



Levels of Accreditation

- ISO 9001:2015 for Quality Management Systems
- ISO/IEC 17025:2017 for Testing and Calibration Laboratories
- ISO 17034:2016 for Reference Material Producers



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Spex CertiPrep is an
Antylia Scientific company
Find out more at antylia.com



Levels of Accreditation

Spex CertiPrep's Three Levels of Quality Enable You to Calibrate with Confidence®

To ensure the validity of results from today's high performance instrumentation, Spex CertiPrep has developed an extensive line of high quality certified reference materials. How can we prove it?

The International Organization for Standardization (ISO) has established a set of guidelines designed to define the common business practices, increase responsibility, and ensure clarity and full disclosure in the industry. As depicted below, there are three ISO quality management systems that are most relevant for reference material manufacturers; ISO 9001, ISO/IEC 17025 and ISO 17034. Each ISO standard has its own set of internationally recognized criteria against which companies are formally measured. From level 1 through level 3, each level is more difficult to achieve and fewer companies are able to meet the required criteria. Spex CertiPrep is proud to have all three. By taking the extra step of choosing to demonstrate our competence and comply with these standards, we are continuously proving that our tests and calibration results are technically competent and our products truly are of the highest quality.



Organic and Inorganic
Certified Reference Materials



Supplied with a
Certificate of Analysis



ISO Accredited
Standards

Levels of Accreditation

Levels of Accreditation: About Each Standard and What it Means to You

Level 1: ISO 9001:2015 – Customer Satisfaction (all types of organizations)

Certified by DQS as an ISO 9001: 2015 facility for our Quality Management System

Open to all types of organizations • Written procedures • Documented complaints

Level 2: ISO/IEC 17025:2017 – Technically Sound Products (testing and/or calibration labs)

Accredited by A2LA as an ISO/IEC 17025:2017 Certified Chemical Testing Laboratory

Specifically for organizations carrying out testing and/or calibration • Competent at quality related tests • Consistent manufacturing

Level 3: ISO 17034:2016 – Traceable and Accurate Reference Materials (reference material producers)

Accredited by A2LA as an ISO 17034:2016 Certified Inorganic and Organic Reference Material Producer

Specifically for reference material producers • Validate methods to prove accuracy • Report uncertainty and sources of error

Below is a brief description of each level and how it is implemented by Spex CertiPrep

Level 1 – ISO 9001:2015 Quality Management System

This is a Quality Management and Quality Assurance System which requires companies to have written procedures and training materials for all aspects of their business. For Spex CertiPrep, this means customer service, product design, product manufacturing, product analysis, product certification, packaging, and shipping must all follow written, documented procedures. This ensures that all of our products are handled and managed the same way from start to finish. ISO 9001 also requires Spex CertiPrep to document all customer complaints, take corrective actions and establish preventative measures so that a similar complaint does not happen again.

While ISO 9001 is ideal for ensuring that customer service and satisfaction is a priority, it does not cover many of the technical and scientific aspects associated with manufacturing and testing certified reference materials. This is why we feel it is a necessity to also be certified under ISO/IEC 17025 and ISO 17034.

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Level 2 – ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories

This is a Quality Standard governing the testing in our laboratories; from determining the purity of the raw materials, to analytical testing, and finally to the record keeping and reporting of our finished product. It is designed to verify that Spex CertiPrep's established procedures are scientifically sound when used to determine measured values and that our chemists demonstrate professional competence when carrying out quality related tests. ISO/IEC 17025 inspects everything such as product design, testing, manufacturing, and quality control for all products. This inspection helps ensure that each product meets the quality, specification and purity levels established. This accreditation ensure Spex CertiPrep is always consistent and competent with the quality testing of our products.

Although ISO/IEC 17025 covers the technical aspects required by testing labs to demonstrate competency, it lacks some of the key requirements that are associated specifically with reference material producers – namely development and measurement of validation methods, the traceability and estimation of uncertainty and stability monitoring. This is why Spex CertiPrep has taken the extra step to achieve the accreditation specifically designed for CRM producers – ISO 17034.

Level 3 – ISO 17034:2016 General Requirements for the Competence of Reference Material Producers

This is a Quality Guidance Standard with specific requirements for the production of Certified Reference Materials and marks the highest level of quality assurance. It ensures that all Spex CertiPrep methods are accurate and meet set requirements. ISO 17034 also requires stability monitoring and for reference materials to be characterized to the level of accuracy for their intended purpose. Spex CertiPrep must report all uncertainty values and their sources of error on the Certificate of Analysis, as well as follow rigid requirements for the certificate's content.

ISO 17034, in conjunction with ISO/IEC 17025, is the current highest mark of achievement for reference material producers because of the amount and level of testing required to accurately characterize a reference material. Users of Spex CertiPrep's reference materials can rest assured, knowing that the products they are using have been manufactured in accordance with strict technical and management system requirements.

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The Most Comprehensive Scope in the Industry

Spex CertiPrep proudly promotes that the scope of our accreditation is the most comprehensive in the industry. What does this really mean? A company is not simply issued a certificate for ISO/IEC 17025 and ISO 17034 without having a scope attached to it. The scope is a key feature because it specifies the categories for which the accreditation applies. Unlike other companies which may have scopes that cover the production of either inorganic or organic reference materials, Spex CertiPrep's scope covers both categories. More specifically, our ISO 17034 scope includes aqueous trace metal element standards, anion and cation standards, buffers, QC samples, and organic standards. Our ISO/IEC 17025 scope covers tests on reference materials using IC, ICP, ICP-MS, GC, GC/MS, and HPLC. It also includes pH, conductivity, titrimetry, ion selective electrode, and gravimetric testing. When you combine these, you get the most comprehensive scope in the industry!

Spex CertiPrep is accredited by the internationally recognized American Association for Laboratory Accreditation (A2LA) for ISO/IEC 17025 and ISO 17034. A2LA is an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory, meaning that laboratory accreditation is based on internationally accepted criteria for competence. We are also accredited by DQS as an ISO 9001:2015 facility. Copies of Spex CertiPrep's certificates and scopes can be downloaded from our site at spex.com.

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