Section 4.1 Impartiality and 4.2 Confidentiality

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Presented by:

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Section 4.1 Impartiality and 4.2 Confidentiality

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Duration of webinar is set for one hour.

Section 4.1 Impartiality and 4.2 Confidentiality

You can type any questions directly into your webinar box; We will review them at the conclusion of today's session; Please keep question presented related to the topic of today's webinar.

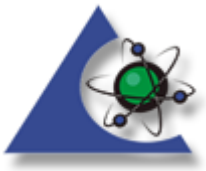
4.1 Impartiality

ISO/IEC 17025:2017 defines impartiality

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 "freedom from conflict of interests", "freedom from bias", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "even-handedness", "detachment", "balance"



4.1 Impartiality

ISO/IEC 17025:2005 addressed impartiality however not as directly as ISO/IEC 17025:2017:

ISO.IEC 17025:2005

4.1.4 – organization performing activities other than testing and/or calibration, the responsibilities key personnel that have involvement need to be defined to identify potential conflicts of interest;

4.1.5 b - have arrangements to ensure that its management and personnel are free from any undue internal and external pressures;

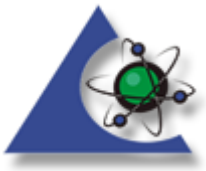
4.1 Impartiality

ISO.IEC 17025:2005 (continued)

4.1.5 d - have policies and procedures to avoid involvement in any activities that would diminish confidence in its impartiality;

4.1.5 e - define the organization and management structure of the laboratory, its place in any parent organization, and the relationships within organization;

4.1.5 f - specify the responsibility, authority and interrelationships of all personnel that has an effect in laboratory activities;



4.1 Impartiality

The issue of impartiality is magnified in 2017

- In ISO 17025:2005 Impartiality mostly mentioned in notes and conflict of interest is only mentioned once.
- ISO/IEC 17025:2017 there is a new section 4.1 dealing with impartiality
- now more important for laboratories to show how they have handled the issue about impartiality.

4.1 Impartiality

The ISO 17025:2017 has a bigger emphasis on impartiality and managing conflicts of interest. How do you plan to address these issues in a way that you can discuss with your assessor?

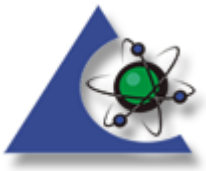
Situations of undue influence, conflicts of interest can lead to test results being either intentionally or unintentionally incorrect! If this is discovered after the results have been issued, it could be devastating to your business.

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;



4.1 Impartiality

4.1.1 states the organization shall be structured and managed so as to safeguard impartiality

Review the structure and reporting lines: look for potential conflicts of interest (such as results being used internally). This is common for production related organizations but also those involved in design engineering. Where possible, removing direct reporting lines such as the laboratory technician or manager reporting directly to the Production Manager or Design Engineer. It may be an option to look at alternate reporting lines.

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

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

This may be demonstrated by:

- 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;

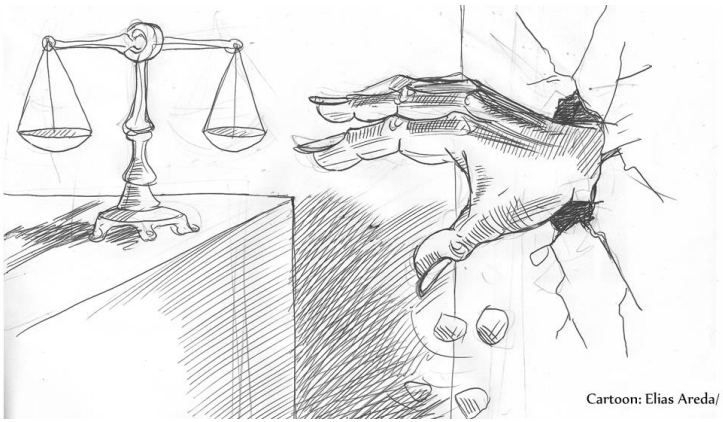
ISO/IEC 17025:2017 requirements Sec. 4.1 "Impartiality

Management installing a culture of openness, honesty and integrity goes a long way. Make sure employees know that they can speak up if they don't feel something is right without the worry of some form of repercussion. Establish a quality culture within the organization.

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;



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*

8.5 Actions to address risks and opportunities

Would expect to see this area has been evauated and how it is going to be done on an ongoing basis. Shall = requirement

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

Identifying risks to impartiality (ongoing)

- 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. (not a specific input or output requirement as specified in 8.9 Management Review)
- 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"

Examples of possible risks to impartiality

Conflicts of interest due to shareholdings, family relationships, etc

Under-pricing jobs, putting time pressures on staff

Being pressured onsite to give a pass result, repeat the test, probably with instruction for a slightly different location.

Testing for compliance on an in-house product especially if the tester also has production responsibilities

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 conduct 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 “Actions to address risks and opportunities;

4.2 Confidentiality

Confidentiality can be though of as the state of keeping or being kept secret or private. Is the principle that an institution or individual should not reveal information about their clients to a third party without the consent of the client or a clear legal reason.

4.2 Confidentiality

Even though the new version of ISO 17025 is including a lot more text about confidentiality the basic requirements from ISO17025:2005 have not changed but is more detailed. ISO/IEC 17025:2005 addresses confidentiality

4.1.5 (c) have policies and procedures to ensure the protection of customers' confidential information;

4.7.1 service to customer: The laboratory shall be willing to cooperate with customers provided that the laboratory ensures confidentiality to other customers;

5.4.7.2 (b) control of data : procedures are established and shall include, but not be limited to, integrity and confidentiality of data;

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.

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. “legally 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;*

Do they want to remain anonymous?

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.

Impartiality and Confidentiality Requirements of ISO/IEC 17025:2017

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

Will provide 5 minute time frame at this moment to submit questions.

At the end we will attempt to answer as many as possible.

Please keep questions related to areas covered during this webinar;

Training Opportunity (November 19-20)

10-18-2019 PJLA Training Courses - 17025.pdf - Adobe Acrobat Reader DC

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This section of the course will cover the aspects of ISO/IEC 17025:2017 and any additional accreditation body requirements as required by the International Laboratory Accreditation Cooperation (ILAC). Participants will be educated on the requirements outlined in 17025 in order to implement a comprehensive quality and technical laboratory management system. Participants will exit this course with the ability to develop and administer the requirements of the standard among their entire laboratory system and gain the necessary technical skills required to achieve ISO/IEC 17025: 2017 Accreditation.

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Price

17025:2017 Internal Auditor Training (2 Days): $1,000.00

$100 discount per registration for 2 or more company registrations.

Location

PJLA Headquarters
755 W. Big Beaver Rd., Suite 1325
Troy, MI, 48084
(PNC Building - 13th Floor)

Save the Date

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