CRM & ISO Information

What is a CRM (Certified Reference Material)?

Certified Reference Materials (CRMs) are 'controls' or standards used to check the quality and traceability of products. A reference standard for a unit of measurement is an artifact that embodies the quantity of interest in a way that ties its value to the reference base for calibration.

At the highest level, a primary reference standard is assigned a value by direct comparison with the Standard (metrology). For example, mass is defined by an artifact maintained by the Bureau International des Poids et Mesures in Sèvres, France. A primary standard is usually under jurisdiction of a national standards body.

Since most analytical instrumentation is comparative, it requires a sample of known composition (reference material) for accurate calibration. These reference materials as produced under stringent manufacturing procedures and differ from laboratory reagents in their certification and the traceability of the data provided.

Quality management systems involving laboratory accreditation under national and international accreditation/certification standards such as ISO 9000 and ISO 17025 require the use of Reference Materials.

Whilst Certified Reference Materials are preferred, their availability is limited. The available Reference Materials generally differ only in the detail provided on the certificate.

What is ISO/IEC 17025?

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories is the main ISO standard used by testing and calibration laboratories. Originally known as ISO/IEC Guide 25, ISO/IEC 17025 was initially issued by the International Organization for Standardization in 1999. There are many commonalities with the ISO 9000 standard, but ISO/IEC 17025 adds in the concept of competence to the equation. And it applies directly to those organizations that produce testing and calibration results. Since its initial release, a second release was made in 2005 after it was agreed that it needed to have its quality system words more closely aligned with the 2000 version of ISO 9001.

The standard was first published in 1999 and on 12 May 2005 the alignment work of the ISO/CASCO committee responsible for it was completed with the issuance of the reviewed standard. The most significant changes introduced greater emphasis on the responsibilities of senior management, and explicit requirements for continual improvement of the management system itself, and particularly, communication with the customer.

The contents of ISO/IEC 17025 - The ISO/IEC 17025 standard itself comprises five elements that are Scope, Normative References, Terms and Definitions, Management Requirements and Technical Requirements. The two main sections in ISO/IEC 17025 are Management Requirements and Technical Requirements. Management requirements are primarily related to the operation and effectiveness of the quality management system within the laboratory. Technical requirements includes factors which determines the correctness and reliability of the tests and calibrations performed in laboratory.

Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results. It is also the basis for accreditation from an accreditation body. Since the standard is about competence, accreditation is simply formal recognition of a demonstration of that

competence. A prerequisite for a laboratory to become accredited is to have a documented quality management system. The usual contents of the quality manual follow the outline of the ISO/IEC 17025 standard.

What is ISO Guide 34:2009?

ISO Guide 34:2009 specifies general requirements in accordance with which a reference material producer has to demonstrate that it operates, if it is to be recognized as competent to carry out the production of reference materials.

Guide 34:2009 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.

Guide 34:2009 is not intended to be used as the basis for conformity assessment by certification bodies.

Guide 34:2009 sets out the management system requirements in accordance with which reference materials shall be produced. It is intended to be used as part of a reference material producer's general quality assurance (QA) procedures.

Guide 34:2009 covers the production of certified and non-certified reference materials. For non-certified reference materials, the production requirements are less stringent than for certified reference materials. The minimum requirements for the production of non-certified reference materials are specified throughout the Guide.

What is ISO 9001:2008?

ISO 9001:2008 is an international standard, recognized throughout the world for establishing a business management system. ISO 9001:2008 is applicable to any manufacturing and service organization and provides a focus on system performance and ongoing improvement.

Created by the International Organization for Standardization, ISO 9001:2008 is based on eight quality management principles: customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, fact based decision-making and mutually beneficial supplier relationships. When fully adopted, these principles have been proven to enhance organizational performance.