

3. RISKS



Recurring question: Is the following statement more of a threat or an opportunity?

RISK 01 The most important thing is that the company's strategy was established in the past

Threat § 4.1 ★

Every three years on average, it's advisable to verify the strategy's adequacy with the company's context and the expectations and needs of stakeholders. It's a threat because the date when the strategy was developed isn't specified

RISK 02 No pressure (commercial, financial, or hierarchical) compromises the quality of the results (even when the boss is away)

Opportunity § 4.1 ★★★

The laboratory shall ensure that its activities are carried out with complete impartiality

RISK 03 A medical biologist, asked to validate lab tests for an associate of a private company he co-manages, refuses to get involved (because the boss said to handle it ourselves)

Opportunity § 4.1 ★

Personal conflicts of interest are eliminated or minimized so as not to compromise the laboratory's impartiality

RISKS

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4. MCT (multiple choice test)



MCT 01 The first edition of ISO 15189 was published in:

1. 2003
2. 2007
3. 2012
4. 21022

Foreword ★

2007 is the first revision, 2012 is the second revision, 2022 is the third revision (in progress)

MCT 02 The ISO 22870 standard has been withdrawn because its requirements are incorporated into the 2022 version of ISO 15189 and, most notably, into (even if the boss has no opinion on the matter):

1. Clause 4
2. Clause 5
3. Clause 6
4. Clause 7
5. Clause 8
6. Annex A

Foreword ★★★

It is mainly in Annex A

MCT 03 Examples of laboratory users:

1. Patient
2. Clinician
3. Consultant
4. Prescriber (physician)
5. Parents of a minor child
6. Clinic

§ 3 ★

A consultant is a service provider who offers professional advice

MCT

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5. PRACTICES



Recurring question: Is the following statement more a good or a bad practice?

PRACTICE 01 The declaration of no conflict of interest is signed by every employee (even if the boss is unaware of it)

Good practice § 4.1 ★

Impartiality is a non-negotiable requirement

PRACTICE 02 No documentation regarding the analysis of risks related to impartiality

Bad practice § 4.1 ☆☆☆

The laboratory demonstrates its impartiality in all its activities, particularly in: medical analyses (diagnostics, screenings), quality-related decisions (validation of results, management of nonconformities), and relationships with stakeholders. Top management must first determine the internal and external issues

PRACTICE 03 A shared identifier used by a few employees

Bad practice § 4.2 ☆☆☆

Access to LIS is individual, in order to ensure the confidentiality of patient data

6. CASES



CASE 01 THREATS

Situation: Threats to impartiality include, among other things, conflicts of interest, commercial pressure, personal relationships, and unfair competition.

Challenge: How can threats to impartiality be addressed?

Solution 1: By identifying situations in which the laboratory's impartiality could be compromised

Solution 2: By documenting these threats

Solution 3: By assessing their severity

§ 4.1



All these activities are very useful for meeting the impartiality requirement.

CASE 02 DATA PROTECTION

Situation: The laboratory uses a LIS (Laboratory Information System) to manage patient results

Challenge: How can patient data within the LIS be protected?

Solution 1: Perform weekly backups to the technical manager's hard drive

Solution 2: Encrypt the data

Solution 3: Perform daily backups to a remote server

Solution 4: Add an automatic alert for any unauthorized access attempts

§ 4.2



Solution 1 is not sufficient

Solutions 2, 3, and 4 are sensible

CASE 03 PATIENTS AND INFORMATION

Situation: The laboratory should enable patients and clinicians to provide input on the choice of examination methods and the interpretation of results

Challenge: What actions should be implemented?

Solution 1: Regularly send out questionnaires to gather feedback on the quality of examinations, the clarity of results, and turnaround times

Solution 2: Establish an online platform where patients and professionals can suggest improvements or report issues

Solution 3: Organize weekly meetings with patients and clinicians to discuss their needs and expectations

§ 4.3



Solutions 1 and 2 offer good opportunities for patients and users to provide feedback

Solution 3 is not recommended; it occurs too frequently and is unlikely to provide any added value