

## IMPARTIALITY AND CONFIDENTIALITY

---

### IMPARTIALITY

#### Introduction

In previous versions of ISO/IEC 17025, the issue of a laboratory's impartiality was not a big issue. In ISO/IEC 17025 [1] the impartiality is only mentioned in notes and the conflict of interest is mentioned only once. However, in the revised version of the ISO/IEC 17025:2017 [2] there is a new Section 4.1 dealing with the impartiality derived from the general ISO requirements. Therefore, it is now more important for laboratories to explain how they have handled the issue of impartiality. Section 4.1.1 states that "Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality" and later Section 4.1.3 "The laboratory shall be responsible for the impartiality of its laboratory activities".

It is important for the laboratory to be sure that there is no commercial, financial or other pressure that could compromise impartiality and if there is a risk it shall be eliminated or minimized. Examples of such risks are ownership, employee contracts, etc.

#### Commitment

The laboratory management shall be committed to impartiality. Two possible ways of demonstrating this are a specific impartiality policy or a statement of impartiality in the quality policy and the discussion of impartiality in the context of management review, and the inclusion of discussions and decisions in the minutes of meetings. A combination is possible.

There are other documents besides the policies and minutes of management reviews, where a declaration of commitment to impartiality can be made, e.g. articles of association of a company, if the laboratory has only limited liability (Private Limited Company).

#### Identification of risks related to impartiality

Section 4.1.4 of the ISO/IEC 17025 (2017) states: "The laboratory shall identify risks to its impartiality on an on-going basis". The laboratory shall therefore carry out risk analyses. The analyses may use contract reviews (to determine whether a risk is associated with the client or the activity), management reviews, internal audits and performance reviews (to identify risks associated with the personnel) as an input. Since this shall be an ongoing activity, it is important to identify changes in the laboratories activities that could become a risk. Even if the laboratory's activities do not change, the analyses of the risk with regard to impartiality should be reviewed, at least as part of the management review. This includes the risks arising from its activities, or from its relationships, or from the relationships of its personnel.

A relationship that threatens laboratory impartiality may be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of sales commission or other incentives for the referral of new customers, etc.

#### Eliminate or minimize risks related to impartiality

In the new standard, there is a requirement for the laboratory to eliminate or minimize the identified risk to impartiality. Note that there is no requirement to eliminate the risk. There are many possibilities to eliminate or minimize risks, such as

- having the tests carried out by other parts of the laboratory if the original part is compromised for any reason,
- changing the personnel if the original personnel is compromised,
- quarantine time for compromised personnel (it is recommended to determine the duration of the quarantine time for the personnel in general),
- employment contract,
- making changes in the activity, e.g. omit the most critical part.

Even though impartiality is particularly mentioned in ISO/IEC 17025 and development efforts pose a risk to impartiality, laboratories may test prototypes and new products without compromising their impartiality. The laboratory shall be able to demonstrate how it has handled the issue of impartiality. Therefore, these activities shall be documented.

## **CONFIDENTIALITY**

### **Introduction**

Although the new version of ISO/IEC 17025 (2017) includes more text about confidentiality, the basic requirements of ISO/IEC 17025:2005 have not changed but are more detailed. The main requirement is that the laboratory shall have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting electronic storage and transmission of results, as already described in ISO/IEC 17025:2005.

### **Handling**

ISO/IEC 17025:2017 requires the laboratory to legally commit itself to keep information confidential obtained or generated during the performance of assignment for client. When information is made publicly available, either by the customer, by an agreement between the laboratory and the customer, or by requirements in the law, the laboratory shall inform the customer in advance.

Information about the customer, obtained from sources other than the customer, and the provider of the information are confidential between the customer and the laboratory.

The personnel shall keep the customer information confidential. This can be specified in the employment contract.

The laboratory should preferably regulate all confidentiality issues in the contract. As a general rule customer information shall be treated confidentially.

### **References**

- [1] ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories
- [2] ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories