ISO/IEC 17025;2017, Section 4.1 Impartiality and 4.2 Confidentiality

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ISO/IEC 17025;2017, Section 4.1 Impartiality and 4.2 Confidentiality

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Duration of webinar is set for one hour.

You can type any questions directly into your webinar box; We will review them at the conclusion of today's session;

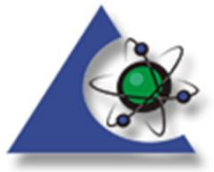
Impartiality

ISO/IEC 17025:2017 defines partiality

Impartiality - *presence of objectivity*

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the laboratory .

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include ñfreedom from conflict of interestsò, ñfreedom from biasò, ñlack of prejudiceò, ñneutralityò, ñfairnessò, ñopen-mindednessò, ñeven-handednessò, ñdetachmentò, ñbalanceò



Impartiality

In earlier versions of ISO/IEC 17025 the issue of a laboratory´s impartiality has not been a big issue. In ISO 17025:2005 , impartiality is only mentioned in notes and conflict of interest is only mentioned once. However, ISO/IEC 17025:2017 there is a new section 4.1 dealing with impartiality . It is therefore now more important for laboratories to show how they have handled the issue about impartiality.

Impartiality

Wikipedia defines as;

Impartiality is a principle of justice holding that decisions should be based on objective criteria, rather than on the basis of bias, prejudice, or preferring the benefit to one person over another for improper reasons

Section 4.1 Impartiality

ISO/IEC 17025:2017 requirements Sec 4.1 "Impartiality"

4.1.1 Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.

- It is therefore now more important for laboratories to show how they have handled the issue about impartiality
- The laboratory shall be responsible for the impartiality of its laboratory activities
- Laboratories activities extend beyond the testing or calibration activities. It also incorporates activities such as internal auditing, procurement, or maintenance;

Impartiality

Shall be Structured and Managed as to Safeguard Impartiality

Laboratory operations should not be influenced by other areas of an organization that may have a different agenda which may risk the integrity of the results produced by the laboratory.

There should be a clear separation of the responsibilities of the laboratory personnel from those of the personnel employed in the other functions. This should be established by organizational identification and the reporting methods of the laboratory operations within the parent organization.

The personnel involved in laboratory activities shall not engage in any activities that may conflict with their independence of judgment and integrity in relation to their laboratory duties In particular, they should not be engaged in the design, manufacture, supply, installation, use or ownership of the items tested or calibrated.

Impartiality

Common Ownership

Risk may have to be reduced by the following*:*

- Producing a barrier showing how ownership has no influence on results.
- Common ownership appointees on the boards or equivalent of the organizations, except where these have functions that have no influence on the outcome of laboratory results. This may be an appointee to the board who will overview how the company is managed but will not be involved in any decision-making regarding laboratory operations.
- Directly reporting where this cannot influence the outcome of laboratory results

ISO/IEC 17025:2017 requirements Sec. 4.1 "Impartiality"

4.1.2 *The laboratory management shall be committed to impartiality.*

<u>This may be demonstrated by:</u>

- Have a special impartiality policy or involve a statement about impartiality in the quality policy;
- Discuss impartiality on the management review and to include the discussions and decisions in the minutes of meeting;
- Documented training and agreement of staff, including the top management, on potential threats to impartiality;

ISO/IEC 17025:2017 requirements Sec. 4.1 "Impartiality"

4.1.3 The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

- Puts the responsibility on the laboratory;
- Safeguards should be put in place;

Safeguards may include prohibitions, restrictions, disclosures, policies, procedures, practices, standards, rules, institutional arrangements, and environmental conditions

ISO/IEC 17025:2017 requirements Sec. 4.1 "Impartiality"

4.1.4 The laboratory shall identify **risks** to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

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

ISO/IEC 17025:2017 requirements Sec. 4.1 "Impartiality"

Identifying risks to impartiality

- The laboratory shall make a risk analyses.
- Should be incorporated in contract reviews (to identify if there is risk connected to the customer or the activity)
- Management reviews, internal audits and performance review can provide inputs to identify any potential risk to personnel.
- Since this shall be an ongoing activity it is important to identify changes in the laboratories activities that may become a risk. Even if there are no changes in the laboratories activities the impartiality risk analyses should at least be reviewed during the management review.

ISO/IEC 17025:2017 requirements Sec. 4.1 “Impartiality”

Create Awareness

Threats and inducements aimed at laboratory operations may represent serious risks to impartiality. Threats and inducements may originate from inside or outside the organization and may happen at any time. All personnel having an influence on laboratory results should be aware of the responsibility to act impartially, be involved accordingly in the laboratoryôs impartiality measures and have appropriate access to provide records as issues arise. The accredited laboratories analysis of risks to impartiality should include details of the responses to such risks

ISO/IEC 17025:2017 requirements Sec. 4.1 "Impartiality"

4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

- Can eliminate or reduce to an acceptable level (risk mitigation*);*
- The laboratory should be able to show how it has handled the issue of impartiality so these activities should be documented;

Examples may include:

- Change the personnel if the initial personnel are compromised
- Letting other parts of the laboratory perform the test if the initial part is compromised
- Employment contract update

Examples on how to reduce risk to an acceptable level

- Quarantine time ; For example In the instance that staff has received additional payment for the recruitment of a new client, then they are not permitted to be involved in testing or calibration within one year of this additional payment for this client.

RISK REVIEW EVALUATION AND DETAILS OF ANY NECESSARY MITIGATION		
Does some impartiality risk exist?	Yes	No
If "No" then no further action required.		
If "Yes" (some impartiality risk exists):		
Can all the impartiality risks be mitigated?	Yes	No
If "no" - services cannot be offered until all impartiality risks are mitigated		
If "yes" complete details of how the risks will be mitigated.		

- Additional requirement specific to risk 8.5 ñActions to address risks and opportunities;

ISO/IEC 17025:2017 requirements Sec. 4.1 "Impartiality"

Impartiality also appears:

6.2 Personnel

6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.

8.2 Management system documentation

8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.

Section 4.2 ISO/IEC 17025:2017 “Confidentiality”

Confidentiality can be though of as the state of keeping or being kept secret or private;

Section 4.2 ISO/IEC 17025:2017 “Confidentiality

General practices should include

- Store confidential information in locked file cabinets.
- Encrypt all confidential electronic information with firewalls and passwords.
- Employees should keep their desks clear of any confidential information.
- Employees should keep their computer monitors clear of any confidential information
- Shed records or documents
- Employee Training

4.2 Confidentiality Requirements

ISO/IEC 17025:2017 Requirements:

4.2.1 The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

Legally enforceable commitments can be, for example, contractual agreements.

4.2 Confidentiality Requirements

4.2.1 highlights

- Requires that the laboratory shall legally commit itself to keep information obtained or created during the performance of assignment for client secret. ñlegally enforceable commitments can be, for example, contractual agreements;
- Inform the customer in advance, of the information it intends to place in the public domain., except when customer makes publicly available, or when agreed with the customer;
- All other information is considered proprietary information and shall be regarded as confidential

4.2 Confidentiality Requirements

4.2.2 When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, **unless prohibited** by law, be notified of the information provided;

4.2.3 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source;

4.2 Confidentiality Requirements

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

- Personnel shall keep customer information confidential. This may be handled in the employment contract
- External bodies can be subcontractors.

ISO/IEC 17025:2017 Impartiality and Confidentiality

This time is allocated for answering questions. You should have a space provided for submitting questions.

Please keep questions related to the topic covered in this webinar;

SAVE The Date

Next Webinar

Thursday, May 27, 2021

A look at the requirements specified in PJLA Policy on Proficiency Testing Requirements "PL-1"