

THE IMPORTANCE OF ACCREDITATION

One of the ways ERA demonstrates a company-wide commitment to quality is through our comprehensive list of internationally recognized quality designations. ERA achieves registration or accreditation when an outside authority that has been qualified to review our processes and procedures evaluates us against an internationally developed set of strict requirements. These requirements span from making certain we maintain the proper physical facilities to evaluating the calculations we use in our statistical analysis.

ERA customers recognize that the products and services we provide are among the very best in the world. Our certifications and accreditations are just one facet of what distinguishes ERA as an elite manufacturer of CRMs and PTs globally. Very few manufacturers can document (through the accreditation process) the same rigorous quality programs we have in place—programs that affirm ERA's ability to provide customers with the highest quality products possible and allow for international acceptance of ERA products by laboratory accreditation bodies. Your selection of a CRM or PT provider means you are accepting of the provider's quality levels and programs and are willing to integrate their quality programs into your laboratory processes.

If quality is important to you then you should be discriminating in your vendor selection process and diligently consider your vendor's demonstrated commitment to quality.

WHAT ERA'S ACCREDITATIONS MEAN TO YOU

ERA is accredited as a provider of proficiency testing and certified reference material products.

Our two facilities in the U.S. and UK are registered to ISO 9001:2008 and accredited to ISO Guide 34, ISO 17025 and ISO 17043.*

ISO 9001

ISO 9001 is a quality management standard that applies to all types of organizations regardless of size or function. This international standard helps both product and service oriented organizations achieve standards of quality that are recognized and respected throughout the world. This is accomplished mostly through quality management practices that extend into all areas of an organization. ISO 9001 registered companies must have written procedures and training documentation in the areas of customer service, complaint handling, product design, purchasing, manufacturing, product evaluation, packaging and shipping. Included on our ISO 9001:2008 accreditation scope are Synthetic Reference Materials and Quality Control Standards.



ISO 17025

ISO 17025:2005 certification, covering the competence of testing and calibration laboratories, ensures that a company's laboratory tests are performed correctly, and that attestations of product quality are appropriate and defensible. All aspects of raw material, in-process and final product verification are covered by this accreditation. It certifies the company's ability to demonstrate the robustness of their quality program through comprehensive and accurate product testing.



ISO Guide 34

Our ISO Guide 34:2008 accreditation is targeted specifically to Certified Reference Material (CRM) manufacturers. For a manufacturer to become ISO Guide 34 registered, the policies and processes employed to design, manufacture and certify reference materials must be validated and proven to be accurate and robust. For CRMs, ISO Guide 34 also requires that each Certificate of Analysis (C of A) include an uncertainty statement that reflects all sources of error involved in certifying the standard, including measurements and material purity; it must allow for complete traceability of the CRM. In fact, the C of A itself must also conform to a strict set of criteria.

ISO/IEC GUIDE 34:2009



ISO Guide 17043

ISO Guide 17043 is designed specifically for Proficiency Testing providers. ISO 17043 specifies the essential activities that need to be evaluated when conducting inter-laboratory testing comparisons. ISO 17043 defines the criteria related to study design, sample manufacture and the ensuring of homogeneity and stability, which must be taken into account in the design and execution of proficiency testing schemes.

ISO/IEC 17043:2010



* ERA's U.S. facility is accredited to ISO Guide 34, ISO 17025 and ISO 17043 by American Association of Laboratory Accreditation (A2LA) and registered to ISO 9001:2008 by National Quality Assurance (NQA).

ERA's UK facility is accredited to ISO Guide 34 and ISO 17025 by United Kingdom Accreditation Society (UKAS) and registered to ISO 9001:2008 by Lloyd's Register Quality Assurance (LRQA).



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