PRINCIPLES BEHIND THE REQUIREMENTS OF ISO/IEC 17025

6 June 2002

Prepared by: J.E.J. (Ned) Gravel, P.Eng., NQI-LA
Canadian Association for Environmental Analytical Laboratories (CAEAL)

BACKGROUND

ISO/IEC 17025 is a standard that sets out the specific requirements to be met by laboratories wishing to achieve the production of competent results as a matter of course. These requirements were developed by groups of laboratory experts from around the world over the course of 30 years. From the first, laboratory competence has been the paramount consideration.

In today's world, recognition of such competence generally requires that laboratories which have implemented the requirements of the standard obtain accreditation. This accreditation is the mark of recognition of their competence. Accreditation involves assessment and, like all audit-associated activities, assessment of technical competence requires trained assessors to deliver these assessments. Assessors must be fully cognisant of each of the requirements in the standard.

During the course of their work, assessors will often encounter a situation where they are forced to defend a particular requirement to a laboratory seeking accreditation and, while they understand the specific requirement under discussion, they may not be able to clearly articulate why such a requirement exists, in the first place. That is to say - they may not be able to identify the principles which underlie the stated requirement.

At the same time, a laboratory's blind adherence to each of the requirements of the standard, while better than no system at all, is not an approach which instils confidence in their ability to produce competent results. Nor is it the best approach to use in acquiring recognition of such competence.

Finally, ISO 9000:2000 is now well known and respected around the world as a standard which today aims at allowing conforming organisations to implement a "model for excellence." While some may see this aim as a very ambitious one for any organisation, the standard effectively breaks down the elements which an organisation can readily achieve in their implementation of such a model. One of the great strengths of ISO 9000:2000 is its clear basis on principles which can be easily articulated and understood.

Those who live and work in the world of laboratories also adhere to specific principles, but these have not been articulated in one collection. Such principles would provide a clearly understood basis for the requirements of the standard which most directly impacts laboratory operations.

OBJECTIVE

The objective of this paper is to provide a listing of the principles behind ISO/IEC 17025. These can be used by laboratories to better appreciate individual requirements of the standard. The paper can also be used by assessors, in understanding how or why a specific requirement can help (or perhaps hinder) a laboratory to implement the processes required for the recognition of their competence.

THE PRINCIPLES

From study of the standard and its impact on laboratory operations over the course of the last nine years, the following single word principles are considered to be the main forces behind all of the requirements of ISO/IEC 17025. A description of each follows.

- Capacity
- Exercise of Responsibility
- Scientific Method
- Objectivity of Results
- Impartiality of Conduct
- Traceability of Measurement
- Repeatability of Test
- Transparency of Process

CAPACITY

Concept that a laboratory has the resources (PEOPLE with the required skills and knowledge, the ENVIRONMENT with the required facilities and equipment, the QUALITY CONTROL, and the PROCEDURES) in order to undertake the work and produce COMPETENT results.

EXERCISE OF RESPONSIBILITY

Concept that persons in the organisation have the authority to execute specific functions within the overall scope of work – and that the organisation can demonstrate accountability for the results of the work.

SCIENTIFIC METHOD

Concept that the work carried out by the organisation is based on accepted scientific approaches, preferably consensus-based, and that any deviations from accepted scientific approaches can be substantiated in a manner considered generally acceptable by experts in that field.

OBJECTIVITY OF RESULTS

1. Concept that the results produced within the scope of work of the organisation, are mainly based on measurable or derived quantities.

2. Concept that subjective test results are produced only by persons deemed qualified to do so and that such results are noted as being subjective, or are known by experts in that field of testing to be mainly subjective.

IMPARTIALITY OF CONDUCT

Concept that the pursuit of competent results through the use of generally accepted scientific approaches is the primary and overriding influence on the work of persons executing tests - all other influences being considered secondary and not permitted to take precedence.

TRACEABILITY OF MEASUREMENT

1. Concept that the results produced, within the scope of work of the laboratory, are based on a recognised system of measurement that derives from accepted, known quantities (SI system) or other intrinsic or well-characterised devices or quantities.
2. Concept that the chain of comparison of measurement between these accepted, known quantities or intrinsic devices or quantities, and the device providing the objective result, is unbroken for the transfer of measurement characteristics, including uncertainty, for the whole of the measurement chain.

REPEATABILITY OF TEST

Concept that the test which produced the objective results, will produce the same results, within accepted deviations during subsequent testing, and within the constraints of using the same procedures, equipment and persons used during a previous execution of the test.

TRANSPARENCY OF PROCESS

Concept that the processes existent within the laboratory producing the objective results, are open to internal and external scrutiny, so that factors which may adversely affect the laboratory's pursuit of objective results based on scientific method, can be readily identified and mitigated.

CONCLUSION

These eight principles may not cover every aspect of every requirement in the standard, but they are broad enough to allow persons working in laboratories to appreciate the reasons behind most of the individual requirements. They may also allow assessors to use their professional judgement in assessing the conformance of a laboratory to each of the requirements within the standard.

About the Author

J.E.J. (Ned) Gravel, P.Eng., NQI-LA, is the Manager, Quality and Training at the Canadian Association for Environmental Analytical Laboratories (CAEAL). The association is a public-private partnership which provides services to over 315 member laboratories including PT services, assessments for accreditation, and training. Assessments are delivered in Canada and Latin America under the Program for the Accreditation of Laboratories - Canada (PALCAN) the accreditation partnership led by the Standards Council of Canada (SCC). Ned represents Canada on ISO/CASCO Working Group 25 - the group which has been assigned the task of aligning ISO/IEC 17025 with ISO 9000:2000.