Accred Qual Assur (2004) 9:397–398
DOI 10.1007/s00769-004-0805-2

GENERAL PAPER

Tina Engelhard
Orna Dreazen

Current best practice for traceability in testing laboratories, when certified reference materials are unavailable

Received: 15 December 2003
Accepted: 15 March 2004
Published online: 30 April 2004

Presented at the Second International Conference on Metrology—Trends and Applications in Calibration and Testing Laboratories, 4–6 November, 2003, Eilat, Israel

T. Engelhard (✉) · O. Dreazen
Israel Laboratory Accreditation Authority (ISRAC), Rehov Habonim 2,
52522 Ramat Gan, Israel
e-mail: tinae@israc.gov.il
Tel.: +972-3-5751690
Fax: +972-3-5751695

Abstract Since the implementation of ISO/IEC 17025 in 2002, all accredited laboratories (at the least) need to establish traceability in all their tests and calibration methods. Traceabilty, though well understood in the calibration field (through an unbroken chain of comparisons to the International System of Units—SI), is less straight forward and not so well understood in the testing laboratories. Traceability in analytical and biological testing is found through the use of reference materials, and the validated steps of a test method. This article describes the possibilities to comply with the traceability requirement of ISO/IEC 17025 in testing laboratories , when certified reference materials are unavailable.

Keywords Traceability · Reference materials · ISO/IEC 17025

Introduction

ISO/IEC 17025 [1] Section 5.6.3.1 requires that "...reference standards shall be calibrated by a body that can provide traceability..." all accredited laboratories need, therefore, to request/find appropriate reference materials (RMs) that meet the requirements of the market and the requirement for traceability to calibrate their test systems.

The accreditation of RM producers (based on ISO/IEC Guide 34 and/or ISO/IEC 17025) has been discussed frequently within the International Laboratory Accreditation Cooperation (ILAC), but a final decision or agreement has yet to be made. When accreditation of RMs is implemented any significant impact on the market will probably take several years. Accredited laboratories have no option, therefore, other than to be cautious and seek clear evidence of the quality and traceability of the property values of the materials from their suppliers. Though the Eurachem/CITAC Guide [2] provides excellent guidance on identifying traceability requirements, this short paper attempts to highlight availability and practicality related issues.

The International Vocabulary of Basic and General terms in Metrology (VIM) [3], defines traceability as the "property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually using national or international standards, through an unbroken chain of comparisons all having stated uncertainties".

In practice traceability to the International System of Units (SI) is obtained either through traceability to a value of a compound or through traceable calibrated equipment. When the above routes of traceability are unavailable then one is left with the traceability to the test method.

Reference materials

The RMs used for calibration in industry and in all sections of analytical laboratories are essential for the comparability of chemical and biological test results.

Currently the "best" available RMs are the certified reference materials (CRMs). CRMs are expensive, since their value has been assigned after being tested in many laboratories including metrology institutes with different valid procedures. Each CRM has the

uncertainty calculated within a defined confidence level for each assigned value, which includes the uncertainties from homogeneity and stability. This information is available on the Certificate of Analysis (COA) of each specific CRM and can be used as the calibrator and basis for traceability in chemical testing reports.

CRMs, however, can be used only where they are available and are relevant to the test being performed. For many of the chemical, biological and physical tests, this is not the case. It is, therefore, necessary to define which measures should be taken, in order to work as traceable as possible.

We propose the Israel Laboratory Accreditation Authorities (ISRAC) policy as a current "best working practice" to ensure (as far as possible) traceability, which includes the following:

1 Look for and use traceable RMs whenever available, preferably primary standards or CRM.
2 Enquire whether the RM producer has or intends to pursue accreditation to ISO/IEC Guide 34 [4] or ISO/IEC 17025 since an RM from an accredited producer would save the customer valuable resources in confirming the links for traceability.
3 Define the uncertainties of the results and the variables in the test method which may affect the quality of the results. Concentrate on these variables that they be traceable to SI units where possible.
4 Work traceable to SI units:
4.1 Temperature (K): Calibrated thermometers, temperature and humidity meters.
4.2 Mass (kg): Ensure the weights and the balances are calibrated.
4.3 Volume (L): Use defined glassware (class A) calibrated pipettes, volumetric flasks, etc.
4.4 Length (m): Where the length has an effect on the result of the test use calibrated measuring meters.

5 Work with a valid method.
6 Perform on-going QC monitoring in the initial validation procedure and then on a regular basis (calibration curve, vs response, control charts, etc.)
7 Perform intermediate verification checks with master calibrated weights, secondary thermometers, etc.
8 Prepare solutions in calibrated volume vessels. Perform intermediate checks with working solutions, which are comparable to the RM or CRM.
9 Document and monitor historical data collected for identification of possible trends.
10 When preparing a working RM in the lab:
10.1 Ensure that the equipment is calibrated.
10.2 Monitor the stability and homogeneity.
10.3 Document procedures and the test results.

11 When no CRM can be found:
11.1 Request that the producer of a compound/RM used be ISO/IEC 9001 certified.
11.2 Check whether the COA received with the compound defines the type of the RM (secondary, working or it may not be stated).
11.3 Request additional information from the supplier/producer regarding stability, homogeneity, traceability and uncertainty assigned to the values stated in the COA.
11.4 Continuously document all available information of the standard/RM (collect on-going and historical data).

When all else fails there is the possibility to be traceable to the valid test method. If the test method is used in the same manner with the same materials in the same conditions with sufficient controls, then the traceability would be to the method itself.

To summarize

The subject of RMs is very complex especially since today's market does not have sufficient answers for the use of traceable RMs in all areas of testing. This situation poses a significant problem especially for accredited laboratories as well as for all those aware of the importance of the quality and comparability of test results through traceablity to common references.

There are a few accreditation bodies that have started accrediting the producers of RMs to ISO/IEC Guide 34, so with a little hope and positive encouragement in the next 10 years we may see an increase in the number of accredited RM producers that may provide subjective evidence of traceability, and lessen the burden on the laboratories.

References

1. ISO/IEC 17025. General requirements for the competence of testing and calibration laboratories. The International Organization for Standardization (ISO), Geneva
2. Eurachem/CITAC Guide (2003) Traceability in chemical measurements, a guide to achieving comparable results in chemical measurements. Eurachem http://www.eurachem.ul.pt/
3. International vocabulary of basic and general terms in Metrology (1993) ISO, Geneva
4. ISO/IEC Guide 34. General requirements for the competence of reference materials producers. ISO, Geneva