Independence and Impartiality in Testing Laboratory Operations
INDEPENDENCE AND IMPARTIALITY IN TESTING LABORATORY OPERATIONS

Background

In the current EN 45001 standard and ISO/IEC Guide 25 (1990), there are references to the independence and impartiality of organisations involved in testing and calibration operations. As there are changes proposed in the latest draft of the revised ISO/IEC Guide 25 (5 draft 1996), it is worthwhile to review the situation and clarify the position of Eurolab.

In EN 45001 (1990) it is stated that the standard specifies general criteria for the technical competence of testing laboratories, including calibration laboratories (§ 1). In § 4 requirements of impartiality, independence and integrity are given as follows:

- The testing laboratory and its personnel shall be free from any commercial, financial and other pressures which might influence their technical judgement.
- Any influence on the results of examinations and tests exercised by persons or organisations external to the testing laboratory shall be excluded.
- The testing laboratory shall not engage in any activities that may endanger trust in its independence of judgement and integrity in relation to its testing activities.
- The remuneration of personnel engaged in testing activities shall not depend on the number of tests carried out, nor on the results of such tests.
- When products are tested by bodies (e.g. manufacturers) who have been concerned with their design, manufacture or sale, provision for a clear separation of different responsibilities and an appropriate statement shall be made.

Further there is a requirement (§ 5.4.3) that a test report shall not include any advice or recommendation arising from the test results. In EN 45002, which describes general criteria for the assessment of testing laboratories, and in EN 45003, which gives general criteria for laboratory accreditation bodies, there is no further guidance on how to assess the independence and impartiality of testing laboratories.

The current ISO/IEC Guide 25 (1990) includes the following independence and impartiality requirement:

- The laboratory shall be organised in such a way that confidence in its independence of judgement and integrity is maintained at all times (§ 4.2.c.).
In the current revision of ISO/IEC Guide 25 (5 draft, 1996) a different approach has been taken. It is stated (§ 1.1.1) that the guide is applicable to all organisations performing tests and/or calibrations irrespective of their scope, number of personnel or organisational status.

The revision thus covers, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration form part of inspection and certification. It also focuses on the technical competence of laboratories. In § 2.2.3 and § 2.2.4 there are comments relating to independence and impartiality:

- The responsibility of all staff in a multifunctional organisation shall be developed in order to avoid conflicts of interest.
- (Note) Legal requirements may require that the laboratory shall be a third-party laboratory.
- (Note) A laboratory wishing to be recognised as a third-party laboratory may need to produce documentary evidence to show clients and other interested parties that they are not subjected to any influence that may compromise their independence and impartiality.

Although this paper does not deal with certification and inspection bodies, it might be of interest to see how questions related to independence and impartiality are dealt with in documents related to these bodies.

For product certification bodies, there are requirements in EN 45011 describing the administrative structure (§ 4). The governing board shall consist of members from the interest parties, without any single interest predominating. The permanent staff shall be free from control by those who have a direct commercial interest in the certification to be carried out. EAC has issued guidelines (EAC/G2) on the application of EN 45011. In this document impartiality is discussed briefly.

The requirements set forth for certification bodies in ISO/IEC Guide 62 (1996) and 65 (1996) are simply that they shall be impartial (§ 2.1.2 and § 4.2, respectively). The certification body shall have a documented structure, which safeguards impartiality; this structure shall enable the participation of all parties significantly concerned in the development of policies and principles. The structure shall be chosen so that there is a balance of interests and no single interest predominates.

EN 45004 deals with the competence of bodies performing inspection. They shall have adequate liability insurance. For inspection bodies three different categories (Types A, B and C) have been introduced and they are separated by different criteria:

- independence of the parties involved
- possible conflict with independence of judgement and integrity
- access to the services of the inspection body
- separation of responsibilities.
Requirements of independence and impartiality of inspection bodies are given as:

- Personnel shall be free from any commercial, financial and other pressures which might affect their judgement (§ 4.1).

- The inspection body shall be independent to the extent that is required with regard to the conditions under which it performs its services (§ 4.2).

A joint working group consisting of experts from inspection bodies as well as EAC and EAL have prepared explanations (JIG/WP (96)3) of the requirements in EN 45004. The interpretations are mainly focused around those inspection bodies not being clearly in a third-party position.

The assessment of independence and impartiality in testing laboratories has so far been a part of the accreditation process, but due to superficial requirements it has not been an well-defined process. This fact was one of the reasons why the revision of ISO Guide 25 has focused on the technical competence of the laboratories and not on their status, position or duties.

**Interpretation of independence and impartiality**

Generally speaking, „independence“ implies that an organisation or operation is not controlled, nor unfairly influenced by other people or things. Independence is also related to the purpose for which it is used, as it also means „not under the same authority“. The word „impartiality“ means that one is not favouring any organisation, person or thing more than another and that operations are fair and neutral.

Independence and impartiality are explicitly mentioned in some of the EN 45000 series standards as well as in some prescriptive documents. However, there is no generally accepted and unambiguous definition. Clear and objective elements and/or criteria for assessing independence and impartiality are missing. Today the interpretation and application is left to common sense. The words „independence“ and „impartiality“ have in different contexts, different meanings. Within one organisation independence may mean managerial independence but certainly not a third party position. For example, a manufacturers’ laboratory can in certain cases be considered independent from production, but it is not independent if one looks upon it from the outside. On other occasions independence may indicate that the organisation is free from undue external influences.

Accreditation is a way to demonstrate technical capability and competence and should as such be applicable to all categories of involved organisations, i.e. manufacturers, buyers, third-party laboratories etc. Moreover, accreditation was intended to be an assurance of an appropriate level of independence and impartiality. The attributes of independence and impartiality are of a judicial, legal and economic nature, especially when third-party organisations are involved. But, as there is no categorisation of laboratories in EN 45001, ISO/IEC Guide 25 (1990) or the revised ISO/IEC Guide 25 (draft 5, 1996), difficulties connected with the assessment of these criteria, unfortunately, often lead to doubts as to whether accreditation is proof of independence...
and imperality or not. Redefinition of „independence“ and „impartiality“ with respect to laboratory operations, also in relation to the modules of the Directives and/or categorization of types of laboratories, could strengthen the meaning and position of accreditation in this respect. However, as stated above, independence and impartiality have not been included in the present version of the ISO/IEC Guide 25 revision.

Even first- and second-party laboratories should give their clients and other parties a clear picture of their position with respect to independence and impartiality.

Independence and impartiality entail two major elements:

- freedom from external influence
- honesty in operation and reporting.

In a technical sense this means that the organisation must be free to select the appropriate working methods and carry out such calculations, analyses etc. it considers necessary to ensure that the results are reliable. In an organisational and managerial sense, economic and social pressures shall not be such that they affect the performance of work and professional judgement. Honesty relates to good working ethics, elimination of cheating possibilities and openness in reporting all results and findings. Honesty is a concept very easy to understand, but very difficult to demonstrate and/or assess.

**Third-party involvement**

All types of testing laboratories should strive to achieve the above mentioned principles. In practice, however, the most effective and straight-forward assurance of independence and impartiality is provided by third-party laboratories which are not in the same category as those of the producers (sellers) and users (buyers), who have the main economic and legal interest and who in principle could use „forged“ results for the purposes of marketing, public relations etc.

Testing laboratories belonging to or controlled by producers or users can never be considered as third-party laboratories when their own interest (e.g. products) are at stake. They can, however, if they offer their testing or calibration services to external organisations and fulfil the relevant requirements, be considered to be third-party laboratories in these cases. If a company is a majority stakeholder in a testing or calibration laboratory, that laboratory cannot be considered to be independent and impartial from the major stakeholder and consequently it cannot act as a third-party laboratory for the major stakeholder.

When are third-party testing laboratories needed? The answer to that question should either be found from the legislation or when agreed upon between the buyer and the seller. In the mandatory area third-party laboratories are needed when issues of safety, health, environmental and large economic values are concerned. Unfortunately the legislation is under-developed in this respect.
As far as impartiality is concerned it is not realistic to envisage that a testing or calibration laboratory can be completely free from external influences. After all, they perform on a commercial basis, assignments for their clients. Impartiality can, however, be secured if the operations are, for example, controlled by a structure where members are chosen to provide a balance of interests and where no single interest predominates.

As testing laboratories may have several functions, the question of challengeability arises. It is quite clear that an organisation developing a product cannot operate as an acceptance body for it. Complete orthodoxy is, however, not needed, as demonstrated by the following example. If somebody performs a certain test (e.g. tensile test) in the product development phase, that organization is not "contaminated", as the results are unbiased.

Each third-party laboratory should clarify its independence and impartiality in a transparent way and describe its position, in that respect, in their Quality Manual. It is important that clients have a clear picture of the independence and impartiality of the testing laboratory.

In some of the EN 45000 series standards there is a requirement of non-exclusiveness. That requirement has nothing to do with independence and impartiality and should be handled separately.