THE ROLE OF ACCREDITATIONS IN THE PRODUCTION AND USE OF ANALYTICAL VOLUMETRIC SOLUTIONS (TITRANTS)

Author: John Barron, Managing Director, Reagecon Diagnostics Ltd, Shannon Free Zone, Shannon, County Clare, Ireland.

Introduction

The acquisition and maintenance of accreditations and certifications, has and continues, to play a major role in the commercial production, of high quality analytical volumetric solutions. For a producer of such materials, accreditations and certifications should be an integral part of the customer service value proposition, leading to significant competitive advantage. Sometimes, there is confusion and lack of delineation in relation to the differences between Accreditations and Certifications. Our interpretation of these differences is presented in Figure 1 on the following page. There is also a value in reiterating the benefits of Reference Materials and Standards to the user and how an accredited producer of such products, gives the analyst confidence in the quality and integrity of the Standards, used. Finally, in the case of a producer holding ISO 17025 accreditation, it is the test method used in the assay and certification of the standards that is accredited rather than the standards themselves.

To be awarded ISO 17025 accreditation, the accredited company must cover competence in the testing laboratory that involves analysis, dissemination of the test results and maintenance of records. So, in the case of ISO17025 the sole emphasis relates to the testing component of the process.

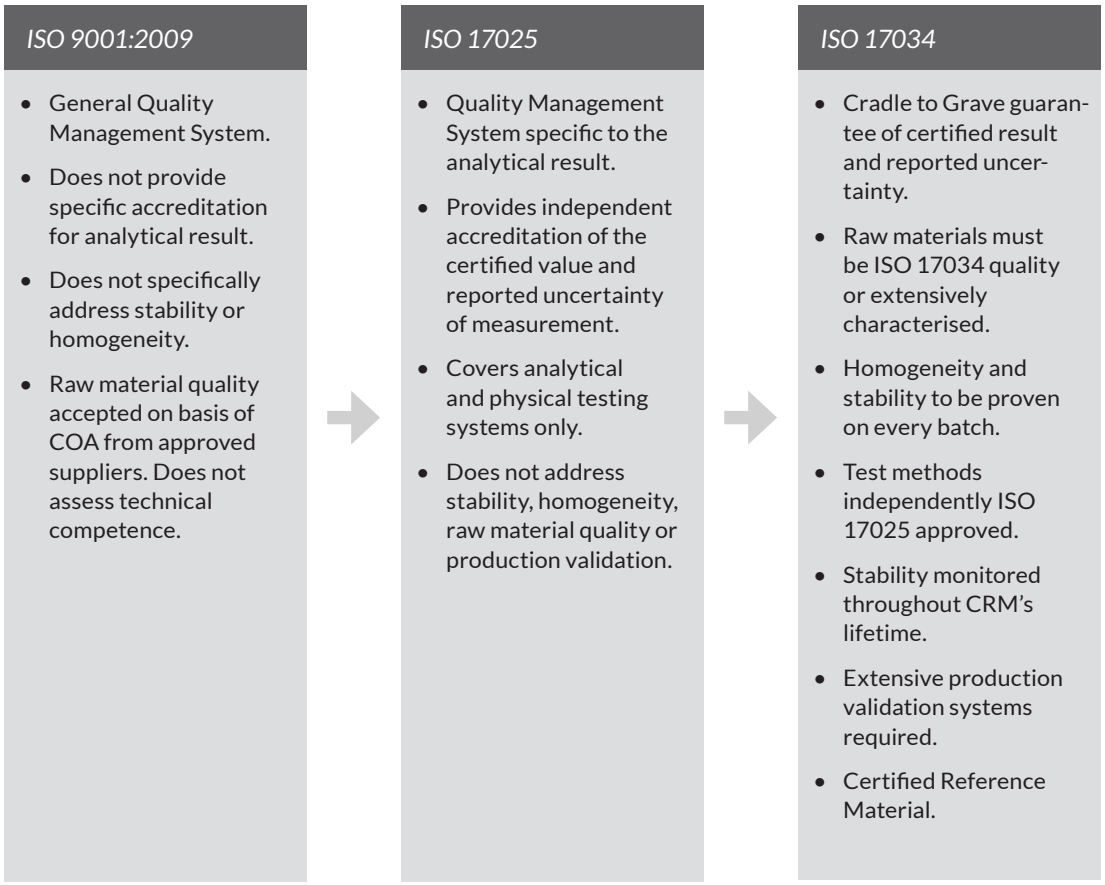

Figure 1

The Relationship Between ISO 9001:2009, ISO 17025 and ISO 17034

The Applications of Reference Materials and Standards

Reference Materials and Standards are used in laboratories for a number of reasons as follows:

1. **Instrument Calibration** – almost all analytical chemistry is comparative – thus the concentration of an unknown analyte is compared with the concentration of a known or series of known analytes which calibrate the instrument. The use of a reputable Reference Material or Standard as a calibrant also establishes metrological traceability which in turn establishes that analyses are comparable in time and place. This comment applies to all comparative methods. How it applies to analytical volumetric solutions is detailed very comprehensively throughout this book.
2. **Control Material** – the use of a Reference Material or Standard is a very effective means of Quality Controlling an unknown test result, provided that matrix, homogeneity and stability are taken into account. The reference material may be used as a once off control, or can be used to verify that a measurement process is in statistical control, where repetitive testing is performed.

3. **Method Validation** – the validation of a test method provides objective evidence that the particular requirements of a test method are complied with and that the method is fit for purpose. The Reference Material or Standard enables metrological data pertaining to accuracy, precision, reproducibility, bias and uncertainty of measurement to be ascertained.
4. **Instrument Qualification (IQ, OQ, PQ, MQ)** – although such processes were originally the preserve of the Pharmaceutical Industry, they are now seen as good laboratory practice and are now widespread as formally documented processes in a whole host of other industries.
5. **Inter-laboratory comparison by blind analysis of the material** - comparison of the laboratory's performance is provided by this test as well as the performance of the individual analyst.
6. **Analyst Qualification** – in this instance the laboratory results are not compared with those of other laboratories, but compared with the analytical value obtained by the producer of the Reference Materials or Standard. The values obtained are generally withheld from the Analyst until after the test is performed and form an objective view of the level of training and competence of the analyst to perform a particular test.

Irrespective of application, it is an imperative that the producer of the Reference Materials or Standards be competent and accreditation is the most important means of determining and proving such competence.

This recognition of competence may relate to properties of the material produced such as stability or homogeneity, but certainly relates to the assigned values and their accuracy.

Why Use Standards Certified by an ISO 17025 Accredited Company.

ISO17025 accreditation demonstrates that analytical tests are performed in a technically valid manner and controlled by a rigorous quality system. ISO17025 examines all aspects of contracts, method development, method validation, equipment, personnel and routine performance of the analytical test method. The qualification, education and training of all individuals involved in the process are scrutinised against their job responsibilities. Even the quality attributes of vendors and collaborators are checked, as well as every Quality Critical specification requirement.

To be ISO 17025 accredited, a company must not only be consistent, but must also be proficient in testing the quality of their products. Using standards from a producer with this accreditation helps to ensure your laboratory is technically competent. ISO 17025 Accreditation is now an essential requirement for several types of laboratories and highly desirable for all other types of laboratories.

The Scope of ISO 17025

Documentation control, corrective & preventive actions, complaint handling, supplier & subcontractor management, non-conflicting organizational structure and internal audits are all part of the scope of ISO 17025. Figure 2 illustrates how the workflow steps involved interact, with particular emphasis on the testing component. Some requirements impact on more than one workflow step:

- All analytical methods and procedures must be validated. This includes methods and procedures for sampling, testing and data evaluation.
- Equipment used for sampling and testing must be calibrated, tested and well maintained. Certified values of calibration standards must be traceable to System International (SI) units.
- Nonconforming test results must be documented and controlled.
- Personnel must be qualified for their assigned tasks through education, experience and training.
- Environmental conditions such as temperature, humidity, and electromagnetic interference must be monitored and controlled.

All routine tasks must be performed according to written procedures and records of the execution of tasks must be made and retained

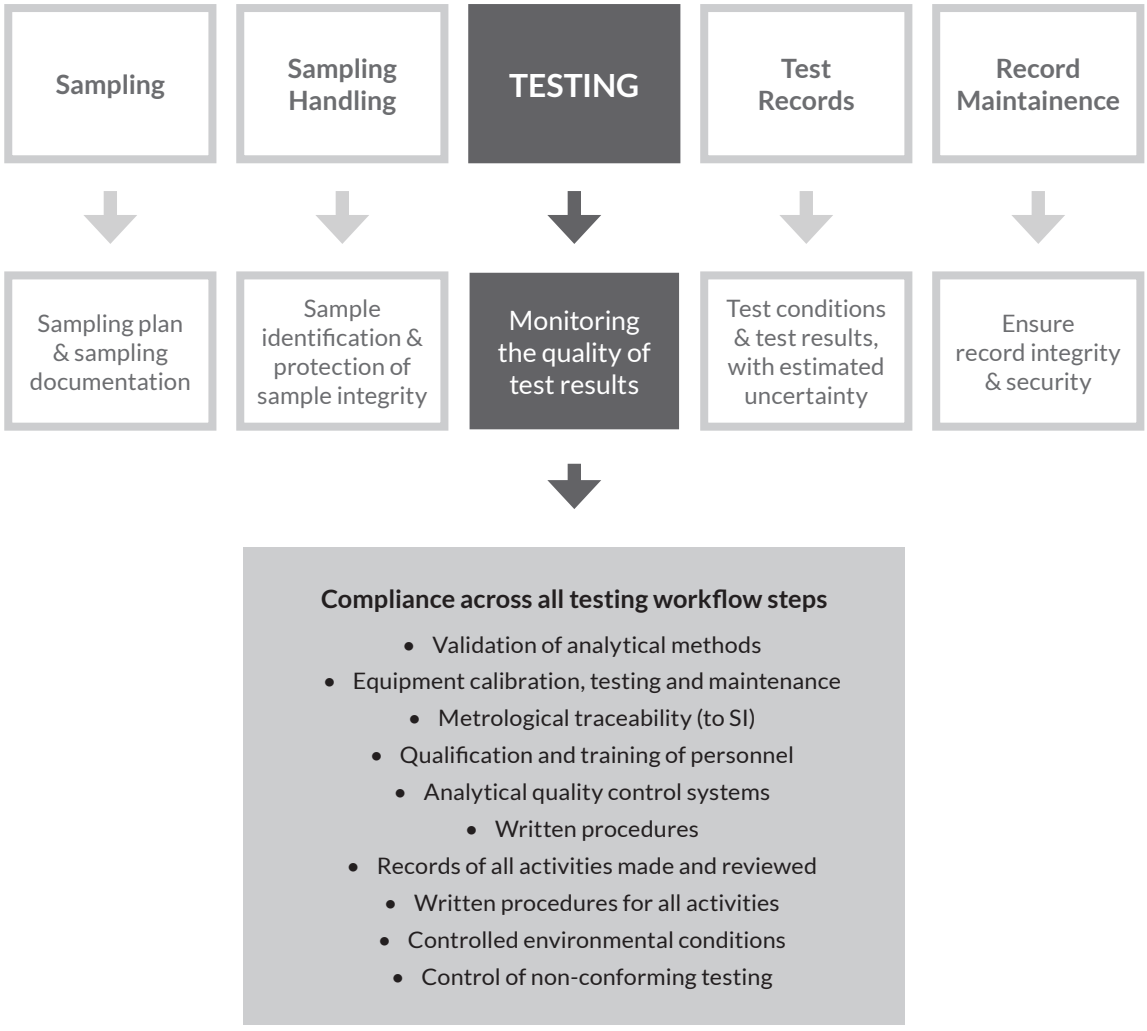

Figure 2

Certified Reference Materials from ISO 17034 Accredited Producers

ISO 17025 accreditation does not address raw material quality, character, homogeneity or stability of an analytical volumetric solution. On the other hand, ISO 17034 addresses all of these parameters and therefore, provides a complete cradle to grave guarantee that the material can be classified as a Certified Reference Material (CRM). The raw materials must be thoroughly characterised, prior to use and on an ongoing basis so that error due to batch to batch variation can be eliminated or quantified.

The stability and homogeneity of every batch of CRMs must be evaluated. Typically, this requires an extensive and onerous testing program. ISO 17034 accreditation requires that all of the test methods for characterising raw materials, assigning CRMs' property values, homogeneity testing and stability testing, must be accredited to ISO 17025. In addition to that, extensive production validation systems are required to manufacture CRMs.

Whilst the production of CRMs is considered the "holy grail" of standards, it must be remembered that such materials tend to be very expensive and will have a significantly wider total measurement uncertainty than the test measurement uncertainty achieved for a standard whose certified value is provided by an ISO 17025 accredited test method – as this includes contributions for instability and inhomogeneity.