The Role of Accreditations in the Production and Use of Standards and Reference Materials.

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1.0 Introduction

Reagecon is the largest producer in the world of Standards, Reference Materials and Reagents. We are committed to providing you with products of the highest quality and the achievement and acquisition of Accreditations and Certifications has and continues to play a major part in that objective. Furthermore, Accreditations and Certifications are an integral part of our customer service value proposition, lead to competitive advantage and are an integral part of our business strategy.

Sometimes, there is confusion and lack of delineation in relation to the differences of Accreditations and Certifications and our interpretation of these differences in Reagecon are presented in Section 1.1 below. There is also a value in reiterating the benefits of these Reference Materials and Standards to you the user and how as a producer of such products, Accreditations give you confidence in the quality and integrity of the Standards, you use. Finally, although in the case of a producer of ISO 17025 accredited standards, it is the test procedure used in the assay and certification of the standards that is accredited rather than the standards themselves. All of the standards from the accredited company cover competence in the testing laboratory that involves sampling right through to production, dissemination and storage of the test results, records and certification. So, in the case of ISO17025 the major emphasis relate to the testing component of the process, but also the relationship between the testing component and other parts of the process that input on the testing component as presented in Section 1.3.

1.1 Reagecon's Commitment to Quality

We are committed to providing you with the highest quality Standards and Reference Materials, both accreditations and certification play a major role in that offering. Accreditation is a recognition of competence and Reagecon has held ISO17025 accreditations for the testing of several standards since 1989 and the list of Accredited Test Methods continues to grow. Reagecon has also been certified to ISO 9001:2015 (or its equivalent Certification) also since 1989 and recently the company has achieved ISO 17034 accreditations as a certified Reference Material for our first family of products. All of the certifications and accreditations achieved by the company are critical to our corporate evolution and the role played by each is presented in Figure 1 on the next page.

The relationship between ISO9001:2015, ISO17025 and ISO 17034 within Reagecon.

ISO 9001:2015

- General Quality Management System
- Does not provide specific accreditation for analytical result
- Does not specifically address stability or homogeneity
- Raw material quality accepted on basis of COA from approved suppliers
- Does not assess technical competence

ISO 17025

- Quality Management System specific to the analytical result
- Provides independent accreditation of the certified value and reported uncertainty of measurement
- Covers analytical and physical testing systems only
- Does not address stability, homogeneity, raw material quality or production validation

ISO 17034

- Cradle to Grave guarantee of certified result and reported uncertainty
- Raw materials must be Guide34 quality or extensively characterised
- Homogeneity and stability to be proven on every batch
- Test methods independently ISO 17025 approved
- Stability of every batch monitored 5 times during its lifetime
- Extensive production validation systems required
- Certified Reference Material

Figure 1

1.2.1 Why Use 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 comparability,thus, ensuring that analyses are comparable in time and place.
2) Control Material – the use of a Reference Material or Standard is a very effective and an almost universally mandatory means of Quality Controlling an unknown test result, provided 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. This can also facilitate comparability. A study on the use of controls in conductivity measurement is presented elsewhere in this publication.
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 are the preserve of the Pharmaceutical Industry and are mandatory in that industry, they are seen in several industries as good laboratory practice and are now widespread as formal documentation processes or as fit for purpose processes (carried out less formally than in the Pharma Industry) in a whole host of other industries.
5) Proficiency Testing – here the test results of the Reference Materials or Standards are compared with the results of a statistically significant number of other laboratories and are a mandatory component of method validation and a mandatory component of the requirements of accreditation bodies for a laboratory that wishes to obtain an accreditation.
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.

1.2.2 Why Use ISO 17025 Accredited Standards

ISO17025 accreditation demonstrates that analytical tests are performed in a technically valid manner, controlled by a rigorous quality system. ISO17025 examines all aspects of quotations and contracts, method development, method validation, equipment and personnel and routine performance of the analytical test method. The qualification, education, and training of all individuals involved in the process are scrutinized 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 certified, 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.

1.3 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, which in figure 2 has been expanded out (green boxes)to emphasise the criticality of the testing component.
Some requirements impact on more than one workflow step:

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

All routine tasks should be performed according to written procedures

ISO17025 Requirements for Testing Laboratories

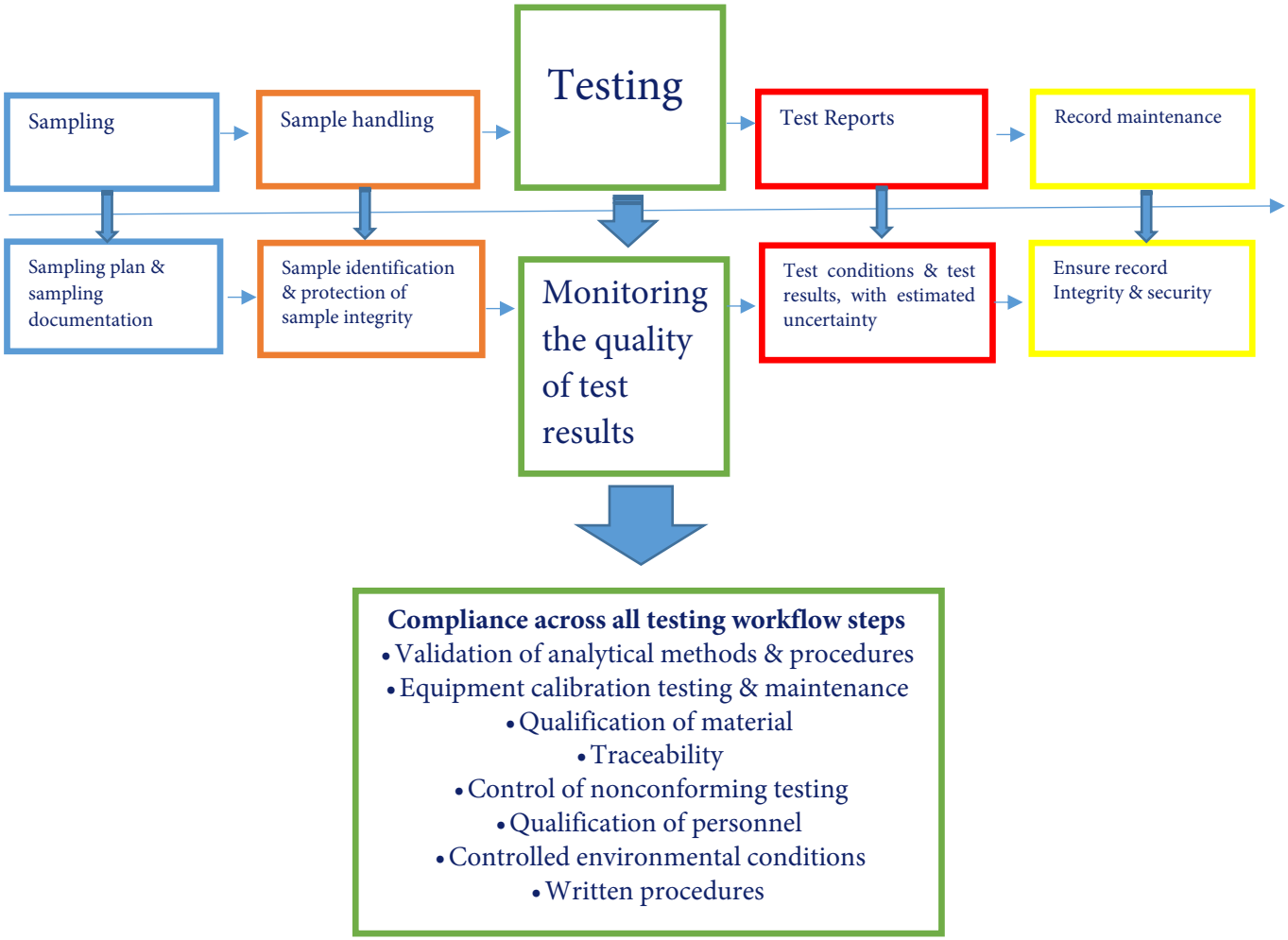

Figure 2