34

The first edition of ISO Guide 34 was published in 1996 and dealt with the interpretation of ISO/IEC Guide 25 in the area of Reference Material Production (RMP). At this time Inorganic Ventures was a Guide 25 RMP, and accreditation to Guide 34 was not available. The interpretation of Guide 25 as it is related to RMP was a popular topic and was considered important.

The assessment of the competence of reference material producers was gaining more attention, and to fill that need the second edition of ISO Guide 34 was published in 2000. Guide 34:2000 set forth all the general requirements a reference material producer has to demonstrate that it operates within. It was made available for accreditation by A2LA. Inorganic Ventures was one of the first three organizations to obtain accreditation to Guide 34:2000, along with Brammer Standard and Bethlehem Steel. Inorganic Ventures obtained this accreditation in July of 2000, just five months after Guide 34:2000 was made available.

The 2009/current edition makes these requirements mandatory and in line with ISO/IEC 17025:2005. The third edition also includes the production of non-certified reference materials as well as CRMs. The production of RMs leaves CRM requirements such as purity characterization of the material, stability assessment, the assignment of a property value and uncertainty and metrological traceability up to the discretion of the RMP. If you decide to purchase a RM, rather than a CRM, make certain that you have checked with your Quality Manager, otherwise you may find yourself in non-compliance at audit time.

The third edition also requires compliance with the following guides:

- ISO Guide 30, Terms and Definitions used in Connection with Reference Materials
- ISO Guide 31, Reference Materials — Contents of Certificates and Labels
- ISO Guide 35, Reference Materials — General and Statistical Principles for Certification
- ISO/IEC Guide 17025, General Requirements for the Competence of Testing and Calibration Laboratories

ISO Guide 34 — Standards

A **True Value** in the field of Analytical Chemistry is a theoretical goal that every RMP and analyst strives for, but ONE that no one will ever achieve. A **True Value** would be obtained by a perfect measurement. Since a perfect measurement does not exist, the best an RMP can provide is a Certified Value with an uncertainty in the goal of containing the **True Value**.

In other words the goal is to produce an accurate CRM. RMPs have only been using the ISO standards for Quality Management and Assurance since ISO issued the ISO 9000 Series Standards in 1987. ISO Guide 34, which deals specifically with the production of CRMs, has resulted in a significant improvement in the reliability of CRMs produced by RMPs. This section is for the analyst that has been told that they are now required to buy Certified Reference Materials (chemical calibration standards) that adhere to ISO Guide 34. It would only be natural to wonder what the differences are between Guide 34 CRMs and what they are using.

The bottom line is that the use of Guide 34 CRMs is rapidly becoming a requirement for any company involved directly with

international business. The ISO quality standards have helped greatly to lower the risks of doing business with unfamiliar international, as well as national and local businesses. However, Guide 34 cannot guarantee that your analytical measurement will not be inaccurate due to an inaccuracy in the CRM. The intention of a Guide 34 CRM is to be as close to perfect as humanly possible.

The following is a list of the steps and precautions taken by Inorganic Ventures based upon the requirements of Guide 34:2009 and our interpretation of it:

- All testing methods are traceable to the SI. The SI is an abbreviation for *Système International d'Unités* (International System of Units).
- All testing is performed using methods that have been validated (shown to be accurate).
- Quality control CRMs are analyzed with each test or assay and the data are statistically reviewed (shows that the method was executed properly and that nothing has changed since the method was validated).
- For stock, multiple testing methods are used for each CRM certified value when possible.
- For stock, multiple samples are taken for CRM certification.
- All batches/lots of CRM are tested for homogeneity before and after packaging.
- Long-term stability studies are conducted for every CRM.
- CRMs are shipped to extreme temperature locations and then tested to determine short-term stability during shipment.
- The uncertainty for each Certified Value is determined from an error budget that includes the uncertainty due to characterization, long-term stability short-term (shipping) stability and homogeneity.
- Packaging containers are selected, tested and cleaned according to product requirements using controlled methods.
- All quality critical volume measuring apparatus such as pipettes, burettes and volumetric flasks are identified, calibrated, checked and maintained according to Class A specifications.
- All quality critical laboratory area temperatures are maintained and kept at 20 ± 1 °C. Temperature corrections for measurements sensitive to temperature are made.
- All balances are certified, checked and logged before each use.
- All methods associated with the design, production, storage, shipping and technical support of every CRM are controlled documents.
- All starting materials, chemicals, equipment, and laboratory supplies are purchased from approved and evaluated vendors.
- ISO Guide 34 RMPs are audited and must conform to the following ISO Guides:
 - » ISO Guide 30, terms and definitions used in connection with reference materials,
 - » ISO Guide 31, Reference materials — Contents of certificates and labels,
 - » ISO Guide 35, Reference materials — General and statistical principles for certification.

- » ISO/IEC Guide 98-3, Uncertainty of measurement — Part 3: Guide to the expression of uncertainty measurement (GUM),
- » ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.
- CRMs are assessed for commutability where appropriate.
 - » Post-certification stability monitoring is conducted if applicable.
- An adequate post-distribution service for reference material customers is required.

ISO Guide 34 — pH Buffers

Inorganic Ventures produces a broad range of ISO Guide 34 pH buffers from 1.68 to 12.45 pH units. Custom pH CRMs are also available upon request. Traceability to the SI is achieved through primary pH standards (PS), which are produced by NIST. All of IV's pH buffers are directly measured versus NIST standards where the pH measurements are carried out by means of the following cell:

Reference electrode | KCl || solution [pH (NIST STD) or pH (unknown)] | glass electrode

The uncertainty of the pH standards produced by a commercial RMP should be given lots of attention by the analyst. Uncertainties using a Harned Cell by an National Meteorology Institute (NMI) such as NIST in the production of a PS are ~0.004 pH units. Commercial manufacturers, such as Inorganic Ventures, using a glass electrode obtain uncertainties of no better than 0.02 pH units. Cells used by an NMI do not have transference errors when using a hydrogen gas electrode (cells without transference, Harned cell) as compared to cells with transference errors that are used by commercial RMPs. It has been the experience of Inorganic Ventures, and others, that when using a glass electrode an uncertainty of no better than 0.02 pH units is possible¹ (Ref (1) gives an excellent treatment of pH measurement uncertainty using different cell configurations and explains the sources of pH measurement errors). Our uncertainties are not intended to impress you, but rather to provide you with an accurate and reliable level of uncertainty and are values you can rely upon.

(1) *MEASUREMENT OF pH. DEFINITION, STANDARDS, AND PROCEDURES R.P.BUCK, et.al., Pure and Appl. Chem., Vol. 74, pp 2169–2200, 2002*

ISO Guide 34 — Conductivity Buffers

Inorganic Ventures produces a broad range of stock and customized electrolytic conductivity CRMs that range from 2–175,000 µmhos/cm. Custom Conductivity CRMs are also available upon request. All of our electrolytic conductivity CRMs are manufactured using 18 MΩ water and high purity KCl. Electrolytic conductivity CRMs are certified by direct comparison to NIST SRMs.

The stabilities of these CRMs have been extensively studied including instabilities due to biological growth, transpiration, leaching from the container walls, adsorption on the container walls and adsorption of CO₂ from the air. The uncertainty of each product includes the uncertainty components from characterization as well as long-term stability, short-term stability and homogeneity. Our uncertainties are intended to provide you with an accurate and reliable level of uncertainty and are values you can rely upon.

ISO Guide 34 — Evaluating Suppliers

Many of our business, medical and legal decisions are being made based upon chemical measurements. This places more pressure on the analyst to produce accurate and reliable data to defend a given decision, explain an occurrence, plan the future or predict an outcome. Many companies now require that their analysts and suppliers use certified reference materials (CRMs) that are produced by an ISO Guide 34 accredited reference material producer (RMP). It is likely that you are using CRMs in several capacities including the calibration of testing equipment, validation of test methods and as quality control samples. Calibrating, validating and monitoring the quality of your analytical results are all tasks that are critical to the accuracy of your data. Inaccurate CRMs lead to inaccurate data resulting in poor decisions. Below is a list of considerations for the potential customer before deciding upon a RMP provider.

DON'T FAIL TO:

- Check your RMP to confirm that they are accredited. A CRM manufacturer that claims adherence to the Guide 34 requirements, but is not accredited may not meet your company's requirements. The RMP should have a Certificate number and validation period on their Certificate of Accreditation, which is typically available through their website.
- Confirm that you are purchasing a Certified Reference Material CRM and not a noncertified Reference Material (RM). The third edition of Guide 34 has provided for the production of noncertified Reference Materials. The production of RMs leaves CRM requirements, such as a purity characterization of the material, stability assessment, the assignment of a property value and uncertainty and metrological traceability, up to the discretion of the RMP. If you decide to purchase a RM rather than a CRM make certain that you have checked with you Quality Manager otherwise you may find yourself in non-compliance at audit time.
- Confirm that the CRM you intend to purchase is included in the Scope of Accreditation. An RMP is accredited to Guide 34, but this does not mean that all of the products are produced according to the requirements for a CRM. Therefore, finding a product on the Scope of Accreditation is critical. Hopefully the RMP will make this process easy for you.
- Check a sample certificate of analysis to make certain that your areas of key importance have been addressed to your satisfaction, and to that of your Quality Manager. If you are still not sure after inspecting a sample certificate, ask for the actual Certificates of Analysis to be sent for your approval prior to purchase. This should be available for all stock products.
- If you have technical questions about the applicability of the CRM to the intended use, ask the RMP. Remember that there are no bad questions.
- For aqueous atomic spectroscopic CRMs, confirm that the expiration date meets your accuracy requirements by weighing the CRM one month after opening, and then by calculating the % increase in concentration at the expiration date. A long expiration date may wind up costing much more than is saved.

ISO Guide 34 — Summary

A lot is riding on the accuracy of your calibration, quality control and validation data. Accurate test measurement data requires accurate CRMs. In support of this fact, ISO has written Guide 34, which is used to assess the competence of reference material manufacturers.

The ISO Guides have been instrumental in breaking down international trade barriers and Guide 34 is a critical component. Reference material producers (RMPs) from around the world are now assessed by the same Quality Standards. In a world where more and more decisions are being made based upon chemical test results, the use of CRMs manufactured by a Guide 34 RMP is a requirement for doing business.

ISO Guide 34 — Product Lines

Inorganic Ventures Scope of Accreditation can be viewed from the following link: <http://www.inorganicventures.com/sites/default/files/ISOGuide34-Certificate-and-Scope.pdf>

The product lines that are included in our Guide 34 Scope are as follows:

- Stock ICP-OES single element CRMs
- Stock ICP-MS single element CRMs
- Stock ICP-MS single element isotopic CRMs
- Stock speciation CRMs
- Stock Multielement CRMs for instrument tuning, set-up and calibration with instrument manufacturer cross-referencing
- Stock Multielement CRMs for EPA Methods using ICP-OES and ICP-MS
- Stock Ion Chromatography single anion CRMs at 1000 µg/mL
- Stock Ion Chromatography single cation CRMs at 1000 µg/mL
- Stock multicomponent CRMs for Ion Chromatography including EPA Methods 300.0 and 300.1 (parts A and B)
- Stock Conductivity CRMs ranging from 2 to 175,000 µmhos/cm at 25 °C
- Stock pH CRMs at 1.68, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12 pH units
- Customized CRMs for ICP-OES, ICP-MS, Ion Chromatography, Conductivity and pH